การประยุกต์ใช้เทคโนโลยีการระบุเอกลักษณ์ด้วยคลื่นวิทยุ (อาร์เอฟไอดี) เพื่อติดตามการผลิตกลุ่มยาเสพติดและสารออกฤทธิ์ต่อจิตและประสาท : กรณีศึกษาการผลิตยาเม็ดฟีโนบาร์บิทัล

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วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาเภสัชศาสตรมหาบัณฑิต
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APPLICATION OF RADIO FREQUENCY IDENTIFICATION (RFID) TECHNOLOGY FOR TRACKING THE MANUFACTURE OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES : A CASE STUDY OF PHENOBARBITAL TABLETS PRODUCTION

Miss Jesdaporn Rachivong

A Thesis Submitted in Partial Fulfillment of the Requirements
for the Degree of Master of Science in Pharmacy Program in Industrial Pharmacy
Department of Pharmaceutics and Industrial Pharmacy
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Thesis Title	APPLICATION OF RADIO FREQUENCY IDENTIFICATION (RFID) TECHNOLOGY FOR TRACKING THE MANUFACTURE OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES: A CASE STUDY OF PHENOBARBITAL TABLETS PRODUCTION
By	Miss Jesdaporn Rachivong
Field of Study	Industrial Pharmacy
Thesis Advisor	Phanphen Wattanaarsakit, Ph.D.
Thesis Co-Advisor	Assistant Professor Anuchai Theeraroungchaisri, Ph.D.
	Natapol Pornputtapong, Ph.D.

Accepted by the Faculty of Pharmaceutical Sciences, Chulalongkorn University in Partial Fulfillment of the Requirements for the Master's Degree

.....Dean of the Faculty of Pharmaceutical Sciences
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THESIS COMMITTEE

.....Chairman
(Associate Professor Parkpoom Tengamnuay, Ph.D.)

.....Thesis Advisor
(Phanphen Wattanaarsakit, Ph.D.)

.....Thesis Co-Advisor
(Assistant Professor Anuchai Theeraroungchaisri, Ph.D.)

.....Thesis Co-Advisor
(Natapol Pornputtapong, Ph.D.)

.....Examiner
(Narueporn Sutanthavibul, Ph.D.)

.....External Examiner
(Associate Professor Poj Kulvanich, Ph.D.)

เจษฎาภรณ์ ราชิวงศ์ : การประยุกต์ใช้เทคโนโลยีการระบุเอกลักษณ์ด้วยคลื่นวิทยุ (อาร์เอฟไอดี) เพื่อติดตามการผลิตกลุ่มยาเสพติดและสารออกฤทธิ์ต่อจิตและประสาท : กรณีศึกษาการผลิตยาเม็ดฟีโนบาร์บิทัล (APPLICATION OF RADIO FREQUENCY IDENTIFICATION (RFID) TECHNOLOGY FOR TRACKING THE MANUFACTURE OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES: A CASE STUDY OF PHENOBARBITAL TABLETS PRODUCTION) อ.ที่ปรึกษาวิทยานิพนธ์หลัก: อ. ภญ. ดร. พรรณเพ็ญ วัฒนาอาษากิจ, อ.ที่ปรึกษาวิทยานิพนธ์ร่วม: ผศ. ภก. ดร. อนุชัย ธีระเรืองไชยศรี, อ. ภก. ดร. ณฐพล พรพุทธพงศ์, 135 หน้า.

งานวิจัยนี้ศึกษาการนำเทคโนโลยีการระบุตัวตนด้วยคลื่นความถี่วิทยุ (อาร์เอฟไอดี) มาประยุกต์ใช้ในการติดตามกระบวนการผลิตยาเม็ดต้นแบบฟีโนบาร์บิทัล ตรวจสอบ และสืบย้อนกลับยาเพื่อป้องกันการสูญหาย ซึ่งองค์การเภสัชกรรมเป็นผู้ได้รับอนุญาตผลิตยากลุ่มยาเสพติดและสารออกฤทธิ์ต่อจิตและประสาท ได้ทำการผลิตตามหลักเกณฑ์และวิธีการที่ดีในการผลิต และตามข้อกำหนดพระราชบัญญัติยาเสพติดให้โทษและพระราชบัญญัติวัตถุที่ออกฤทธิ์ต่อจิตและประสาท โดยศึกษาออกแบบการนำอาร์เอฟไอดีมาใช้ ระบุความต้องการผู้ใช้และกำหนดหน้าที่ของระบบงาน คัดเลือกอุปกรณ์ที่เหมาะสม ทดสอบปัจจัยที่มีผลต่อการใช้งาน ตรวจสอบความถูกต้องการทำงานของซอฟแวร์ และทดลองการใช้งานจริงที่โรงงานผลิตยา ประเมินความเสี่ยงด้วยเครื่องมือเอฟเอ็มอีเอ ประเมินความพึงพอใจการใช้งานระบบ และประเมินผลกระทบต่อกระบวนการผลิต โดยทั่วไปการจัดลำดับความเสี่ยงในโรงงานที่มีการปฏิบัติตามหลักเกณฑ์และวิธีการที่ดีในการผลิตจะมีค่าลำดับความเสี่ยงในกระบวนการผลิตน้อยมาก จากการประเมินพบว่าค่าลำดับความเสี่ยงภายหลังจากการใช้อาร์เอฟไอดีของความความเสียหายที่อาจจะเกิดขึ้นจากการเปิดถุงวัตถุดิบในช่วงการขนส่งระหว่างแผนก ความสับสนของวัตถุดิบระหว่างการขนส่งมีค่าลดลงจากค่าลำดับความเสี่ยงเล็กน้อยไปเป็นลำดับไม่มีความสำคัญ ซึ่งทำให้ค่าลำดับความสำคัญของความเสี่ยงลดลงมากกว่าร้อยละ 50 อาร์เอฟไอดีจึงมีประสิทธิภาพในการสนับสนุนกระบวนการผลิตตั้งแต่การจัดการวัตถุดิบ การติดตามกระบวนการผลิต และลดความเสี่ยงในการขนส่งระหว่างการผลิต ซึ่งใช้เป็นแนวทางในการพัฒนากระบวนการ สนับสนุนระบบคุณภาพ และสร้างความได้เปรียบทางการแข่งขันในตลาดยาได้

ภาควิชา	วิทยาการเภสัชกรรมและเภสัชอุตสาหกรรม	ลายมือชื่อนิสิต .....
		ลายมือชื่อ อ.ที่ปรึกษาหลัก .....
สาขาวิชา	เภสัชอุตสาหกรรม	ลายมือชื่อ อ.ที่ปรึกษาร่วม .....
ปีการศึกษา	2560	ลายมือชื่อ อ.ที่ปรึกษาร่วม .....

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JESDAPORN RACHIVONG: APPLICATION OF RADIO FREQUENCY IDENTIFICATION (RFID) TECHNOLOGY FOR TRACKING THE MANUFACTURE OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES: A CASE STUDY OF PHENOBARBITAL TABLETS PRODUCTION. ADVISOR: PHANPHEN WATTANAARSAKIT, Ph.D., CO-ADVISOR: ASST. PROF. ANUCHAI THEERAROUNGCHAISRI, Ph.D., NATAPOL PORNPUTTAPONG, Ph.D., 135 pp.

This study applied RFID tracking of the manufacturing process and tracing back of product for preventing API loss with phenobarbital tablets as a case study. GPO has produced narcotic drugs, and psychotropic substances complied with GMP, Narcotics Act, and Psychotropic Substances Act. It included designing RFID implementation, determining user requirement and functional specification, selecting suitable devices, evaluating significant parameters and verifying the designed system. The verified software was continuously tested in stages of site testing and was assessed the risk with FMEA tool, user's satisfaction and the impact on the manufacturing process. The risk priority class of a plant which followed GMP shall be negligible generally. The result showed the risk priority class of RFID implementation for potential failure modes that cannot protect opening a material container or confuse with other materials during shipping between sections were reduced from minor class to negligible and RPN values were decreased up to 50%. Thus, the RFID has effectively supported throughout the manufacturing process, material management, tracking and tracing of product and process, and risk reduction. The finding also suggests in the process development, supports the quality system, and builds the competitive strength in the pharmaceutical market.

Department:	Pharmaceutics and Industrial Pharmacy	Student's Signature .....
		Advisor's Signature .....
Field of Study:	Industrial Pharmacy	Co-Advisor's Signature .....
Academic Year:	2017	Co-Advisor's Signature .....

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LIST OF ABBREVIATIONS

API	Active Pharmaceutical Ingredient
BP	Bulk Product
BPR	Batch Processing Record
COA	Certificate Of Analysis
Date/Time	Date and time
CDT	Card Tag
CTT	Cable Tie Tag
EPC	Electronic Product Code
ERP	Enterprise Resource Planning
EXP	Expiry Date
FDA	Food and Drug Administration
FMEA	Failure Mode and Effect Analysis
FP	Finished Product
FIFO	Frist In Frist Out
FP-QC	Finished Product Quality Control
FP-WH	Finished Product Warehouse
FMEA	Failure Mode and Effect Analysis
GAMP	Good Automation Manufacturing Practice
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
GSP	Good Storage Practice
GPO	Government Pharmaceutical Organization
MES	Manufacturing Execution System
MFD	Manufacturing Date
MTT	Metal Tag

No.	Number
QA	Quality Assurance
QC	Quality Control
Qty.	Quantity
Reg. no.	Registered Number
RFID	Radio Frequency Identification
RPN	Risk Priority Number
SM	Starting Material
SM-QC	Starting Material Quality Control
SM-WH	Starting Material Warehouse
Temp/Hu	Temperature and humidity
URS	User Requirement Specification
WIT	Wet Inlay Tag
WH	Warehouse

CHAPTER I
INTRODUCTION

1.1 Background of the study

Pharmaceutical manufacturing is an industry that produces one of the most important human need. There are two major groups of Thai manufacturer, the public and private sectors, mainly emphasized on manufacturing of generic drugs. The public, Government pharmaceutical organization (GPO), aims to produce essential drugs with lower cost for affordability. As a major domestic manufacturer supporting the growth of medical demand, GPO produces a variety of medicines including a controlled drug groups following a Good Manufacturing Practice (GMP) and Regulations.

The manufacturing process of a controlled drug groups, such as narcotic drugs and psychotropic substances, are required to comply with both GMP standard and Regulatory Act. The important contents for the pharmacist who is responsible in production activity of Narcotics Act (1979) and Psychotropic Substances Act (1975) are he shall supervise of all operation and a person shall not produce a narcotic drugs and psychotropic substances as a fake, a deteriorated, a drug differing from the standards (Narcotics Control Division, 1975, 1979). Furthermore, risk management is also an effective tool that many firms use to assist and improve their organization. They applied the International Conference on Harmonization (ICH) Q9 guidelines to manage the risk of production in order to ensure quality of their products (ICH, 2005). According to ICH Q9, the Failure Mode and Effect Analysis (FMEA) model is a prominent tool to prioritize the problem in various institution systematically and scientifically. Risk Priority Number (RPN) will be calculated on the highest value for higher risk of a problem that should be prioritized solving. After the problem is resolved, the risk and the reassess RPN value should be reduced (Chitmetha, 2013; Feili, Akar, Lotfizadeh, Bairampour, & Nasiri, 2013; Segawa et al., 2016).

In general, pharmaceutical manufacturing of one batch production consist variety of starting material (SM) as well as one batch SM can be divided into several batch productions as shown in Figure 1. The managing of SM that first received should be first used by a first-expire, first-out rule. Therefore, to produce a high quality pharmaceutical with the rigorous GMP requirement and high competition internationally, an appropriate technology should be adopted to expedite the production process.

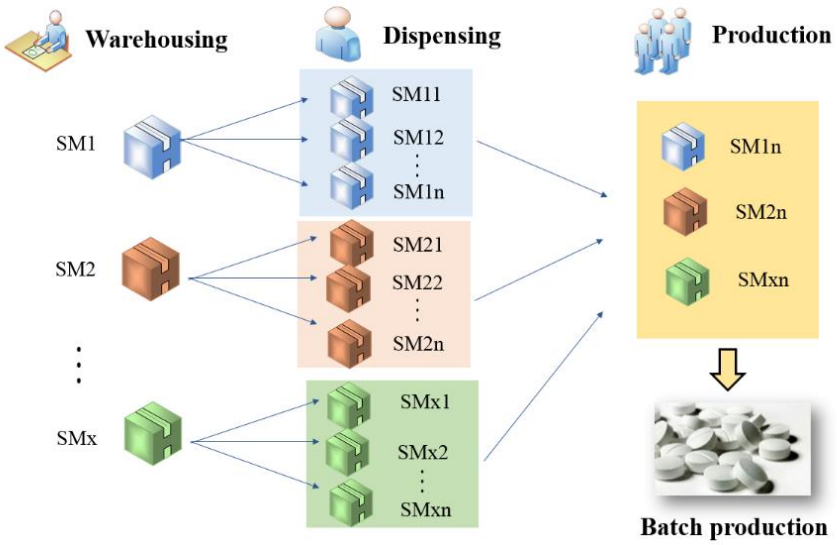


Figure 1 A variety of SM to produce for a batch production

RFID is an alternative technology that identifies any object with radio frequency. This technology has been used successfully in a variety of industries which is currently used commercially and more likely to replace the barcode system in the future owing to its advantages, such as contactless usage applications, simultaneously multiple RFID tag readings, and information accuracy during the reading process. It has higher security than barcode systems and is difficult to counterfeit. In many industries, it has been applied for warehouse management that greatly reduces inventory costs. It has smart searching and smart shelving thus prevented the loss of goods and reduced employee errors. RFID is also applied to assess a secure area in order to increase of asset security. Furthermore, RFID is the most promising technology of electronic tracking in the supply chain of pharmaceutical product. Since USFDA proposed standards for tracking prescription drugs; the counterfeit incidences have been increased. RFID is significantly considered adoption of drugs to preventing anti-counterfeit drugs (Domdouzis, Kumar, & Anumba, 2007; Iizroaum Choosri, 2013; Kamran AHSAN, Hanifa SHAH, & Paul KINGSTON, 2010; Mackey, Liang, York, & Kubic, 2015; Potdar, Chang, & Potdar, 2006; Sachdeva & Debi Prasad Pati, 2009; U.S. FDA, Office of the Commissioner (OC), Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), & Office of Regulatory Affairs (ORA), 2010; US. FDA., 2006b; WHO, 2007; D. L. Wu et al., 2010; Yan, Chen, & Meng, 2008; Yue, Wu, & Bai, 2008; ประจวบ กล่อมจิตร, 2555).

In this study, GPO was selected as a case study plant because it has been granted by Thai FDA to produce the narcotic drugs (Category II and III) and psychotropic substances (Schedule II and IV). In the current situation, there is a risk during the transportation process within the production line and the lack of effective tracking technology for production support. The USFDA has recommended using the RFID to track pharmaceutical products; however, there is no study applying the RFID in the manufacturing tracking process, especially the manufacturing of narcotic drugs, psychotropic substances, and other controlled drugs (US. FDA., 2006a). Therefore, this research studies an application of RFID for tracking and tracing in a production process

of narcotic drugs and psychotropic substances. This may prevent a drug lost (e.g., lost from stolen, lost during production, transportation) and control all production processes by pharmacists. The research used phenobarbital tablets production as a model of narcotic drug. FMEA tool is used to evaluate the risk management.

1.2 Objectives of the study

To study a process tracking, process traceability and starting material loss prevention of narcotic drug and psychotropic substance manufacturing using radio frequency identification (RFID) technology with phenobarbital tablets production as a case study

1.3 Scope of the study

Phenobarbital tablets production, which was produced at the Government Pharmaceutical Organization (GPO) Rama VI, Bangkok, was used as the case study in the research. The production was planned to be processed from January to February, 2017. The tracking processes of starting material (SM) are composed of material receiving, dispensing, production, packaging and storage in a warehouse. Only the active ingredient tracking was discussed in the research. The design of RFID system in this research was verified at Faculty of Pharmaceutical Sciences, Chulalongkorn University, Bangkok and evaluated by GPO.

1.4 Significance of the study

- Achievement of the formation of process tracking, process traceability and raw material loss prevention of phenobarbital tablets production using RFID technology.

- Achievement of guidelines for using RFID technology tracking process, process traceability and starting material loss prevention for pharmaceutical productions especially a special drug groups e.g., controlled drugs, narcotic drugs, high-valued drugs.

CHAPTER II
LITERATURE REVIEWS

2.1 Requirements for pharmaceutical production

The Ministry of Health has issued regulations to establish the Good Manufacturing Practice (GMP) effect as a law of operations for all government and individual manufacture of medicines since 2004 (Thai FDA, 2003). In accordance with definition of WHO GMP 2014 (World Health Organization Good Manufacturing Practice), GMP contributes to assuring the product is invariably controlled manufactured which consider GMP as part of quality management. The topics of quality system, documentation, good practices in production and quality control are also stated in the guideline (WHO technical report series no. 986, 2014). Thai FDA commits to develop the legal regulations associated to improve domestic drug manufacturing standards, e.g. a non-GMP compliant manufacturers are not allowed to submit a registration of their products, moreover, they establish the policies for public health facilities, where under the Ministry of Public Health, and the drug store to purchase the medicine from the GMP certified pharmaceutical company (ไพบูลย์ อมตมหัทธนะ, 2014). Whereas that product quality focuses on the manufacturing process, the storage and transport of products throughout the supply chain are important as well (สิริมน อุบลพงศ์, 2014). Good Distribution Practice (GDP) and Good Storage Practice (GSP) are also used as a guideline for the storage and delivery of pharmaceutical products reason for maintaining product quality throughout the supply chain. The WHO GDP guideline 2010 (World Health Organization Good Distribution Practice) indicated that the firm should apply a secure transportation system with an appropriate technology, an international coding, and identification systems to ensure product traceability throughout the supply chain (WHO technical report series no. 957, 2010) and the WHO GSP guideline (World Health Organization Good Storage Practice) indicated that the appropriate device is recommended to use for temperature monitoring and recording during product distribution and the product should be employed followed the first expired/first out (FIFO) rules (WHO Technical Report Series no. 908, 2003).

Narcotic drugs and psychotropic substances are classified under the category of controlled drugs that require special control. According to Narcotics Act (1979), narcotics shall be classified into 5 categories as;

- Category I: dangerous narcotics
- Category II: Ordinary narcotics
- Category III: narcotics which are in the form of medicinal formula and contain narcotics of category II as ingredients
- Category IV: chemicals used for producing narcotics of category I or category II
- Category V: narcotics which are not included in category I to category IV

And Psychotropic Substances shall be classified into 4 schedules as;

- Schedule 1 drugs with no current medical use that shall not be produced, imported and sold
- Schedule 2 drugs with current medical use that shall be produced, imported by the Ministries and sold to a medical practitioner, dentistry and veterinarian to his patient
- Schedule 3 drugs with current medical use that less risk to addition than drugs in schedule 2, shall be sold according to a prescription of a medical practitioner.
- Schedule 4 drugs with current medical use that less risk to addition than drugs in schedule 3

For the manufacturing of narcotic drugs and psychotropic substances not only should comply with GMP standard, but also meet to Narcotics Act (Narcotics Control Division, 1979) and Psychotropic Substances Act (Narcotics Control Division, 1975). The requirements under both of these Acts are similar in manufacturing part:

1. Section 36 of Narcotics Act is similar to section 33 of Psychotropic Substances Act, the pharmacist who is responsible in production activity shall supervise of all operation and
2. Section 39 of Narcotics Act is similar to section 36 of Psychotropic Substances Act, a person shall not produce a narcotic drugs and psychotropic substances as a fake, a deteriorated, a drug differing from the standards.

Any licensee violates or does not comply with this Act, shall be liable to a fine, imprisonment, moreover, the licensing authority with the approval of the committee shall have the power to suspend the license.

Concluding from the above requirement, all pharmaceutical facilities should meet GMP standards according to the announcement of the Ministry of Public Health. In part of GSP and GDP, they can be adopted as a guideline for quality management to ensure their product quality throughout storage and transportation. For the factory has requested registration or be hired by Thai FDA in the production of narcotic drugs and psychotropic substances shall also be produced comply with Narcotics Act and Psychotropic Substances Act.

2.2 RFID technology

2.2.1 The principle of RFID system

A good logistics information system results in a logistics infrastructure network that connects to intra-organizational and inter-organizational. Presently, there are many technologies to help manage such as barcode and RFID. Even though the high investment, many companies are adopting these technologies to help to strengthen the organization. It is believed that these systems will be commercially successful in the future (ธนิต โสรัตน์, 2552; ไมเคิล เอช ฮิวโกส์, 2548) . We have seen RFID adoption increasingly because it is an automation technology that can be versatile adapted to a variety of business, for examples, the payment system of the mass rapid transit (MRT), contactless smart card, stored-value ticket and single-journey token, intelligent library system, farm

automation system, parking automation system, access control system and tracking automation system. While an automation technology improves convenience, it also plays an important role in improving productivity ensuring consistency and product quality and safety of the manufacturing process (Basu, Friedli, & Bellm, 2013). All industries have the opportunity to use RFID, depending on how the technology is used, however, the food industry is the most trend used (Iizroaum Choosri, 2013; วิทยา พรพัชรพงศ์, 2548).

Radio frequency identification (RFID) technology was developed at the beginning of the 20th century, which is achieve used in the variety of industries (Domdouzis et al., 2007). Because it has many advantages over the barcode so RFID can be used to replace barcode systems. Comparison of RFID system performance with barcode system is shown in Table 1 (ประจวบ กล่อมจิตร, 2555). RFID is more accuracy in the information reading (99.5%) than barcode (80%), more data storage, can distinguish on each piece even the same product), more speed of reading, can read several tag at the same time, no need to direct line-of-sight requirement which does not require contact with the product (contactless usage), protection of duplicate scanning that could often happen in barcode system, endurance for dampness, vibration and concussion, more security that difficult to fake and imitate, furthermore, RFID can read the always change data of objects (while barcode cannot modify the data) that help reduces the cost of producing.

Table 1 Comparison of RFID system performance with barcode system

Attributes	RFID	
The information reading accuracy	99.5%	80%
Tag data storage	Large	Small
Can distinguish on each piece (Whether the same product)	yes	no
Speed reading	faster	slower
Can scan several tag	Yes	No
Direct line-of-sight requirement	No	Yes
Protection of duplicate scanning	Yes	No
Endurance	More	Less
Security	high	low
Reusable	Yes	No

In general, the system consists of essential parts such as an antenna or coil, transceiver or reader, RFID tag or transponder and processing software. The internal circuits in RFID tag are composed of memory and microprocessor that are divided into two types according to the storage capacity, read only tag and read/write tag, more expensive than the barcode but more information storage. Furthermore, the variety of shape and size of the tag (including ship, card, wristband, sticker, cable tie etc.) are also divided into two categories, passive and active RFID tags. The passive RFID tag requires power from a reader, does not need an internal battery, so that a reading distance is not too far (not more than one meter) depending on the strength of the transmitter and the radio frequency. The active RFID tag requires an internal battery supply power to the internal circuitry which can read data at more longer distance up to ten meters with higher memory capacity up to one megabyte (Domdouzis et al., 2007).

The frequency used in this system was in the frequency band of Industrial Scientific Medical (ISM). It is divided into four main frequencies range as Table 2. The HF and UHF band are chosen for logistic application depending on the usage (Domdouzis et al., 2007; พิภพ ลลิตาภรณ์, 2552).

Table 2 An attribute of RFID frequency range and its application

Frequency range	Attribute	Application
Low frequency, LF 125-134 kHz	▪ Transmission distance in a range of less than 0.5 m. ▪ Low cost. ▪ Slow reading for slow moving object ▪ Less data storage without password	Access control system, livestock (animal identification), anti-theft label or system, inventory control system, vehicle anti-theft device
High frequency, HF 13.56 MHz	▪ Transmission distance in a range of up to 1.5 m. ▪ Prices tend to be down in the future. ▪ Fast reading for fast moving object (10-100 tags/sec) ▪ More data storage with/without password	Security smart card and access control system, book tracking system, door closed system
Ultra-high frequency, UHF 920-925 MHz	▪ Transmission distance in a range of up to 3-10 m. ▪ High cost ▪ Fast reading for fast moving object (100-1,000 tags/sec) ▪ More data storage with/without password	Logistics and supply chain management, toll system, warehouse system
Microwave frequency 2.45-5.8 GHz	▪ Transmission distance in a range of up to 10 m. ▪ High cost ▪ Fast reading for high speed moving object ▪ More data storage	Wireless device Mobile, expressway, aircraft, vehicle toll

The RFID system is not too different from barcoding but it is not required direct line-of-sight reading. The operation major use radio waves that the reader transmits to the tag receiver and memory chip. During the tiny coil, is attached via the tag, acts as an antenna, so it converts the radio frequency into an electrical signal and power to integrated circuit (is comprised of an antenna and memory chip that called inlay) for data reading or saving on memory. Finally, the available tag ready to sends the information back to the reader again as a diagram shown in Figure 2. The highlight of that technology is the ability to read and write the data on multiple labels simultaneously without touching or seeing and to read the distant information of many tags that fast movements in a less time. Refer to above reason and many advantages, RFID is the best-represented technology as an automatic identification (RFID-Asia, 2015; ปรเมศวร์ กุมารบุญ, 2550).

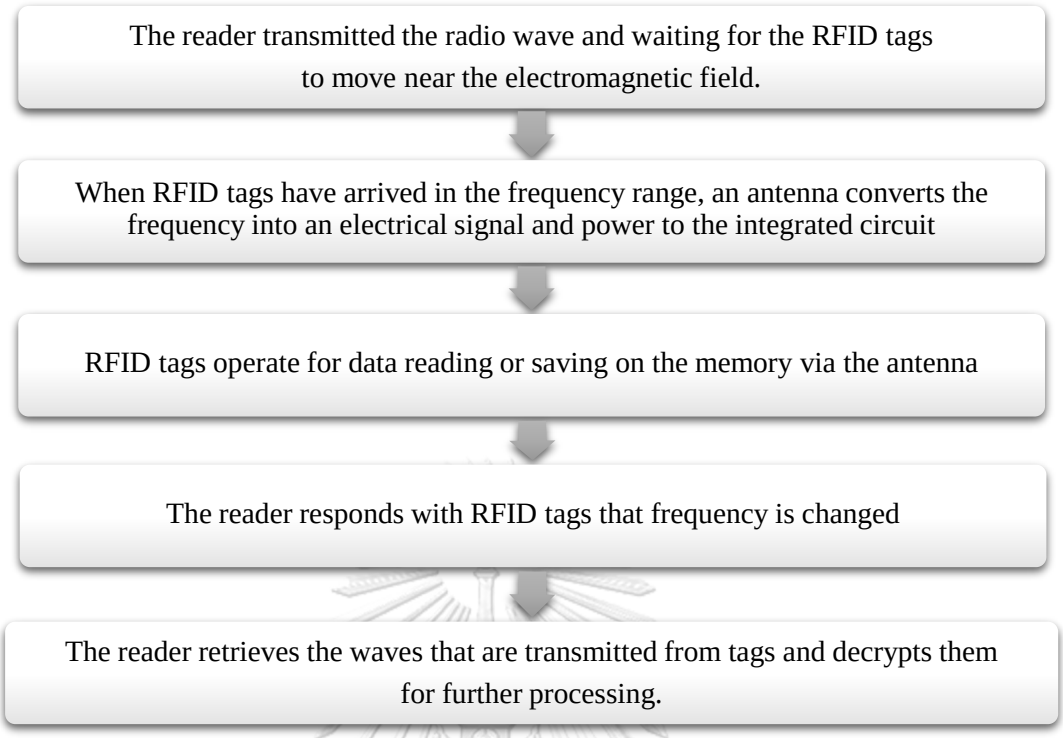


Figure 2 The processing diagram of RFID system

2.2.2 Application of RFID system

RFID technology has been applied in a wide variety of applications, summarized in Figure 3.

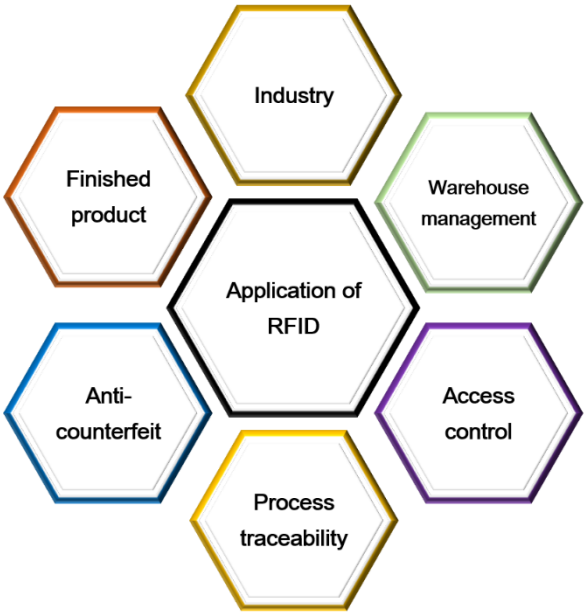


Figure 3 The major application of RFID technology

- **Industry sector**

There are many industries and organizations that adopt RFID. For leading logistics firm in Switzerland, deploying the RFID solution to track temperature conditions during transit of the healthcare goods to provide better care and safe transportation of their product (Violino, 2012). The same as Japan's largest pharmaceutical distribution services companies can monitor expiry dates and auto-ordering via RFID for track the carrying of medications from distribution sections to retailers (Swedberg, 2017) while the French National Agency for Medicines and Health Products Safety (ANSM) develop RFID system replacement barcoding with having a problem which led to defeat in reading on size of biological medicinal product labels (Violino, 2015). In the food industry and restaurant, it is used to prevent the use of expired food and raw materials (Lipton, 2015). For the hospital in Chicago, they used an RFID-based inventory-management solution that deducting product waste due to unused of expired goods. In part of the tourism industry, they printed information of tourist like a name, countries, passport no, a list of sports equipment and their child in form of contactless e-passport, wristband tag or tag to luggage. After most, using in the automatic borrowing system, preventing of the rare or high-value books are lost and book searching system the library application (Zhu, Mukhopadhyay, & Kurata, 2012).

- **Warehouse management sector**

RFID is superior to barcode systems, specifically for warehouse management, RFID reduces inventory costs by up to 55% (FKI Logistex, 2005). The system is available since the receipt process to inventory. It is used to track the entry and exit of starting material, packaging material and finished product these have to maintain the quality control and assurance. It can be used as a smart search and smart shelf and direct the appropriate storage locations that help operators looking for products suddenly, reducing of human error and permits on warehouse management efficiency. Furthermore, it is also used to track the transportation. To protect goods lost and to maintain the quality of the goods throughout their supply chain.(Potdar et al., 2006; Yan et al., 2008; Yue et al., 2008). Furthermore, Fan, T. et al. reviewed the Lee and Özer's indication (2007) that inventory shrinkage could be reduced with RFID adoption by reducing theft and avoid fraud that leading to a direct reduction of inventory shrinkage, by enhancing the accuracy of the information currently more than using barcode scanning which is more vulnerable to human error and by providing visibility that inventory records more closely correspond to actual inventory, replenishment can be more accurate, leading to fewer stock-outs (Fan, Chang, Gu, Yi, & Deng, 2014).

- **Access control sector**

RFID is applied to control access to specialty areas, such as sterile product process area or other critical process areas, accessing to document room, accessing to buildings or laboratories, checking and patients controlling in and out of any department of a hospital for patients' security and RFID is used with a camera for car owner memorize. So if RFID is used to control access to important pharmaceutical manufacturing processes or access to a running of the critical instrument, it can be done as well (Kamran AHSAN et al., 2010; Potdar et al., 2006; D. L. Wu et al., 2010).

- **Process traceability sector**

RFID plays a role in the implementation of traceability. In particular, this technology has grown in the food industry to reduce the loss of expired foods, for example the fresh vegetable from the Royal project, food industry as Betagro and CP All public company. The technology helps to store production information that occurs during the various stages of the production process, checking of the source of the ingredients, production date and time, an amount of production, working time and operator that significant to performance improving and increase problem-solving in the case of product complaint has requested (IET, 2017; Logistics digest, 2553, 2554). The system is developed and deployed in the inventory system, process system and document system which tracking ability of a material of dermal scaffold production, King Chulalongkorn Memorial Hospital by frequency identification. The study indicated that RFID competent to storage of information and trace back as well, which increased ease of operation, reduced error and continued to support the quality system (Thanachareonkit, 2009).

- **Anti-counterfeit sector**

WHO (World Health Organization) has defined a counterfeit drug as a medicine that is deliberately misleading in the manufacturer or contains the incorrect ingredient or an active ingredient is not added or counterfeit packaging. This is a global public health problem causing death, disability and injury affecting customer (WHO Health Technology and Pharmaceuticals, 2005). Due to the incidence of counterfeit drugs has increased dramatically and has to be corrected in many countries (Mackey et al., 2015), the US FDA has commitment and support of identification, validation, authentication, tracking and tracing standard. Since 2010 the Standardized Numerical Identifier (SNI) has been started in the manufacturing and packaging process of prescription drugs. It is flexible usage both 2D barcode and RFID technology that are different in each country to protect the product and consumers and respond quickly to counterfeit products (Abel, 2010; Bansal, Malla, Gudala, & Tiwari, 2013; NAMSDL, 2010; U.S. FDA et al., 2010). Track and Trace technology is a widely used anti-counterfeiting technology that tracking an item through the supply chain, providing traceability the story of any item for automatic warehouse operation as well as to the pharmacy (WHO, 2007). Moreover, it can also be used for anti-theft for valuable asset, high value pharmaceutical products or prescription drug to protect the safety of users and reduce the problem of customer complaints (Potdar et al., 2006).

- **Finished product sector**

RFID technology is operated on the different retailer, stock checking, drug recalling and traceability to manufacturing plant effectively throughout drug supply chain. These could decrease by 15-20 percent of inventory cost (Tohomas, 2016). Walmart, the frequency example and world's essential retailer, is using of RFID to support of inventory management, product recalling and tracking to their production plant for 10,000 worldwide branches. Walmart would like almost 100 supplier to completely implement RFID throughout all business process and all product that might saving at $8.35 billion per year (Weinstein, 2005).

2.3 Risk management

Whether the organization is a small or large, the risk is an essential heading that needs to manage. Attempts to manage risk will not be successful if the person involved in the organization does not have the knowledge, understanding or awareness of existing risk factors (กนกพร สาณะวัฒนา, 2556). Following to ICH Q9, the risk can be assessed by using the highly performance tool namely Failure Mode and Effect Analysis (FMEA) (ICH, 2006). The cause and damage or effect of the problem were considered. The severity of the damage (severity, S), frequency and chance of the cause of the damage (Opportunity, O) and ability to detect the damage (Detectability, D) were determined then the Risk Priority Number (RPN) will be calculated by using equation as below,

Risk Priority Number (RPN) = Severity X Opportunity X Detectability

The problem with RPN value is high should be solved first. After solving by the right and appropriate method, RPN value should decrease that the risk also has to continuously monitor and review (สมภพ ตลับแก้ว, 2004). Further, for the pharmaceutical factory, impact assessment has to be considered whether the solving impact on quality of manufacturing or their product. If the quality is affected by solving, the Good Practice relevance is required.

CHAPTER III
RESEARCH METHODOLOGY

This chapter purposed to present the methodology of this study. There are 5 steps: Case study research, Design of RFID implementation, Verification testing, Site testing and Value estimation. Figure 4 shows the diagram of research procedure.

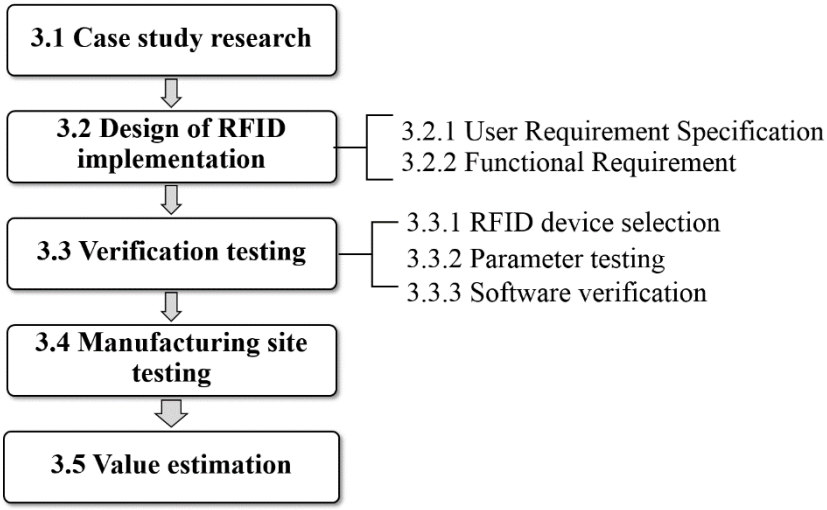


Figure 4 The diagram of the research procedure

3.1 Case study research

The Government Pharmaceutical Organization (GPO) is a state enterprise which was established since AD 1966 under the Ministry of Public Health by the Government Pharmaceutical Organization Act. The plant consists of main building that for the research study are starting material and finished products warehouse section, tableting section and tablet packing section. For production plant, the building related to the manufacturing process are separated as shown in Figure 5. The model of "process layout" was designed for a production plant that conglomerate similar machines in the same area of the plant to produce the goods which are similar processes (ประจวบ กล่อมจิตร , 2555). Many advantages of this layout are decreasing of machinery investment and increasing of the machine capitalization. Moreover, if the manufacturing scales up, the factory expansion cost will be inexpensive because of no need to change of all production lines. Nevertheless, there are few limitations for process layout as well;

- More shipping and complexity of material that might be a problem or waste time during transportation among inter-department,
- The ordering and coordination are rarely interrelated due to the efficiency of machines or the different staff
- Longer work-in-process and the manufacturing lines; controlling the process is difficult.

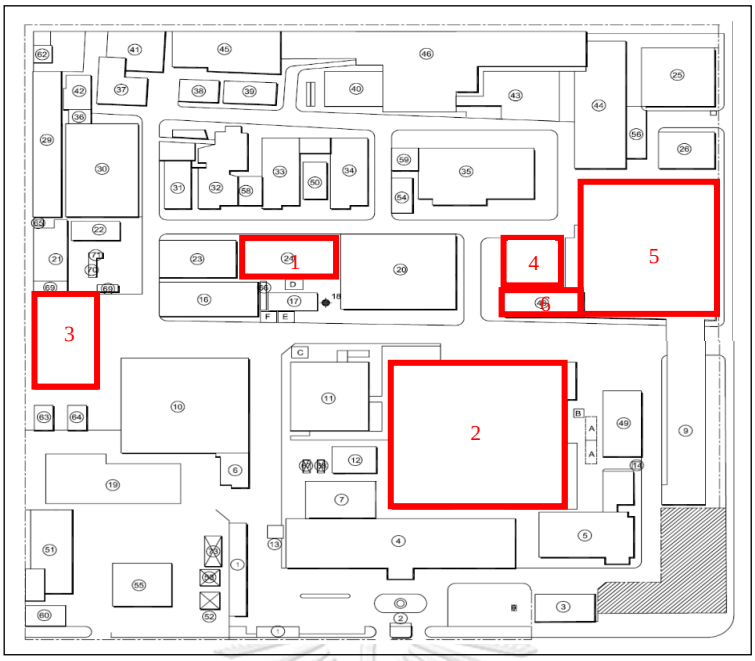


Figure 5 The layout of GPO production plant
Note: No.1 = SM-WH and Dispensing center, No.2 = The 5-floor production building, No.3-No.6 = FP-WH)

The Enterprise Resource Planning software (ERP) is a tool for business management including planning and production management within the organization. Nevertheless, Mfg/Pro software, a ready-to-use program, is used as an existing ERP for manufacturing and laboratory management within the GPO. There is no electronic batch processing record (EBPR) program was applied to replace the paper record.

Seventeen items in Narcotics of category II and III and Psychotropic substances in Schedule II and IV were produced by the GPO which were divided to various dosage forms following Table 3. The manufacturing process of most products are quite similar which start from material receiving, dispensing, production, packaging, and storage in the finished product warehouse until passing to sales. A number of transportation are different as described in Table 4.

Table 3 The product list of narcotic drugs and psychotropic substances produced by GPO

Type of drug	Dosage form			total
	Solid	Liquid	Sterile	
Narcotics of category II	COD15T COD30T MTD05T MOP10T	MTD10L MOP10L CAM10L		7
Narcotics of category III		BRW60L BRW18L BRW45L		3
Psychotropic substances in Schedule II			EPD30S	1
Psychotropic substances in Schedule IV	DIZ02T DIZ05T DIZ10T PBB30T PBB60T		DIZ10S	6
total	9	6	2	17

Note: the abbreviations of solid, liquid and sterile dosage form are coded for confidentiality.

Following to above information, the problem of manufacturing process was analyzed,

A) For manufacturing requirement: Narcotics Act and Psychotropic Substances Act stated that the pharmacist who is responsible in production activity shall supervise of all operation. The plant layout that has more material shipping, complexity of coordinated working and controlling through operation process may cause more work overload of the pharmacist. It is no assistive technology in tracking the production process.

B) For manufacturing management system: The existing ERP is Mfg/Pro that has no effective program enough in tracing back of the manufacturing process. Moreover, Batch Processing Record (BPR) is also a manual record that the signature of the authorized person on BPR may be faked. There is no technology to help identifying of operator which will take risk to operation by an irrelevant person not according to the Act.

C) For risk of transportation: Due to the layout with more shipping of material and work-in-process, thus the risk of transportation may have occurred such as;

- Staff may ship the materials out of the route. Confusion with other materials or other pallets may occurred and waste time shipping to the right department. If the material was sent to the wrong department, it might be produced a counterfeit drug that does not meet to section 36 of Narcotics Act and Psychotropic Substances Act requirement.

Table 4 Manufacturing process and a number of transportation

Dosage form	No.	List	Process	A number of transportation
Solid	1	COD15T	Receiving → Storage → Dispensing → Tabelting 1 sec. → Tableting 2 sec. → Packing → Warehouse → Sale	7
	2	COD30T		
	3	MTD05T		
Solid	4	MOP10T	Receiving → Storage → Dispensing → Tableting 2 sec. → Coating → Packing → Warehouse → Sale	7
Liquid	5	MTD10L	Receiving → Storage → Dispensing → Galenicals sec. → Packing → Warehouse → Sale	6
	6	MOP10L		
	7	CAM10L		
	8	BRW60L		
	9	BRW18L		
	10	BRW45L		
Solid	11	DIZ02T	Receiving → Storage → Dispensing → Tableting 2 sec. → Packing → Warehouse → Sale	6
	12	DIZ05T		
	13	DIZ10T		
Solid	14	PBB30T	Receiving → Storage → Dispensing → Tableting 1 sec. → Packing → Warehouse → Sale	6
	15	PBB60T		
Sterile	16	EPD30S	Receiving → Storage → Sterile production sec. (dispensing, mixing, packaging → Warehouse → Sale	4
	17	DIZ10S		

- Staff can open the material container and thief during the transportation between inter- departments. If the API is lost or the amount of API is lower, it might be produced a drug differing from the standards that does not meet to section 39 of Narcotics Act and Psychotropic Substances Act requirement.

3.2 Design of RFID implementation

3.2.1 User Requirement Specification

As for Pharmaceutical Inspection Co-operation Scheme (PIC/S) suggestion, User Requirements Specifications (URS) should describe the required functions of the computerized system (a set of hardware and software), be based on documented risk assessment and GMP impact and be traceable throughout the life-cycle (Pharmaceutical Inspection Convention Pharmaceutical Inspection Co-Operation Scheme (PIC/S), 2017a). The User Requirement Specification (URS) for RFID implementation system was defined which no changing the existing workflow but increased the use of such technology to prevent the problem and to comply with the GMP of the Narcotics Act and Psychotropic Substances Act. Refer to Table 5, the URS was covered in the topics: System setting, RFID in production process, Process tracking, Loss prevention, Access control, Documentation and report and General feature.

3.2.2 Functional Requirement

Studying a thorough process of phenobarbital tablets manufacturing was required and it was designed with RFID plugin and double setting which no changing the existing workflow. Following the URS from 3.2.1, the detail of system workflow as a place of work, process, the consideration data, recording data, the related document and a double lock system will be set during the process were described in Table 6 and Figure 6 in brief. For other detail as starting material, supplier, product, distribution center and authorized person were defined as the master data using for working the system, in Appendix A.

Table 5 URS of RFID implementation

Topic	Description
System setting	All devices are connected to the system and able to work correctly and properly.
	Users are able to read and write RFID tag.
	The manufacturing data is recorded rightly as working date and time, working location, operator and others.
	The data are read by reader precisely.
	The data are read by reader expeditiously.
	The system is able to record the name of the shipper or receiver.
RFID in production process	The SM data are recorded and connect to the purchase order.
	The SM lot number is recorded and shown what will be used to, which production batch number in the form of the production plan.
	The COA from QC department are recorded and shown and able to connect to all data of the QC department.
	Each dispensed SM should be recorded and shown as : - Which production batch no. of dispensed SM - Received date and time - Received operator - How quantity of dispensed SM and SM inventory
	The handheld reader will display the information of SM and amount of them.
	The MFD/EXP date are recorded in the system on the day of the SM mixing.
	The handheld reader will display the information of the FP.
Process tracking	The production batch data are recorded and shown throughout the process as a lot no. of SM and source of SM.
	The system is able to record and/or connect to the status of analysis results from QC or QA department.
	The manufacturing data is recorded and shown since receiving until packaging and storage as date and time, department, authorized pharmacist, temperature, and humidity.
	The users are able to examine the production status (real time checking) by the screen flow chart
	The system can be used in more or less production processes.
Loss prevention	The RFID tag has a unique identifier that cannot be counterfeit or replacement of the device from elsewhere by the operator.
	The system should have any double-check method to ensure that the weight and type of products that were exported from the previous department to the next is correct such as weighing and recording in the system.
	There should be a double-locking system to prevent openings during transportation such as EAS system
	The system is able to trace back to the operator and the loss of SM during interdepartmental transportation.
Access control	The authorized person is identified for accessibility by the system using RFID tag.
	The system can be added, reduced or modified the user and connected to user information.
	The information of user accessed is shown such as operating time and department.
	The data accessing (reading and writing) should be defined the authorized person.
	Easy to use and learn.
	The authorized person should be added to approve of the critical process.
Document and report	The name and department of the operator are recorded for all process.
	The recorded information can be printed from the system according to the template as required and can be documented as comply GMP guideline.
	After the final process, the customer can examine the information of product by scanning the QR code printed on the packaging. The information is shown as product & strength, batch no., product type, contain, Reg. no., MFD/EXP, manufacturer and serial no.
	The user can view historical data that is still preserved even after the 5-year process has finished.
General feature	The system is easy to use, not complicated.
	The users are unable to edit recorded data.
	There is an intelligible diagram of system operation.
	The letters appearing in a handheld reader are clear, easy to read and the font size is not too small.
	The system can be used as intended.

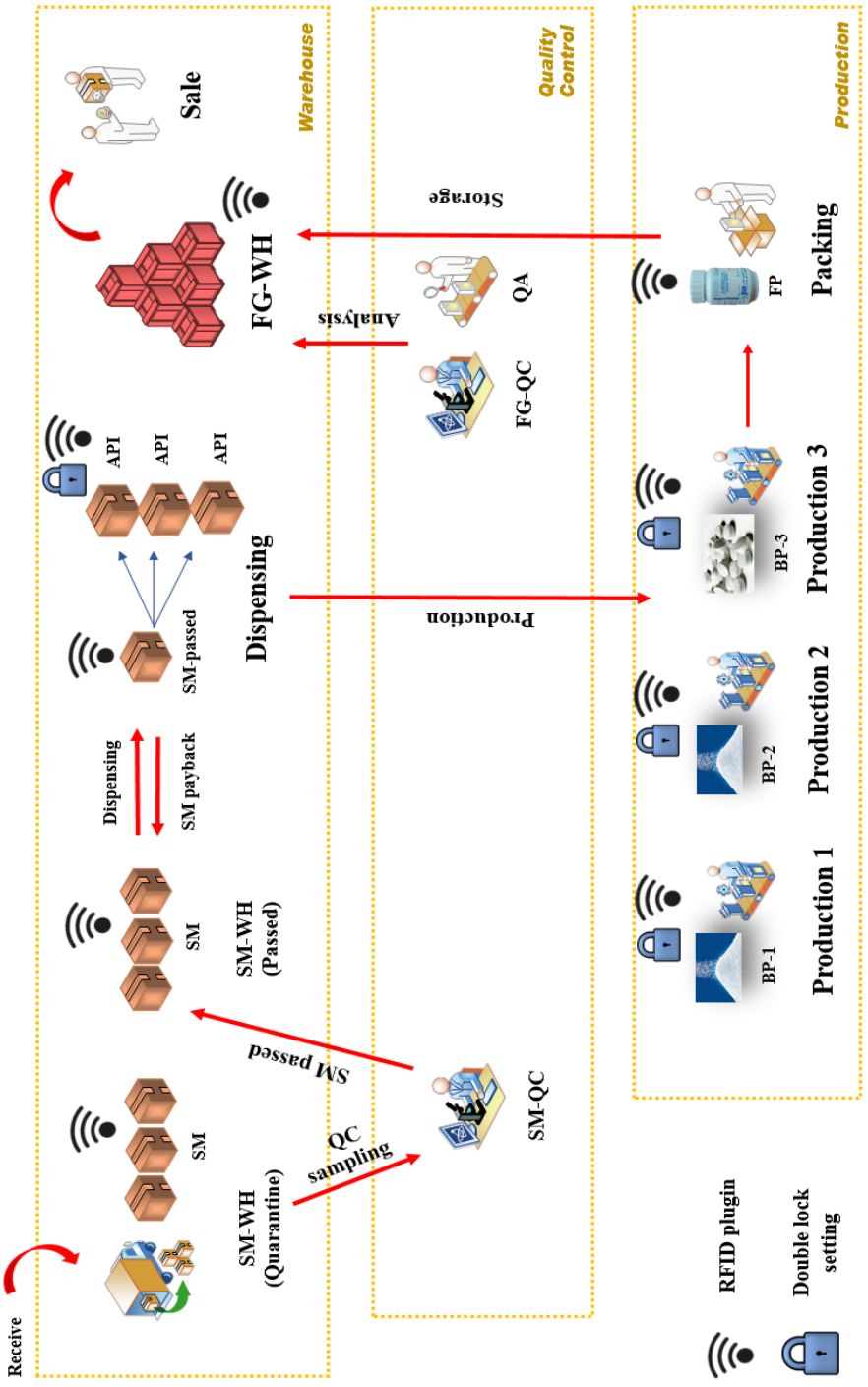


Figure 6 The process flow with RFID plugin

Table 6 The process flow with RFID implementation

Order	Location	Process	Data		Document	Double lock
			Consideration	**Record**		
1	SM-WH	**"Initiation"** received the SM 1. Pharmacist access to the system 2. Pharmacist adheres the tag to the container 3. Pharmacist keys the SM received data into the system	- name of operator	- name and lot no. of SM - detail of supplier - weight and amount - date/time - temp/hu - operator	Receiving doc.	-
		QC takes a sample of SM				
		Waiting for analysis result from QC				
		"Output" export of SM to Dispensing 1. Pharmacist check SM 2. Pharmacist access to the system 3. Pharmacist weighs and records 4. Approved person approves exporting	- name and lot no. of SM - name of operator	- weight - date/time - temp/hu - operator - Approved person	Exporting doc.	-
		"Input" received of SM (loose container) from dispensing 1. Pharmacist check SM 2. Pharmacist access to the system 3. Pharmacist weighs and records	- name and lot no. of SM - received weight and amount are equal to exported - name of operator	- weight - date/time - temp/hu - operator	Receiving doc.	-
2	Dispensing	**"Input"** received the SM 1. Pharmacist check SM 2. Pharmacist access to the system 3. Pharmacist weighs the received SM 4. Pharmacist scans tag and record	- name and lot no. of SM - status "SM-passed" - received weight and amount are equal to exported - name of operator	- weight - date/time - temp/hu - operator	Receiving doc.	-
		Dispense the SM for each production batch 1. Pharmacist check API 2. Pharmacist access to the system 3. Pharmacist adheres the new tag to all of the material bag 4. Pharmacist weighs API and record	- name and lot no. of SM - name of operator	- **Detail of batch of production (name, batch no., category, contain etc.)** - weight of previous tag and new tag - date/time - temp/hu - operator	Transformation doc.	√
		"Output" export of API to production 1. Pharmacist check API 2. Pharmacist access to the system 3. Pharmacist weighs API and record	- name and lot no. of SM - name of operator	- weight - date/time - temp/hu - operator	Exporting doc.	-

Table 6 The process flow with RFID implementation (cont.)

Order	Location	Process	Data		Document	Double lock
			Consideration	Record		
		"Output" export of SM to SM-WH (In case of loose container of SM) 1. Pharmacist check SM 2. Pharmacist accessing 3. Pharmacist weighs SM and record	- name and production batch no. - name of operator	- weight - date/time - temp/hu - operator	Exporting doc.	-
3	Production 1	**"Input"** received the API 1. Pharmacist check API 2. Pharmacist access to the system 3. Pharmacist weighs the received API 4. Pharmacist scans tag and record 5. Pharmacist leave the old tag	- name and production batch no. - status "SM-passed" - received weight and amount are equal to exported - name of operator	- weight - date/time - temp/hu - operator	Receiving doc.	-
		Production 1 (wet granulation) 1. Pharmacist check BP-1 2. Pharmacist access to the system 3. Pharmacist adheres the tag to all of the container 4. Pharmacist weighs BP-1 and record	- name and lot no. of SM - name of operator	- **MFD / EXP** - weight of previous tag and new tag - date/time - temp/hu - operator	Transformation doc.	√
		"Output" export of BP-1 to production 2 1. Pharmacist check BP-1 2. Pharmacist access to the system 3. Pharmacist weighs BP-1 and record	- name and production batch no. - name of operator	- weight - date/time - temp/hu - operator	Exporting doc.	-
4	Production 2	**"Input"** received the BP-1 1. Pharmacist check BP-1 2.Pharmacist access to the system 3. Pharmacist weighs the received BP-1 4. Pharmacist scans tag and record 5. Pharmacist leave the old tag	- name and production batch no. - received weight and amount are equal to exported - name of operator	- weight - date/time - temp/hu - operator	Receiving doc.	-
		Production 2 (dry mixing) 1. Pharmacist check BP-2 2. Pharmacist access to the system 3. Pharmacist adheres the tag to all of the container 4. Pharmacist weighs BP-2 and record	- name and production batch no. - name of operator	- weight of previous tag and new tag - date/time - temp/hu - operator	Transformation doc.	√

Table 6 The process flow with RFID implementation (cont.)

Order	Location	Process	Data		Document	Double lock
			Consideration	Record		
		"Output" export of BP-2 to production 3 1. Pharmacist check BP-2 2. Pharmacist access to the system 3. Pharmacist weighs BP-2 and record	- name and production batch no. - name of operator	- weight - date/time - temp/hu - operator	Exporting doc.	-
5	Production 3	**"Input"** received the BP-2 1. Pharmacist check BP-2 2. Pharmacist access to the system 3. Pharmacist weighs the received BP-2 4. Pharmacist scans tag and record 5. Pharmacist leave the old tag	- name and production batch no. - received weight and amount are equal to exported - name of operator	- weight - date/time - temp/hu - operator	Receiving doc.	-
		Production 3 (tableting) 1. Pharmacist check BP-3 2. Pharmacist access to the system 3. Pharmacist adheres the tag to all of the container 4. Pharmacist weighs BP-3 and record	- name and production batch no. - name of operator	- weight of previous tag and new tag - date/time - temp/hu - operator	Transformation doc.	√
		"Output" export of BP-3 to packaging 1. Pharmacist check BP-3 2. Pharmacist access to the system 3. Pharmacist weighs BP-3 and record	- name and production batch no. - name of operator	- weight - date/time - temp/hu - operator	Exporting doc.	-
6	Packaging	**"Input"** received the BP-3 1. Pharmacist check BP-3 2. Pharmacist access to the system 3. Pharmacist weighs the received BP-3 4. Pharmacist scans tag and record 5. Pharmacist leave the old tag	- name and production batch no. - received weight and amount are equal to exported - name of operator	- weight - date/time - temp/hu - operator	Receiving doc.	-
		Packaging 1. Pharmacist check FP 2. Pharmacist access to the system 3. Pharmacist adheres the inlay tag to all of the bottle 4. Pharmacist counts FP and record	- name and production batch no. - name of operator	- weight of previous tag and new tag - date/time - temp/hu - operator	Transformation doc.	-
		QR code is printed on the bottle				

Table 6 The process flow with RFID implementation (cont.)

Order	Location	Process	Data		Document	Double lock
			Consideration	Record		
		"Output" export of **FP** to FP-WH 1. Pharmacist check FP 2. Pharmacist access to the system 3. Pharmacist counts FP and record	- name and production batch no. - name of operator	- Quantity - date/time - temp/hu - operator	Exporting doc.	-
7	FP-WH	**"Input"** received the **FP** 1. Pharmacist check FP 2. Pharmacist access to the system 3. Pharmacist scans tag and record	- name and production batch no. - received amount is equal to exported - name of operator	- Quantity - date/time - temp/hu - operator	Receiving doc.	-
		Store in warehousing				
		QC takes a sample of SM			* In case of add random analysis	-
		Waiting for analysis result from QC and QA				
		"Output" export of **FP** to distribution center 1. Pharmacist check FP 2. Pharmacist access to the system 3. Pharmacist scans tag and record 4. Approved person approves exporting	- name and production batch no. - name of operator	- Quantity - date/time - temp/hu - operator - Approved person	Exporting doc.	-

3.3 Verification testing

System verification is the process of examining, validating and evaluating of systems and computer programs in order to assure the designed software can be worked as specified in 3.2 and the details of the information required are correct before system testing at the manufacturing site. For verification, the device shall be selected and the process parameter shall be examined.

3.3.1 RFID device selection

Only a few devices are used for system working which was mentioned already in the introduction part. They shall be selected and applied to suit the purpose of use. This study selected at the point including the frequency of system (Fx), RFID tag type (Tx), RFID tag shape (Sx) and RFID reader (Rx) that called FxTxSxRx sequentially as shown in choices of device selection in Table 7 and Figure 7. The equipments in this study was supported by Smart Identify Ltd. For Fx comprised of low frequency (LF, F1), high frequency (HF, F2) and ultra- high frequency (UHF, F3). For Tx comprised of passive tag (T1) and active tag (T2). For Sx comprised of cable tie tag (S1), card tag (S2), wristband tag (S3), metal tag (S4), ship tag (S5), security tie tag (S6) and wet inlay tag (S7). For Rx comprised of a handheld reader (R1) and a fixed reader (R2).

Table 7 RFID device selection

Step	Selection	Choice	
1	Frequency of system (Fx)	F1	LF
		F2	HF
		F3	UHF
2	RFID tag type (FxTx)	T1	Passive tag
		T2	Active tag
3	RFID tag shape (FxTxSx)	S1	Cable tie tag; CTT
		S2	Card tag; CDT
		S3	Wristband tag; WBT
		S4	Metal tag; MTT
		S5	Ship tag; SPT
		S6	Security tie tag; STT
		S7	Wet inlay tag, WIT
4	RFID reader (FxTxSxRx)	R1	Handheld reader
		R2	Fixed reader

Figure 7 The various types of RFID device

3.3.2 Parameter testing

For evaluation of significant parameters that may influence the system, devices which were selected from 1.1 will be tested with controlling for physical and environmental factors. The parameter testing was done at Faculty of Pharmaceutical Sciences, Chulalongkorn University. IBM SPSS Statistics version 22.0 program was used to calculate the statistical value. The significant parameters and detail of experiment are described in Table 8.

Table 8 Method of parameter testing

Parameter test	Experiment	Objective	Detail
A.	Reading distance of non-product attachment.	To examine which the reading angle provide the longest reading distance and how different from reading distance between a fixed reader/a movable tag and a fixed tag/a movable reader.	- The distance reading of four-free tags (WIT, CTT, CDT and MTT) was measured. - Tags were measured at different angles as 0°, 15°, 30°, 45°, 60°, 75° and 90° of tag. - Tags were measured which condition both a fixed reader/a movable tag and a fixed tag/a movable reader.
B.	Reading distance of product attachment	To examine the reading distance of free tag compare to tag which was tracked to object.	- The distance reading of three-installed tags (WIT, CTT and MTT) on tracked objects (carton, plastic bottle, amber glass bottle, SM bag and stainless tank) was measured. - Tags were measured at different angles as 0°, 15°, 30°, 45°, 60°, 75° and 90° of object. - Tags were measured which condition a fixed tag/a movable reader.
C.	The appropriate position of tag attachment.	To examine the optimum side of carton which the WIT was tracked on and the scanning position that provides the optimal reading range.	- The distance reading of WIT was measured which two-size cartons were attached on the various surface area (maximal, medium and minimal area) by scanning at various positions (above, front, back, beside) of tag. - Tags were measured at angles as 45° of carton by assuming the center of the carton was at origin point. - Tags were measured which condition a fixed tag/a movable reader.
D.	Reading distance at different of tag position	To examine the scanning position that provides the optimal reading range for tagging on various objects.	- The distance reading of three-installed tags (WIT, CTT and MTT) on tracked objects (plastic bottle, amber glass bottle, SM tank with metal case, SM bag, stainless tank) was measured by scanning at various positions (front, back, beside) of tag. - Tags were measured at angles as 45° of object by assuming the center of the object was at origin point. - Tags were measured which condition a fixed tag/a movable reader.
E.	Reading distance of multiple RFID tag	To examine the difference of reading range for multiple tags.	- The distance reading of the group of WIT was measured which three-size cartons were stacked for 3, 7 and 10 pieces. - The distance reading of the group of CTT was measured which SM bag were stacked for 3, 7 and 10 pieces. - Tags were measured at angles as 45° of the group of object by assuming the center of them was at origin point and tag was on the front side by scanning position. - Tags were measured which condition a fixed tag/a movable reader.
F.	Impact of overlay object	To examine the effect of the various overlay object in reading range.	- The distance reading of the group of WIT, tags were tracked on plastic bottle and amber glass bottle, was measured. The arrangement of 4, 8 and 12 bottles were inside of three-size cartons. - The distance reading of CDT which inside the clearly plastic zipper bag, paper bag, thick-plastic bag and fabric bag was measured. - Tags were measured at angles as 45° of object by assuming the center of object was at origin point and tag was on the front side by scanning position. - Tags were measured which condition a fixed tag/a movable reader.

A. Reading distance of non-product attachment.

This part is to examine the reading angles providing the longest reading distance and the difference of reading distance between a fixed reader/a movable tag and a fixed tag/a movable reader. The reading distance of four free tags (WIT, CTT, CDT and MTT) chosen from item 1.1 was measured at different angles. The reading angles as 0º, 15º, 30º, 45º, 60º, 75º and 90º (tag angle with a reader which condition both a fixed reader/a movable tag and a fixed tag/a movable reader) were independent variable while the dependent variable was the longest reading distance of a reader can read for each angle. The control variables were the laboratory environment, scale chart, equipment, operator and date of experiment. Eight experiments were done according to the experimental plan (Table 9) with n=10.

Table 9 The experimental plan of reading distance of non-product attachment

Experiment	Testing tag	Distance of reading (a fixed reader and a movable tag)						
		Angle						
		0º	15º	30º	45º	60º	75º	90º
1	WIT							
2	CTT							
3	CDT							
4	MTT							
Experiment	Testing tag	Distance of reading (a fix tag and a movable reader)						
		Angle						
		0º	15º	30º	45º	60º	75º	90º
5	WIT							
6	CTT							
7	CDT							
8	MTT							

B. Reading distance of product attachment

This part is to examine the reading distance of free tag compare to tag which was tracked to object. Comparisons between free tag and three-installed tags (WIT, CTT and MTT) on tracked objects (carton, plastic bottle, amber glass bottle, SM bag and stainless tank) were done in different angles. The type of object and the reading angles as 0^o, 15^o, 30^o, 45^o, 60^o, 75^o and 90^o (tag angle with a reader which condition only a fixed tag/a movable reader) were independent variable while the dependent variable was the longest reading distance of a reader can read for each angle. Same as 1.2.1, the control variables mentioned are the laboratory environment, scale chart, equipment, operator and date of experiment. Five experiments were done according to the experimental plan (Table 10) with n=10.

Table 10 The experimental plan of reading distance of product attachment

Experiment	Testing tag		Distance of reading (a fixed tag and a movable reader)						
	tag	Tracking on	Angle						
			0^o	15^o	30^o	45^o	60^o	75^o	90^o
1		Carton							
2	WIT	Plastic bottle							
3		Amber glass bottle							
4	CTT	SM bag							
5	MTT	Stainless tank							

C. The appropriate position of tag attachment

This part is to examine the optimum side of carton which the WIT was tagged on and the scanning position that provides the optimal reading range. The distance reading of WIT was measured which different two-size cartons were attached on the various surface area at various side of tag. The surface area of the carton (maximal, medium and minimal area) and various scanning position of tag (above, front, back and beside) were independent variable (tag angle with a reader which condition only a fixed tag, but move of reader at reading angle as 45^o of carton by assuming the center of the carton was at origin point) while the dependent variable was the scanning position that provides the longest distance of a reader can read. The control variables mentioned are the RFID tag type, the laboratory environment, scale chart, equipment, operator and date of experiment. Twenty experiments were done according to the experimental plan (Table 11) with n=10.

Table 11 The experimental plan of the appropriate position of tag attachment

Experiment	Testing tag		Scanning of RFID tag which various side		Distance of reading (a fixed tag and a movable reader at reading angle as 45°)
	Object	The surface area of the carton			
1,2,3,4	L-size carton	Maximal area	X	Above Front Back Beside	
5,6,7,8		Medium area			
9,10,11,12		Minimal area			
13,14,15,16	XL-size carton	Maximal area			
17,18,19,20		Minimal area			

D. Reading distance at different of tag position

This part is to examine the scanning position that provides the optimal reading range for tagging on various objects. The distance reading of three-installed tags (WIT, CTT and MTT) on tracked objects (plastic bottle, amber glass bottle, SM tank with metal case, SM bag and stainless tank) was measured at various positions of RFID tags. The type of object and scanning of RFID tag which various scanning positions (front, back and beside) of tag were independent variable (tag angle with a reader which condition only a fixed tag, but move of reader at reading angle as 45° of object by assuming the center of the object was at origin point.) while the dependent variable was the scanning position that provides the longest distance of a reader can read. The control variable mentioned were the laboratory environment, scale chart, equipment, operator and date of experiment. Fifteen experiments were done according to the experimental plan (Table 12) with n=10.

Table 12 The experimental plan of reading distance at different of tag position

Experiment	Testing tag		Scanning position with reader		Distance of reading (a fixed tag and a movable reader at reading angle as 45°)
	Tag	Tracking on			
1,2,3	WTT	Plastic bottle	X	Front Back Beside	
4,5,6		Amber glass bottle			
7,8,9		SM tank with metal case			
10,11,12	CTT	SM bag			
13,14,15	MTT	Stainless tank			

E. Reading distance of multiple RFID tag

This part is to examine the difference of reading range for multiple tags. The distance reading of the group of WIT which three-size cartons and the group of CTT which SM bag were stacked for 3, 7 and 10 pieces were measured. The type of object (three-size cartons and SM bag) and the amount of object (3, 7 and 10 pieces) were independent variable (tag angle with a reader which condition only a fixed tag, but move of reader at reading angle as 45o of the group of object by assuming the center of them was at origin point and scanning position of tag was on the front side) while the dependent variable was the scanning position that provides the longest distance of a reader can read. The control variable mentioned were the laboratory environment, scale chart, equipment, operator and date of experiment. Twelve experiments were done according to the experimental plan (Table 13) with n=10.

Table 13 The experimental plan of reading distance of multiple RFID tag

Experiment	Testing tag	Group of object		Distance of reading (a fixed tag and a movable reader at reading angle as 45^{o})
1,2 ,3		Carton 1		
4, 5, 6	WTT	Carton 2	3, 7, 10 pieces	
7, 8, 9		Carton 3		
10, 11, 12	CTT	SM bag		

F. Impact of overlay object

This part is to examine the effect of the various overlays in reading range. The distance reading of CDT and the group of WIT were measured. The CDT was inside overlay as a bag and the WIT was tagged on plastic bottle and amber glass bottle that were arranged of 4, 8 and 12 bottles inside overlay as a carton. The type of object (plastic bottle, amber glass bottle), the amount of object (4, 8 and 12 bottles) and type of overlay (three-size cartons, clearly plastic zip bag, paper bag, thickly-plastic bag and fabric bag) were independent variable (tag angle with a reader which condition only a fixed tag, but move of reader at reading angle as 45^{o} of object by assuming the center of object was at origin point and scanning position of tag was on the front side.) while the dependent variable was the scanning position that provides the longest distance of a reader can read. The control variable mentioned were the laboratory environment, scale chart, equipment, operator and date of experiment. Twenty-two experiments were done according to the experimental plan (Table 14) with n=10.

Table 14 The experimental plan of impact of overlay object

Experiment	Testing tag	Objects	Overlay object		Distance of reading (a fixed tag and a movable reader at reading angle as 45°)
1, 2, 3	WTT	Plastic bottle	in carton 1	Arrange of X bottle for 4, 8 and 12 bottles	
4, 5, 6			in carton 2		
7, 8, 9			in carton 3		
10, 11, 12		Amber glass bottle	in carton 1		
13, 14, 15			in carton 2		
16, 17, 18			in carton 3		
19	CDT	In the clear plastic zip bag			
20		In the paper bag			
21		In the thick plastic bag			
22		In the fabric bag			

3.3.3 Software verification

System verification is the process of validating, estimating, and evaluating of computer systems to assure that the designed software can be work as the URS requirement including the details of the data are correct. Verification was performed using the appropriate parameters which were tested (from 3.3.2). The simulation workflow of production and a special scenario as SM no-pass, weight loss during shipping and SM and FP sampling were done which receiving of four starting materials (SM) and five production batches were simulated like the manufacturing plant that the detail of simulation of production are shown in Table 15. The evaluation system was done according to the URS by researcher and system specialist who are experienced in the pharmaceutical manufacturing industry.

Table 15 The production simulation

Department	Process	Product detail								
		Starting Material (SM)				Drug Production				
		Diazepam (R2-5900011)	Diazepam (R2-5900022)	Phenobarbital (R2-5900033)	Phenobarbital (R2-5900044)	Diazepam 2 mg (T6001001)	Diazepam 2 mg (T6001002)	Diazepam 5 mg (T6002001)	Phenobarbitone 60 mg (T6003001)	Phenobarbitone 60 mg (T6003002)
SM-WH	SM receive	3 bags	2 bags	3 bags	2 bags					
	SM sampling	Yes SM pass	Yes SM no pass	Yes SM pass	Yes SM pass					
	Sent to Dispensing	yes		yes	yes					
	Receive for return	yes		yes	yes					
Dispensing	Product receive	yes		yes	yes					
	Dispensed	to T6001001 T6001002 T6002001		to T6003001	to T6003002					
	Return to SM-WH	yes		yes	yes					
	Sent to Production	yes		yes	yes	1 bag	1 bag	1 bag	1 bag	1 bag
Production 1	Product receive					1 bag	1 bag	1 bag	1 bag	1 bag
	Produced (wet mixing)					yes	yes	yes	yes	yes
	Sent to production 2					3 bags	3 bags	3 bags	3 bags	3 bags
Production 2	Product receive					3 bags	3 bags	3 bags but weight loss for 1	3 bags but weight loss for 3	3 bags
	Produced (dry mixing)					yes	yes	yes	yes	yes

Table 15 The production simulation (cont.)

Department	Process	Product detail								
		Starting Material (SM)				Drug Production				
		Diazepam (R2-5900011)	Diazepam (R2-5900022)	Phenobarbital (R2-5900033)	Phenobarbital (R2-5900044)	Diazepam 2 mg (T6001001)	Diazepam 2 mg (T6001002)	Diazepam 5 mg (T6002001)	Phenobarbitone 60 mg (T6003001)	Phenobarbitone 60 mg (T6003002)
	Sent to production 3					3 bags	3 bags	3 bags	3 bags	3 bags
Production 3	Product receive					3 bags	3 bags	3 bags but weight loss for 1	3 bags but weight loss for 3	3 bags
	Produced (tableting)					yes	yes	yes	yes	yes
	Sent to packaging					3 bags	3 bags	3 bags	3 bags	3 bags
Packaging	Product receive					3 bags	3 bags	3 bags but weight loss for 1	3 bags but weight loss for 3	3 bags
	Produced (packaging)					yes	yes	yes	yes	yes
	Sent to FP-WH					5 bottles	5 bottles	5 bottles	5 bottles	5 bottles
FP-WH	Product receive					5 bottles	5 bottles	5 bottles	5 bottles	5 bottles
	FP sampling					no	2 bottles	no	1 bottle	no
	Sent to DC					5 bottles	3 bottles	5 bottles	4 bottles	5 bottles
	DC name					Pathum thani	Chiangmai	Songkhla	Phitsanulok	Udonthani

3.4 Manufacturing site testing

PIC/S (2017) recommended that a suitable installation qualification (IQ) and operational qualification (OQ) should substantiate the designed software that that are fit for intended use and the site testing should be tested (Pharmaceutical Inspection Convention Pharmaceutical Inspection Co-Operation Scheme (PIC/S), 2017b). Site testing was performed as the manufacturing case study in GPO with the selected devices and the verified system following topic 3.3. The actual testing of computerized systems was conducted by an operator which were clearly explained about system description and device usage before testing. During site testing experiment, one batch of phenobarbital tablets 30 mg and six batches of phenobarbital tablets 60 mg were produced. The starting material was received to SM-WH (Raw Material section 1) and it was sent to production section (Tableting 1 section) for pulverizing to be fined API, dispensed, wet granulation, dry mixing and tableting. Generally, the bulk products were packed at packaging section (Tablet Packing section 1) and were stored at FP-WH waiting for distribution. Because GPO concerned about the finished product would be contaminated and changed from normal, the site testing terminated tracking when the bulk products were shipped to packaging section. Packaging, shipping FP to FP-WH, analytical reporting of FP by QC and shipping FP to distribution center are not done. The process with RFID plugin and double lock setting for site testing was described in brief in Figure 8.

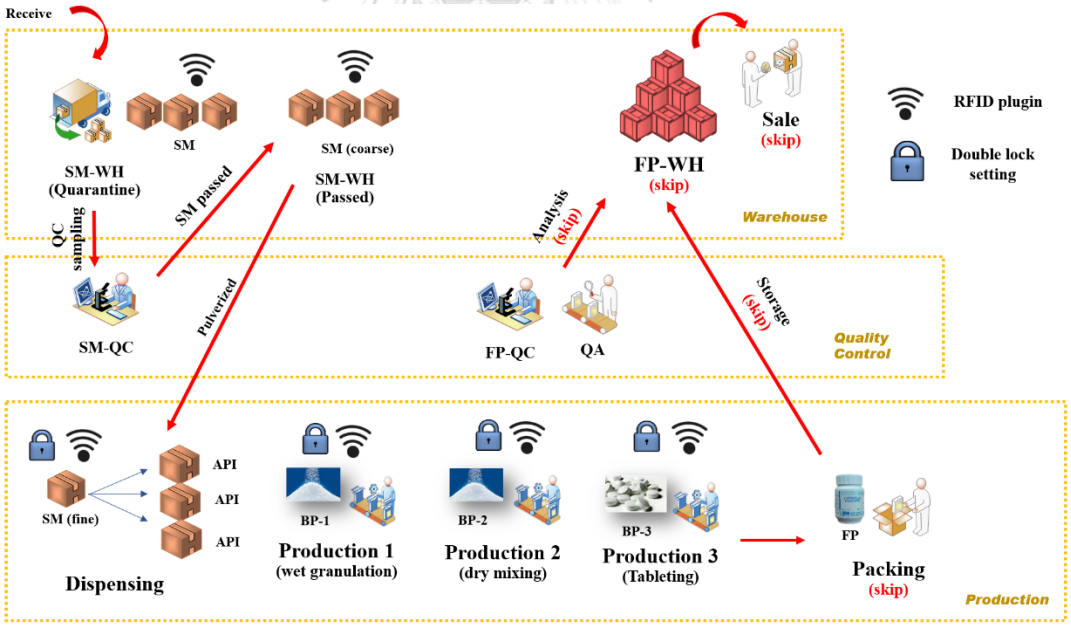


Figure 8 The process with RFID implementation at site testing

To select operators, head of section, pharmacist and staff with experienced in the field at least 2 years were chosen. They all understood system working, program assessing and device using. The evaluation questionnaire should be executed as follows;

Part 1 - Risk Assessment. To determine whether the used software improved the process or reduced risk of work. Eleven potential failure modes which different impact during transportation and production tracking both normal operation and operation with RFID implementation would be evaluated using FMEA tool according to ICH Q9 guideline. The severity of the impact of risk on the quality of the product (Severity, S), the probability of occurrence of risk based on the frequency (Opportunity, O) and the detectability of impact of risk based on the detection control (Detectability, D) were determined as score 1 to 5 as Table 16. The average Risk Priority Number (RPN) will be calculated using equation as shown below. Microsoft Excel 2010 was used to calculate the Risk Priority Number (RPN).

$$RPN = S \times O \times D$$

$$\overline{RPN} = \frac{1}{n}\sum S \times \frac{1}{n}\sum O \times \frac{1}{n}\sum D$$

Table 16 FMEA assessment criteria

FMEA Assessment Criteria*		
Severity: Categorize and identify the severity of impact of risk on the quality of the product/service as High/ Medium/ Low as defined below		
Category	**Score**	**Description of Severity (S)**
Low	1-2	- Limited or no impact on operations and quality of operational efficiency. - No impact to product quality and process robustness.
Medium	3	- Impact on operations and efficiency, but not pervasive. Management intervention required. - Noticeable impact to product quality.
High	4-5	- Very significant and catastrophic impact, significant losses and inefficiencies, necessitating immediate attention. Loss of operating capability, deterioration of efficiency. - Critical deviation from GMP requirements. - Batch failure.
Probability: Categorize and identify the probability of occurrence of risk based on the frequency as High/ Medium/ Low as defined below:		
Category	**Score**	**Probability of Occurrence**
Low	1-2	Seen every more than 3 years.
Medium	3	Seen every 1-3 years.
High	4-5	Seen to occur more than once a year.
Detectability: Categorize and identify the detectability of impact of risk based on the detection control as High/ Medium/ Low as defined below:		
Category	**Score**	**Description of Detectability (D)**
Low	4-5	- Detection controls are absent. - Low likelihood that controls will detect the failure mode or its effects.
Medium	3	- Medium likelihood that controls will detect the failure mode or its effects.
High	1-2	- High likelihood that controls will detect the failure mode or its effects.

The risk class was defined by severity (S) cross with probability (P) which was divided into 5 classes; low, low to medium, medium, medium to high and high class. Then, the priority of risk was specified by the risk class cross with detectability (D) which was divided into 5 priorities; negligible, minor, moderate, major and critical. The finding of risk class and priority of risk were shown in Figure 9. The priority risk of both normal operation and RFID implementation were also specified. If the risk with a priority of RFID implementation was lower than normal operation, we expected that RFID implementation would reduce the risk as stated and the RPN decreasing will be calculated. The percentage of RPN decreasing was calculated from the average RPN of normal operation (RPN_{nor}) and the average RPN of operation with RFID implementation (RPN_{im}) equation as shown below;

$$\text{RPN decrease} = \overline{RPN}_{nor} - \overline{RPN}_{im}$$

$$\text{RPN decrease (\%)} = (\text{RPN decrease}*100) / \overline{RPN}_{nor}$$

Severity \ Probability	1	2	3	4	5
5	Low Med	Medium	Med hi	High	High
4	Low	Low Med	Medium	Med hi	High
3	Low	Low Med	Medium	Med hi	Med hi
2	Low	Low Med	Low Med	Medium	Med hi
1	Low	Low	Low Med	Medium	Medium

Finding the risk class

Risk Class \ Detectability	1	2	3	4	5
High	Minor	Moderate	Major	Critical	Critical
Med hi	Negligible	Minor	Moderate	Major	Critical
Medium	Negligible	Minor	Moderate	Major	Major
Low Med	Negligible	Minor	Minor	Moderate	Major
Low	Negligible	Negligible	Minor	Moderate	Moderate

Priority the risk

Figure 9 Finding the risk class and priority of risk

Part 2 - Satisfaction Questionnaire. To inquire whether the developed software be appropriated for the own manufacturing currently and be intended use to solve the problem (using the same topic as URS). The satisfaction level was divided into 5 levels as follows; very satisfied (5 score), satisfied (4 score), neither satisfied nor dissatisfied (3 score), dissatisfied (2 score) and very dissatisfied (1 score).

Part 3 - System Impact Assessment. To determine whether the RFID technology be impact on GMP requirement or quality of product. For example; does the system support manufacturing?, does the system impact the quality, identity, strength or purity of the product or its components?, does the system record, change, monitor, transmit or make decisions about data related to products or its components?, does the system define what material (starting material or components) are to be used for the product or recording the manufacturing data? or does the system impact the status of starting material, packaging material, work in process material, finished product in warehouse and distribution center? If the evaluation was answered at least

one time of “yes” showing that the RFID technology requires the GxP relevant for application to the manufacturing.

Part 4 – Recommendation. The evaluator could express their opinions in this article.

The software evaluation questionnaires and the FMEA assessment criteria were described in Appendix B.

3.5 Value estimation

The value estimation is the indispensable thing that should be considered for new technology adoption. For this research, the value estimation was enquired directly from the supplier including Smart Identify (Thailand) Ltd. and Fuya Co., Ltd.

CHAPTER IV
RESULTS

4.1 Evaluation of RFID system design

The system which was integrated with RFID technology was designed to track starting material and production throughout the supply chain according to GMP, GDP and GSP guidelines were described in Table 17 and users were able to real-time checking of their information comfortably. The system is focused on checking the weight of received products compared with the output from the previous department. The non-reusable RFID cable tie tags and wet inlay tags were used because of no any device replacement if already used. Moreover, the double lock accessories protected opening the SM bag during transportation which the devices would be unlocked when the products were shipped to the target department.

Table 17 Summary of system process and their data input according to GMP, GSP and GDP guideline

Guildline	GMP GDP						GSP
	GSP						
Location	**SM-WH**	**Dispensing**	**Production 1**	**Production 2**	**Production 3**	**Packaging**	**FP-WH**
Direction	→	→	→	→	→	→	→
Process Data input	**"Initiation"** received the SM - name and lot no. of SM - detail of supplier - weight and amount - date/time - temp/hu - operator	**"Input"** received the SM - weight - date/time - temp/hu - operator	**"Input"** received the API - weight - date/time - temp/hu - operator	**"Input"** received the BP-1 - weight - date/time - temp/hu - operator	**"Input"** received the BP-2 - weight - date/time - temp/hu - operator	**"Input"** received the BP-3 - weight - date/time - temp/hu - operator	**"Input"** received the **FP** - Quantity - date/time - temp/hu - operator
	QC takes a sample of SM Waiting for analysis result from QC **"Output"** export of SM to Dispensing - weight - date/time - temp/hu - operator - Approved person	**"Dispense"** the SM for each production batch - detail of batch of production (name, batch no., category, contain etc.) - weight of previous tag and new tag - date/time - temp/hu - operator	**"Production 1"** (wet granulation) - Mfd / Exp date - weight of previous tag and new tag - date/time - temp/hu - operator	**"Production 2"** (dry mixing) - weight of previous tag and new tag - date/time - temp/hu - operator	**"Production 3"** (tableting) - weight of previous tag and new tag - date/time - temp/hu - operator	**"Packaging"** - weight of previous tag and new tag - date/time - temp/hu - operator	QC takes a sample of SM Waiting for analysis result from QC and QA **"Output"** export of FP to distribution center - Quantity - date/time - temp/hu - operator - Approved person
	"Input" received of SM (loose container) from dispensing - weight - date/time - temp/hu - operator	**"Output"** export of API to production - weight - date/time - temp/hu - operator **"Output"** export of SM to SM-WH (In case of loose container of SM) - weight - date/time - temp/hu - operator	**"Output"** export of BP-1 to production 2 - weight - date/time - temp/hu - operator	**"Output"** export of BP-2 to production 3 - weight - date/time - temp/hu - operator	**"Output"** export of BP-3 to packaging - weight - date/time - temp/hu - operator	**"Output"** export of FP to FP-WH - Quantity - date/time - temp/hu - operator	

"Pharmaceutical Manufacturing Process Tracking System" was local language software which was integrated with RFID system as "On-line mode" (Rachivong, 2017), a handheld reader itself can process data by using the same database as in computer. There are 4 applications to work together appropriately and conveniently including the database, web service API, android application (handheld reader) and web application as showed in Figure 10. Although the design and implementation of each part was cumbersome but overall performance was better when the multiple units were working together. For example, working speed was higher because the work functions were clearly divided, flexible to work, and able to use with any computers (PC, notebook). Briefly, the overview of each applications is as follows:

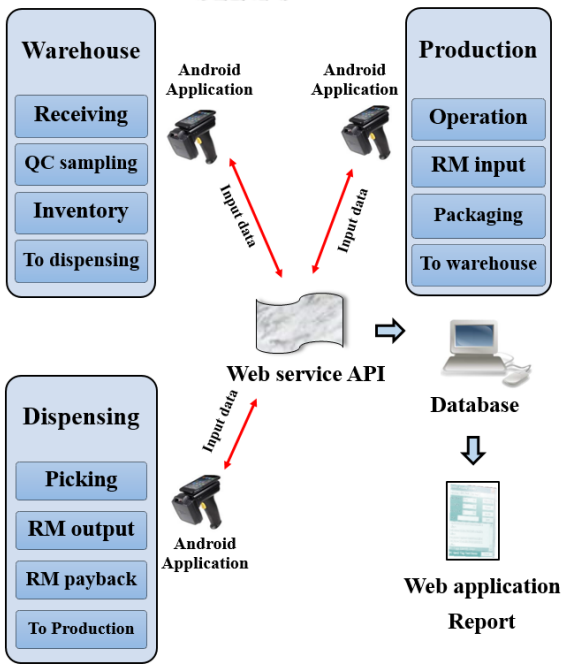


Figure 10 The operation with on-line mode

1. **Database**, SQL server management studio was used to storage and information management for Windows operating system that the operation screen is showed in Figure 11. The database includes document creation, data inspection of received and exported product, approval inspection, accessed control and transformation.

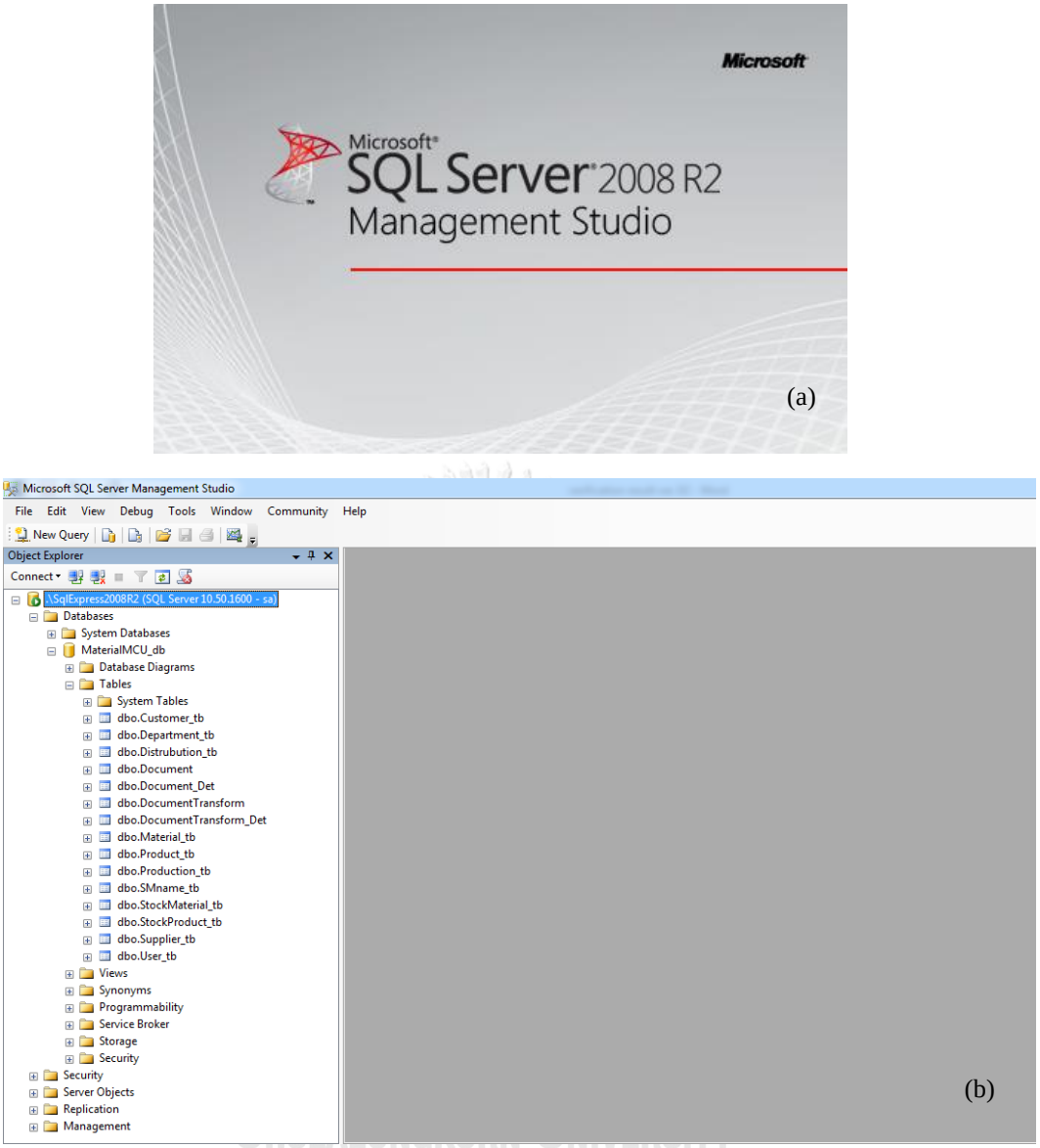


Figure 11 The screen operation of SQL server management studio (a, b)

2. **Web Service API** (Application Programming Interface), the middleware that harmonized or exchanged information among the different systems as the database, web application and android application to work simultaneously when the android application inputted the data, web API will receive, transform, and send to a database for data processing and analysis.
3. **Data input device**, the android operating system used as working device for data entry that was on the handheld reader. Although the handheld reader was the movable tool that easy to use, it was a device with limited memory and performance. No data was stored on the device; it requires a Web Service and can be viewed the report via PC (which provides more detailed information than a mobile device). The application on device consists of 7 work modules as Figure 12 based on authorization as mentioned in topic 3.2.2 Functional requirement.

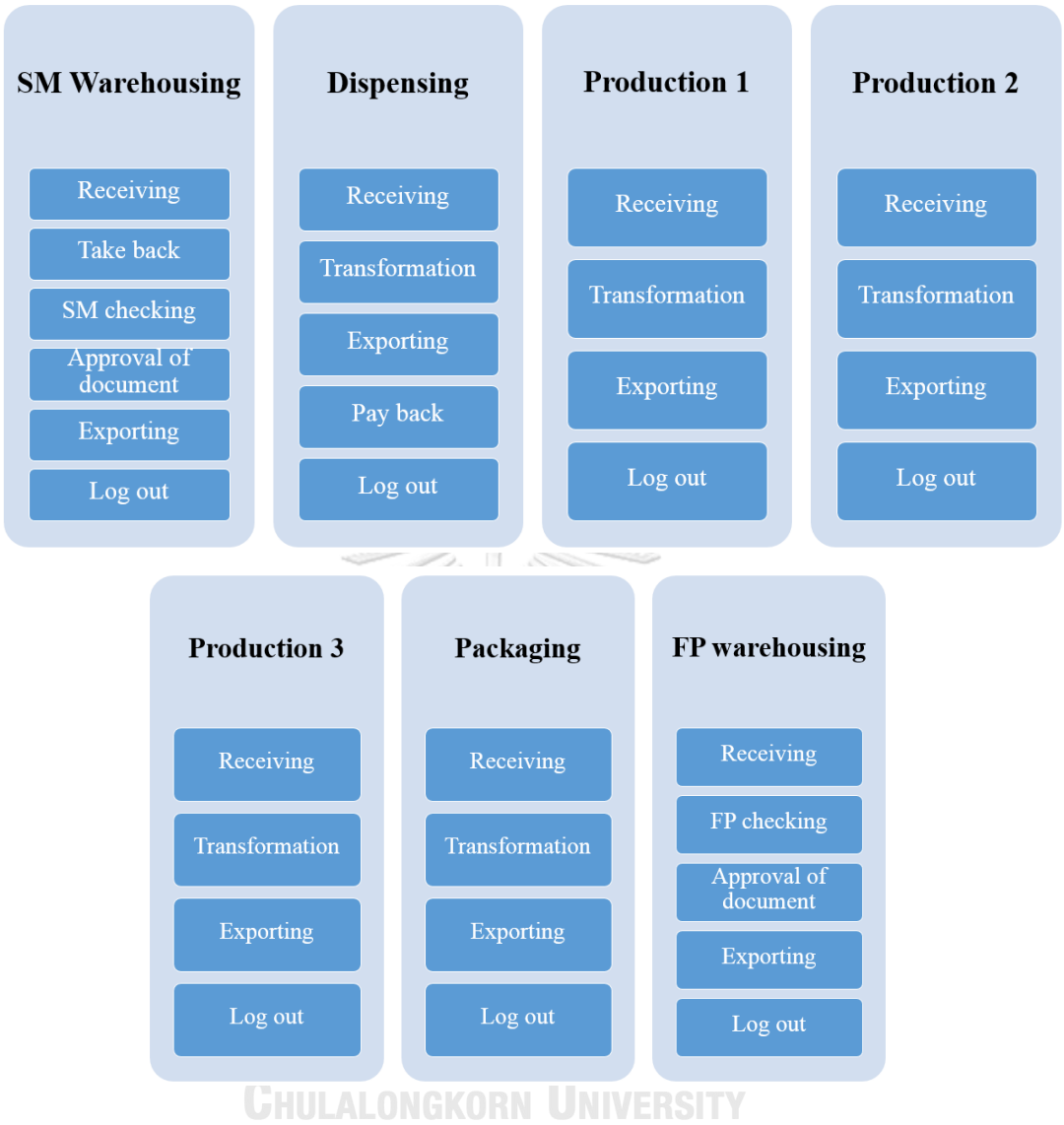


Figure 12 The work module according to authorized accessing of different department

"Pharmaceutical Manufacturing Process Tracking System" was an android application operated via handheld reader. It could work in accordance with work procedures as stated in the topic 3.2. There were eight main tasks as described below,

1. *Login to work*. The system should be logged in by personal RFID card. The operating date and time working in the system will be recorded to operator. Then, the operator should log out of program immediately after work.
2. *Selection of new tag and examining of tag.* The system would have a checking program and were allowed only using the new tag. It was not allow to reuse the tag. The repeated and the reusable tag as personal card tag or metal tag should be removed the former data from the database before use again.

3. *Receiving the SM into SM-WH.* The information about receiving SM was recorded including receiving date, SM name, SM lot, supplier data, weight of each SM box operating humidity and temperature.
4. *Receiving product into department.* This task includes return SM back to SM-WH. All goods which will be imported into the department should be matched with exporting document from the previous department and should be recorded as receiving document including checking name, amount and weight of material and operating humidity and temperature.
5. *Checking of SM and FP.* For SM, the system can be displayed the information of goods in stock as SM name, lot no., supplier, received date, QC sampling weight, status and priority. The SM that showed the status as "SM-pass" and priority as "first out" should be picked it out first. For FP, the system can be displayed the information of products in stock as FP name, amount, batch no., reg. no, contain, Global Trade Item Number (GTIN), status, batch size, category of drug, MFD date and EXP date.
6. *Transforming of product.* All information throughout the transformed process should be documented. For example, the transformation 1) from SM to API, 2) from API to mixed IP, and 3) from mixed IP to FP (tablets). The documents should be recorded information regarding the weight of starting product, product name, batch no (for dispensing section), MFD date, EXP date (for production 1 section), new weight per container, operating humidity and temperature. The upstream information still was recorded in a system database and additional data would be saved throughout the manufacturing process.
7. *Exporting products off.* The finished goods for each department which will be exported to the next department should be recorded as exporting document including sampling weight (for SM-WH section), distribution center name (for FP-WH section), operating humidity and temperature.
8. *Document approval.* Because the system was not designed the screen of the QC and QA section, the COA of SM and FP should be checked by an approved person of SM-WH and FP-WH. They would approve the exporting document before carrying the product out of department.

4. **Web Application**, The login into the system is required to prevent unauthorized person. Web application was used to browse the process output or the report that was proceeded by the database from many operators at the point of use in various places. The screen of the web application working is shown in Figure 13.

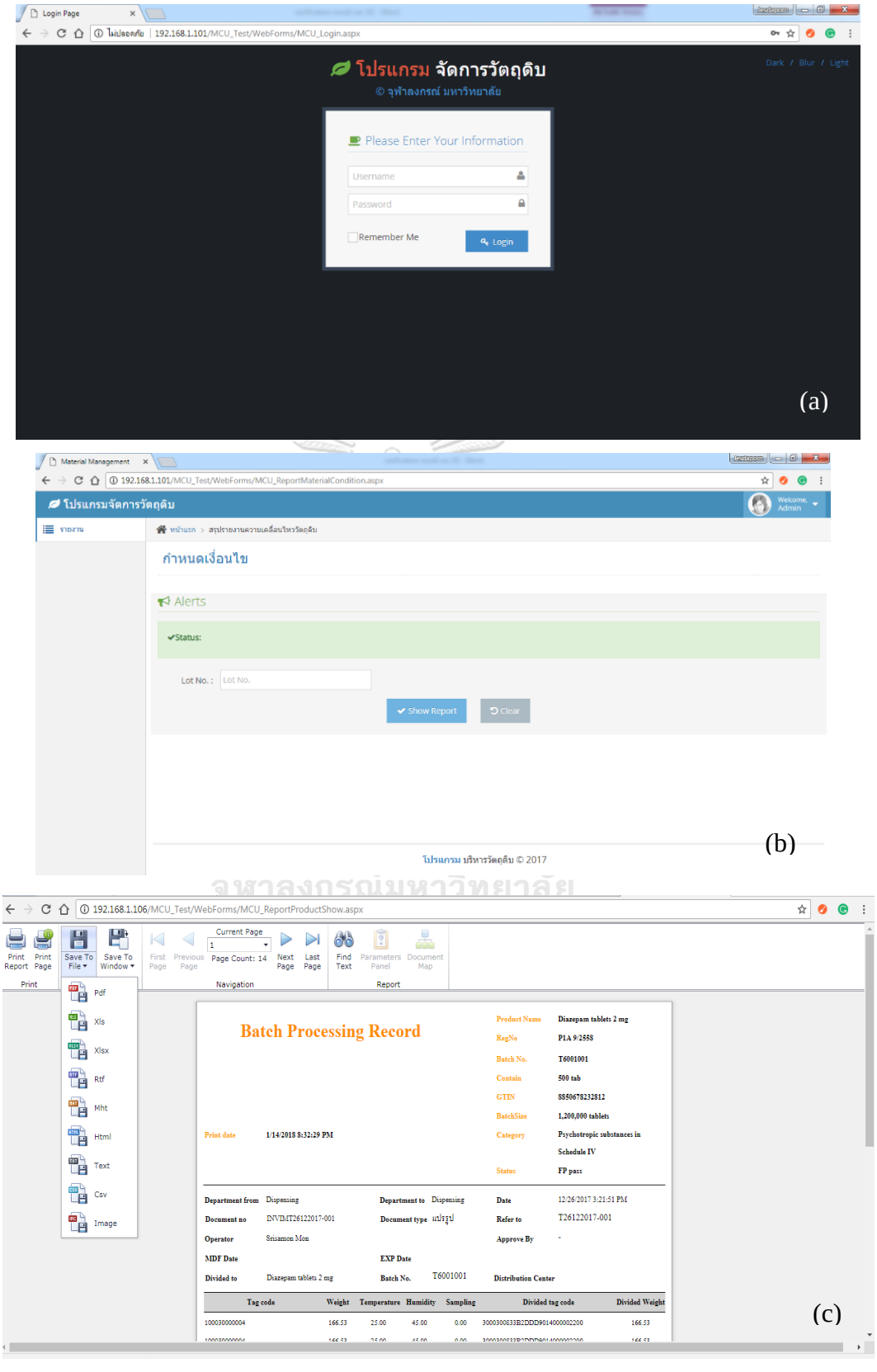


Figure 13 The screen of the web application (a, b, c)

4.2 RFID device selection

The RFID devices were selected to suite for the purpose usage on the subject. Devices were chosen which referred to Appendix C (Evaluation form of select the device). The choice of devices which were stated in topic 3.3.1 as follow: the frequency of system, Fx (F1-F3), RFID tag type, Tx (T1-T2), RFID tag shape, Sx (S1-S7) and RFID reader, Rx (R1-R2) were chosen in term of FxTxSxRx.

For the frequency of system (Fx), the choice of frequency will vary by different applications such as low frequency (LH, 125-135 kHz), high frequency (HF, 13.56 MHz) and ultra-high frequency (UHF, 860-960 MHz). Many researchers have researched technology application on the various fields and applied different frequency. For example, Maselyne (2014) considered that the HF tag tracked on the pig's ears can be used to measure feeding patterns of growing-finishing pigs potentially. Generally, UHF tag is used in the livestock sector whereas Uysal, Emond & Engels (2008) reported that the use of UHF RFID system offers superior performance and readability for pharmaceutical application than the HF system. HF and UHF system can still offer a good performance in different sections.

LH and HF were suitable for requiring access control, logistics and transportation; they are also inexpensive. LH provides fewer data storage without password, short read range, slow reading for slow-moving object and less variety of RFID tag packages. On the other hand, HF which has more data storage with or without password, longer read/write range, and faster reading for faster moving object. Even higher cost, UHF offered a wide design of tag devices, the most data storage with or without password, the longest read/write range and the fastest reading for a moving object rapidly that multiple objects. It can be also identified in a shorter time more than LF and HF. The selection of frequency (Fx) was described in Appendix C-1.

RFID tag type (Tx), using as an intermediary information storage and sending to a database, was varied in term of frequencies on system operation. The active RFID tag can be worked with UHF, recorded all necessary information, and used for identifying the very long length application, but the passive tag was superior to active tag. An economical passive tag has no internal power source, unlike the active tag which is powered by the electromagnetic energy transmitted from an RFID reader, read/write by signalizing from a reader, used for a short length that reasonable distance in a pharmaceutical process, and eased to maintenance. Normally, the use of tags is required tracking one object per one tag. The selection of RFID tag was described in Appendix C-2.

For RFID tag shape (Sx), RFID applications are a wide range, therefore, different tags were chosen according to the usage. The card tag, wristband tag and shipped tag were suitable for accession that could be worked with selected frequency, necessary recorded information, reusable, convenient usage, and lightweight. Even the card tag is inexpensive and more expedient than wristband tag and ship tag, so the card tag was chosen for accessible control using. The cable tie tag, metal tag and wet inlay tag were suitable for material tracking because they can be operated with UHF, lightweight, simplicity of product installation, and essentially recordable information.

The cable tie tag would prevent SM bag from operators open the bag better than metal tag and wet inlay tag. The reason not chosen the metal tag because of too huge and cannot fasten the material bag. The metal tag might be adapted for attaching to stainless tank and it was used for parameter test. The wet inlay tag cannot fasten the material bag. However, the wet inlet tag might be suitable for attaching on a carton or bottle. The security tie tag is the most appropriate for the double lock system, because of high cost, the replacement by using EAS devices. The selection of RFID tag shape was described in Appendix C-3.

Finally, Aliakbar (2015) presented a RFID reader (Rx) study to evaluate the difference between RFID system and barcode scanner for the manufacturing process. The result showed a performance of a RFID scanner enhanced the productivity that works higher the assembly workstation than barcode scanner. So, a handheld reader and a mobile usage were more convenient to read and write promptly, and meet accurately to data processing length transferred via RFID software between itself and RFID tag, and inexpensive than a fixed reader. The selection of RFID reader was described in Appendix C-4.

In summary, the UHF (F3), a passive tag (T1) and a handheld reader (R1) were chosen this study with a various shape of tags which were divided into 4 groups as follows:

Group 1: F3-T1-S1-R1. Using CTT for tracking the material plastic bag (dispensed material and work in process (WIP)).

Group 2: F3-T1-S2-R1. Using CDT for accessing to the system by authorized person.

Group 3: F3-T1-S4-R1. Using MTT for tracking the stainless tank and parameter testing.

Group 4: F3-T1-S7-R1. Using WIT for tracking the plastic tank, SM carton, received material box and finished product bottle.

Electronic Article Surveillance (EAS) system is commonly secure technologies for numerous retailers those are uncomplicated usage and could be reusable accessories. Two normal usage of EAS system, acousto-magnetic (AM) and radio frequency (RF), are the highest theft situations (Bottani, Ferretti, Montanari, Rizzi, & Volpi, 2012). The RFID implementation supports the EAS-AM system for anti-theft purpose better than EAS-RF system. Acousto-magnetic system (AM) is one of the EAS systems that operates at the frequency of 58 KHz. AM technology is a non-identification use that does not interfere with RFID operation or any ambient such as neon signs, overhead fluorescent lights and other electric interference. For those reason, the EAS-AM system was used for alternative accessories which was integrated with RFID to be more safeguarding of product. The system consisted of EAS hard tag, detacher and handheld detector, in Figure 14, which were used as double locker to prevent opening of material bag during inter-departmental shipping. These were supported by Fuya Co., Ltd.

The EAS-AM devices were described as below;

1. EAS tag, the soft tag was attached to a non-reusable product; while the hard tag was to removable, unlimited, and reusable product. There is a variety of EAS tag design, including a hard tag box, a guard set, a canister locker set, or a bottle locker set. A cable tie with a hard tag width 7.8 mm, length 47.64 mm and thickness 8.10 mm is used in this study.

2. Detacher or an unlocked that used to remove a hard tag. For this study, it was installed in each department. The material bags were opened only in the related department. The selected detacher had 63.40 mm diameter and 37.94 mm highness.

Figure 14 EAS-AM double lock kit: handheld detector (left), hard tag (right, top) and detacher (right, bottom)

3. EAS handheld detector. It would alarm if getting a hard tag out of a defined area. Various kinds of detector could be chosen and some kind could be applied for obscuring in the walls or floors of an entrance-exit area. For the research, the detecting distance was about 150 mm with detector size 375 mmx77 mmx33 mm but could be adapted to anti-thief work by using EAS-gates detector that provides widely distance (about 1.2-1.8 mm). If the products are moved into other department through gate sensor alert, they will have not been opened during shipping.

4.3 Parameter testing

A. Result of reading distance of non-product attachment.

According to an experiment A, four free tags were measured at seven different angles which are each condition had both a fixed reader/a movable tag and a fixed tag/a movable reader. During experimentation, the reader was stopped and fully charged for 1.5-2 hours in each tag. The scale chart was installed in the laboratory (25^{o}c, 35-65%RH) which each experiment was the same operation.

For the evaluation, the researcher selected from an actual device representative in the pharmaceutical manufacturing industry, shown in Figure 15. Device-A was a wet inlay tag (WIT), RFID label model UHF-C50 (52x33 mm). Device-B was UHF yellow cable tie tag (CTT) with size 26.76 x 43.02 mm and weight 4.15 g. Device-C was UHF RFID white card tag (CDT) with size 26.76 x 43.02 mm and weight 5.65 g. Device-D was UHF RFID black metal tag (MTT) with size 25.02 x 95.15 mm, thickness 3.84 mm, and weight 17.53 g.

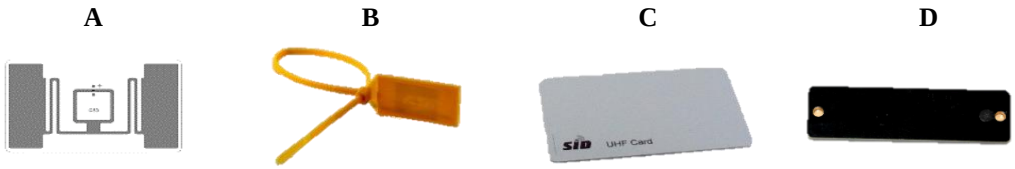


Figure 15 Various types of RFID tag

A reading distance of different materials appeared dissimilar. This might be due to the reflection from different materials surface are differ. According to Table 18, the average reading distance for a fixed reader, a movable tag and a fixed tag, a movable reader with seven reading angles of four free tags are shown. There was a different reading range significantly at the different angle but the same tag type significantly ($p<0.05$, Mann Whitney U test), excluding 15º vs 60º of WIT (a fixed reader/a movable tag), 15º vs 30º of WIT (a fixed tag/a movable reader) 0º vs 15º of CTT (a fixed tag/a movable reader) and 75º vs 90º of CTT (a fixed tag/a movable reader) that their reading distance did not significantly different.

Table 18 The average reading distance (cm) for a fixed reader/a movable tag and a fixed tag/a movable reader of WIT, CTT, CDT and MTT

Testing tag		Distance of reading (cm)													
		A fixed reader/A movable tag							A fixed tag/A movable reader						
		0º	15º	30º	45º	60º	75º	90º	0º	15º	30º	45º	60º	75º	90º
WIT	Avg	133.7	216.0	195.5	294.1	216.1	150.5	161.0	73.3	155.1	154.8	296.7	290.5	259.7	276.7
	SD	8.84	2.58	0.97	2.02	2.28	1.58	2.49	9.42	1.29	1.99	1.57	1.65	2.36	1.77
	Order	min			max				min			max			
CTT	Avg	58.0	75.5	77.3	96.6	49.7	54.1	25.4	16.6	16.7	27.3	53.5	68.2	85.8	85.6
	SD	0.82	1.58	1.06	0.70	1.06	1.20	0.84	0.70	0.67	0.67	0.53	0.63	0.63	0.52
	Order				max			min	min					max	
CDT	Avg	143.7	222.9	244.8	321.2	296.2	268.3	264.8	158.1	56.9	172.2	369.7	332.1	292.4	298.2
	SD	1.89	1.37	1.48	1.03	1.62	1.42	2.15	2.47	1.91	2.15	1.95	2.23	2.84	0.63
	Order	min			max					min		max			
MTT	Avg	70.5	85.6	90.6	104.5	87.3	83.4	74.4	56.1	93.3	109.8	119.9	81.6	89.8	83.9
	SD	1.84	0.70	0.52	0.71	2.06	1.26	1.35	0.99	2.87	0.92	1.85	1.07	1.03	0.74
	Order	min			max				min			max			

Note: WIT=wet inlay tag, CTT=cable tie tag, CDT=card tag, MTT=metal tag

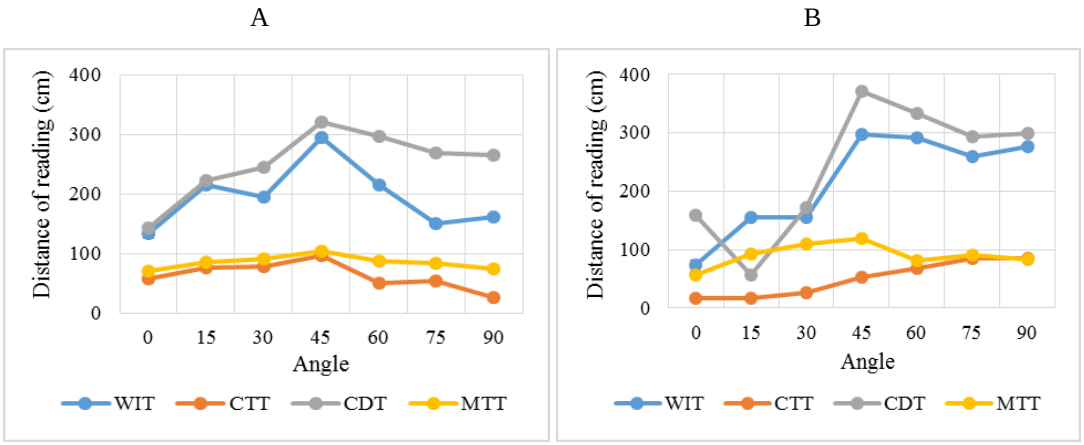


Figure 16 The reading distance (cm) of WIT, CTT, CDT and MTT for a fixed reader/a movable tag (A) and a fixed tag/a movable reader (B)

The Figure 16 (A) and (B) showed the angle as 45^{o} mostly provided the furthest reading distance (a fixed reader of WIT (294.1cm), CTT (96.6cm), CDT (321.2cm), MTT (104.5cm) and a fixed tag of WIT (296.7cm), CDT (369.7 cm) and MTT (119.9cm)) while the angle as 0^{o} mostly provided the nearest reading distance (a fixed reader of WIT (133.7cm), CDT (143.7cm), MTT (70.5cm) and a fixed tag of WIT (73.3cm), CTT (16.6 cm), MTT (56.1cm)).

The Figure 17 showed the difference reading range between two-kinds of tag reading. From this results assumed a fixed reader/a movable tag could be reading from a fixed reader whereas a fixed tag/a movable reader could be reading from handheld reader. The angle as 45^{o} of WIT (A) provided the furthest reading distance which did not differ reading with a fixed reader or a movable reader while the angle as 45^{o} with a movable reader provided further reading distance than a fixed reader for CDT (C) and MTT (D). This results may suggest that CDT and MTT were suitable reading from handheld reader. For the angle as 45^{o} of CTT (B), although the reading with a movable reader provided the wide reading distance, the reading with a fixed reader provided farther than others. It concluded that both 2 types of readers could be selected according to the operation manner.

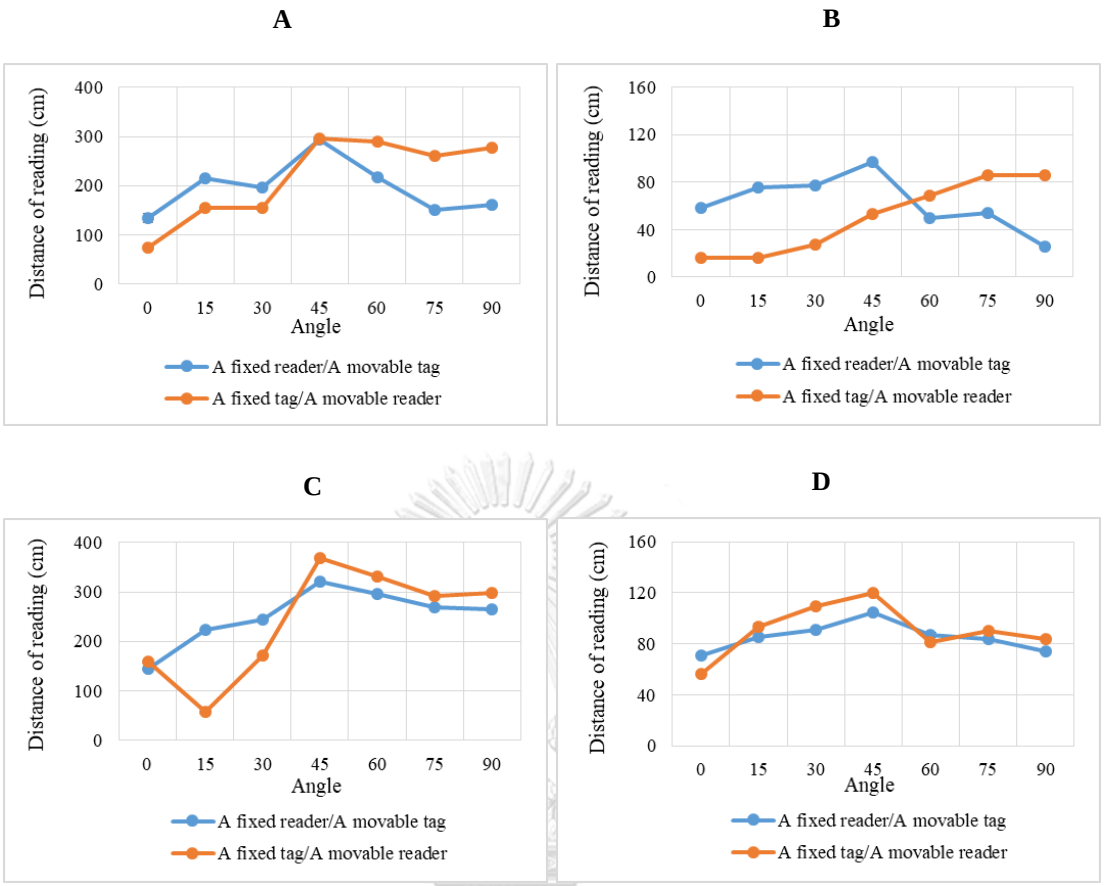


Figure 17 The reading distance (cm) for a fixed reader/a movable tag and a fixed tag/a movable reader of WIT (A), CTT (B), CDT (C) and MTT (D)

B. Result of reading distance of product attachment.

According to experiment B, three-installed tags were measured which were tracked on various objects at seven different angles. Only a fixed tag/a movable reader condition was used since handheld usage in actual operation. During experiment, the reader was stopped and fully charged for 1.5-2 hours in each tag. The scale chart was installed in the laboratory (25°c, 35-65%RH) which each experiment was the same operation.

Following the Figure 18, the researcher selected the installed objects to evaluate from an actual device representative in the pharmaceutical manufacturing industry. A was a large size carton (30x37x14 cm), volume 15.54 L, thickness 3.88 mm. B was an amber glass bottle with aluminum screw white cap, height 101.12 mm, bottle diameter 59.75 mm, glass thickness 2 mm approximately and weight 146.39 g. C was a plastic bottle with plastic screw white cap, height 83.78 mm, bottle diameter 56.47 mm, thickness 1.5 mm approximately and weight 29.29 g. D was a 15x22 cm polypropylene (PP) plastic clear bag. Finally, E was a cylindrical stainless tank with diameter 26 cm, height 30 cm, stainless thickness 3 mm approximately and volume 15.919 L.

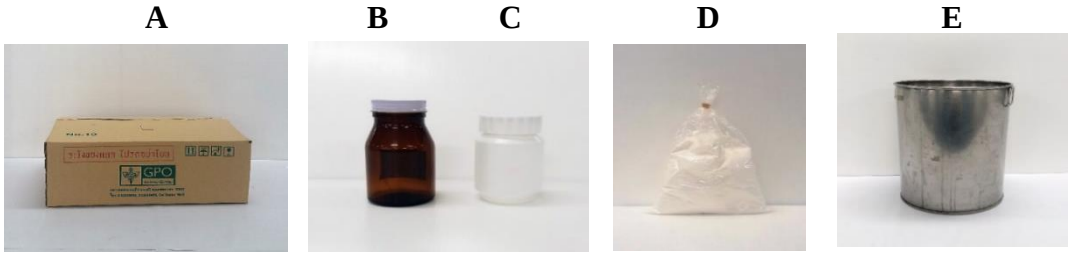


Figure 18 The different type of objects for RFID tag

According to Table 19, the average reading distance for a free fixed tag and tracked tag but move of reader in seven-reading angles of tags in brief are shown. The result showed reading distance for free tags and tracked tags were different significantly even tag type, material and brand were the same ($p<0.05$, Mann Whitney U test). Moreover, these results confirmed experiment A that there was different reading range significantly at the different angle but same tag type even were the tracked tag ($p<0.05$, Mann Whitney U test), excluding 15^o vs 30^o of WIT (free tag), 30^o vs 90^o of WIT (tagged on carton), 30^o vs 75^o of WIT (tagged on amber glass bottle), 0^o vs 15^o of CTT (free tag), 75^o vs 90^o of CTT (free tag) and 15^o vs 75^o of CTT (tagged on SM bag), their reading distance did not significantly different.

Table 19 The average reading distance (cm) for a fixed tags and tagged tags but move of a reader of WIT, CTT and MTT

Testing tag		Distance of reading (cm) (fix of tag and move of reader)													
		0^o	15^o	30^o	45^o	60^o	75^o	90^o	0^o	15^o	30^o	45^o	60^o	75^o	90^o
WIT		**Free tag**							**Carton**						
	Avg	73.3	155.1	154.8	296.7	290.5	259.7	276.7	106.7	148.7	178.5	262.4	224.0	190.1	178.9
	SD	9.42	1.29	1.99	1.57	1.65	2.36	1.77	1.57	0.95	0.97	1.17	0.67	1.20	1.97
	Order	min			max				min			max			
		Plastic bottle							**Amber glass bottle**						
	Avg	75.6	158.0	190.7	326.5	324.6	286.1	281.8	38.3	54.3	63.3	78.4	70.2	63.5	58.3
	SD	0.52	0.82	1.57	1.43	1.96	1.10	3.36	1.25	1.25	1.49	1.71	1.40	0.97	0.67
	Order	min			max				min			max			
CTT		**Free tag**							**SM bag**						
	Avg	16.6	16.7	27.3	53.5	68.2	85.8	85.6	58.7	71.0	94.3	112.5	104.9	71.5	64.4
	SD	0.70	0.67	0.67	0.53	0.63	0.63	0.52	1.77	2.31	1.34	2.27	2.60	1.18	1.07
	Order	min					max		min			max			
MTT		**Free tag**							**Stainless tank**						
	Avg	56.1	93.3	109.8	119.9	81.6	89.8	83.9	82.0	89.6	93.4	122.0	85.8	103.4	105.8
	SD	0.99	2.87	0.92	1.85	1.07	1.03	0.74	1.41	1.65	0.70	1.83	1.69	0.70	2.57
	Order	min			max				min			max			

Note: WIT=wet inlay tag, CTT=cable tie tag, MTT=metal tag

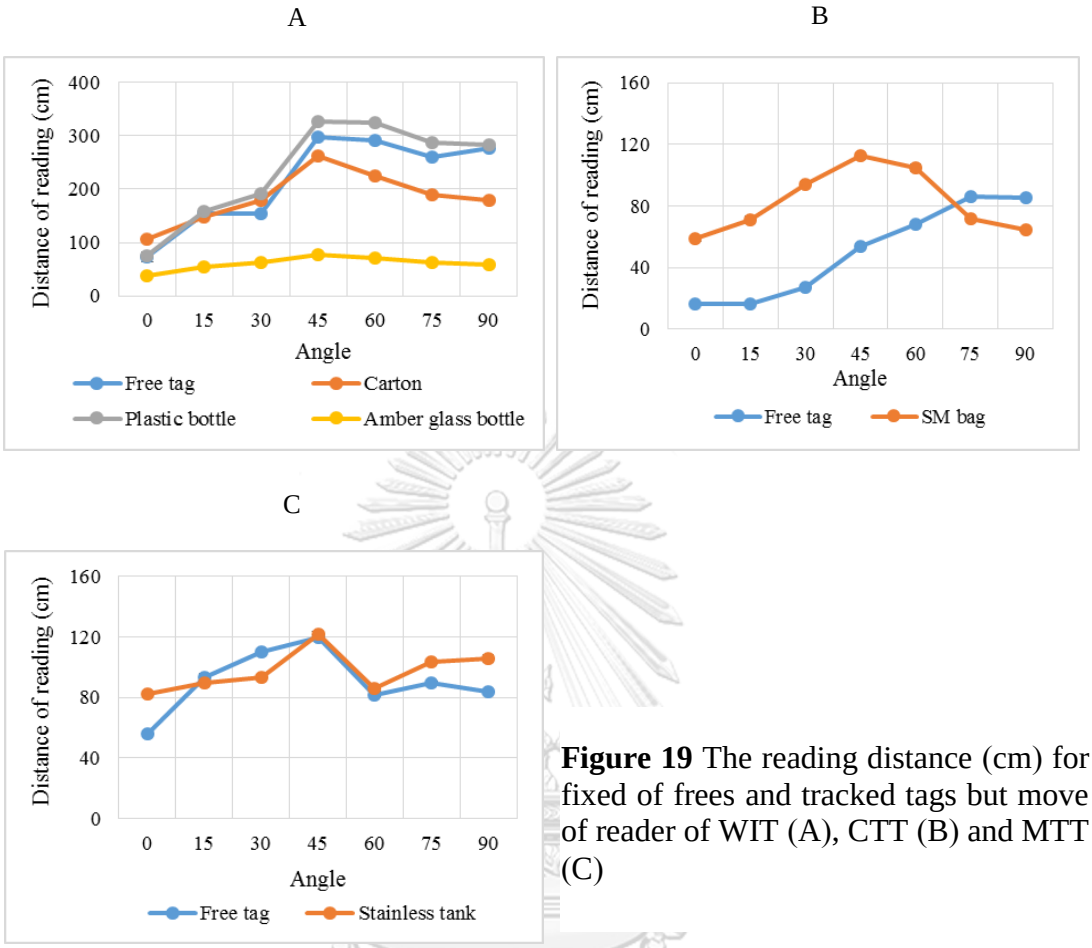


Figure 19 The reading distance (cm) for fixed of frees and tracked tags but move of reader of WIT (A), CTT (B) and MTT (C)

From the Figure 19, these results confirmed the experiment A that the angle as 45º mostly provided the furthest reading distance for WIT free tag (296.7 cm), WIT on carton (262.4cm), WIT on plastic bottle (326.5 cm), WIT on amber glass bottle (78.4 cm), CTT on SM bag (112.5 cm), MTT free tag (119.9 cm) and MTT on tank (122.0 cm) while the angle as 0º mostly provided the nearest reading distance for all free tags and tagged tags. As experiment A and B results could be estimated that reading for each tag could be kept away from others at least 3.3 meters for WIT, 1.2 meter for CTT, 3.7 meters for CDT and 1.3 meters for MTT. Furthermore, the WIT which were tagged on an amber glass bottle provided a reading distance shorter than the WIT which free tag, were tagged on carton and plastic bottle over 200 cm, these may be due to glass would less radio frequency reflection than other materials. It concluded that the WIT was suitable tracked on an opaque material (such as plastic bottle or carton) which if it was tagged on a glass bottle, tracking on the lid will be suggested.

C. Result of the appropriate position of tag attachment.

According to the experiment C, the WIT was measured which was two-size cartons were attached on the various surface area at various scanning positions of tag by the angles as 45º of carton (as a result of the experiments A and B that the angle as

45^{o} provide the longest reading distances). Only a fixed tag/a movable reader condition was used since handheld usage in actual operation. During experiment, the reader was stopped and fully charged for 1.5-2 hours in each tag. The scale chart was installed in the laboratory (25^{o}c, 35-65%RH) which each experiment was the same operation.

Following Figure 20, the researcher selected the installed objects to evaluate from an actual device representative in the pharmaceutical manufacturing industry. A was a large size carton (30x37x14 cm), volume 15.54 L, thickness 3.88 mm while B was a cube extra-large size carton (39x39x43 cm), volume 65.403 L, thickness 6.30 mm.

Figure 20 The carton size for experiment of the appropriate position

For each side of a carton, the area of carton was not equal such as the maximal area (30x37 cm), the medium area (37x14 cm) and the minimal area (30x14 cm) for an L-size carton and the maximal area (39x43 cm) and the medium area (39x39 cm) for a cube XL-size carton. One WIT was attached on the center of each area then scanned the tag on various positions (above, front, back and beside). The repetition was done in another new carton on both L-size carton and XL-size carton as shown in Figure 21-25.

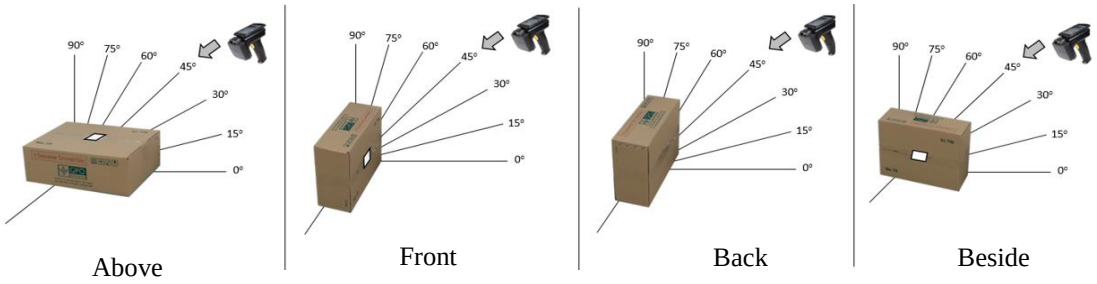


Figure 21 Scanning position of an L-size carton on maximal area

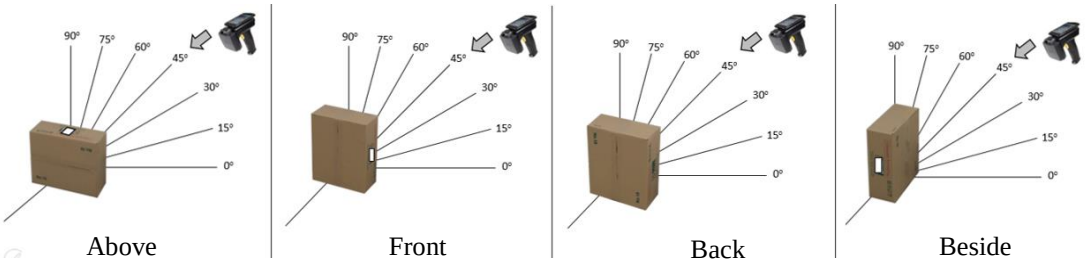


Figure 22 Scanning position of an L-size carton on medium area

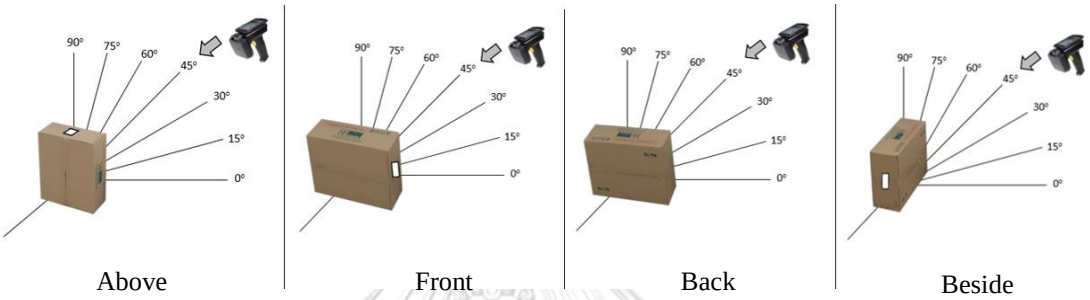


Figure 23 Scanning position of an L-size carton on minimal area

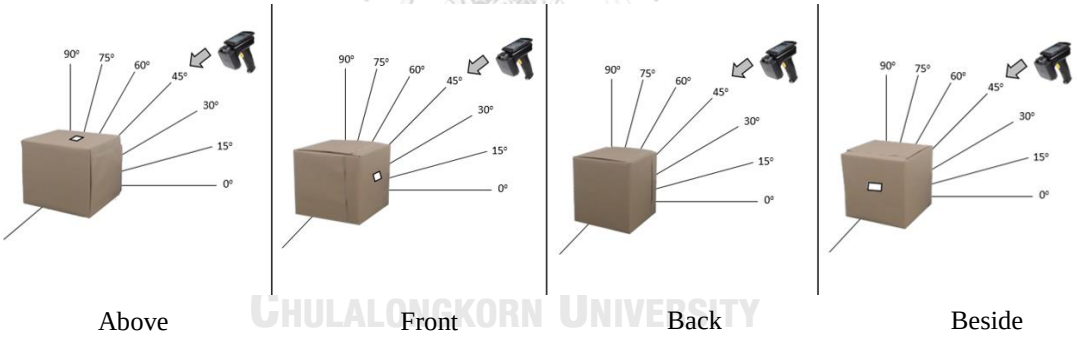


Figure 24 Scanning position of a cube XL-size carton on maximal area

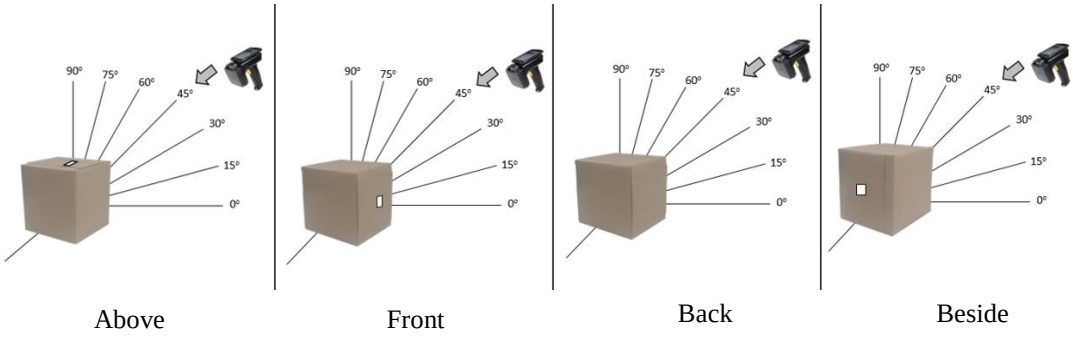


Figure 25 Scanning position of a cube XL-size carton on minimal area

According to Table 20, the average reading distance (cm) for a fixed tag/a movable reader on the various surface areas of the L-size and XL-size cartons of WIT. It was found that the reading distance of WIT for each scanning position (above, front, back, beside) at reading angle as 45^{o} (which were tagged on carton) were different. Scanning positon at the front side provided the further reading distance for L-size carton whether it was tagged on maximal (383.5cm), medium (353.9cm) or minimal area (314cm) while scanning positon at the above side provided the further reading distance for XL-size carton which was tagged on maximal area (262.1cm). Furthermore, the area of the tagged object influenced to the reading distance that at the same scanning position (whether above, front, back or beside) of XL-size carton, the reading distance of the tagged WIT on maximal area was different from the tagged WIT on minimal area significantly ($p<0.05$, Mann Whitney U test). For the convenience of practical work, the researcher suggests that WIT might be tagged on a carton and be scanned either above or front side. If many cartons are arranged by defined pattern, WIT may be tagged and turned out to scan at the front side.

Table 20 The average reading distance (cm) for a fixed tag/a movable reader on maximal, medium and minimal area of L-size and XL-size carton of WIT

Testing tag (WIT)			**Distance of reading (cm) (A fixed tag/A movable reader at reading angle as 45^{o})**			
Object	**The surface area of the carton**		**Above**	**Front**	**Back**	**Beside**
L-size carton	Maximal area	Avg	274.5	383.5*	382.4	314.8
		SD	1.08	1.08	1.17	1.14
	Medium area	Avg	315.0	353.9*	313.9	314.5
		SD	1.25	1.45	1.66	1.08
	Minimal area	Avg	313.3	314*	313.9	314.6
		SD	1.25	1.63	1.45	0.97
Cube-XL-size carton	Maximal area	Avg	262.1*	252.8	194.3	212.0
		SD	1.45	1.14	0.82	1.70
	Minimal area	Avg	243.8	251.1	255.5*	226.7
		SD	1.03	0.74	0.97	1.06

* The data show the maximum value in each group

D. Result of reading distance at different of tag position.

According to the experiment D, three-installed tags were measured. It were tracked on various objects at various scanning tag positions at the 45^{o} angles of the object (as a result of the experiment A and B that the angle as 45^{o} provide the longest reading distances). Only a fixed tag/a movable reader condition was used since handheld usage in an actual operation. During experiment, the reader was stopped and fully charged for 1.5-2 hours in each tag. The scale chart was installed in the laboratory (25^{o}c, 35-65%RH) which each experiment was the same operation.

Following the Figure 26, the researcher selected the installed objects to evaluate from an actual device representative in the pharmaceutical manufacturing industry. A was an amber glass bottle with aluminum screw white cap, height 101.12 mm, bottle diameter 59.75 mm, glass thickness 2 mm approximately and weight 146.39 g, B was

a plastic bottle with plastic screw white cap, height 83.78 mm, bottle diameter 56.47 mm, plastic thickness 1.5 mm approximately and weight 29.29 g, C was a SM cylindrical tank with metal case, diameter 40 cm, height 44 cm, thickness 3 mm approximately and volume 55.264 L, D was a plastic clear bag size 23x15 cm and E was a cylindrical stainless tank with tank diameter 26 cm, height 30 cm, stainless thickness 3 mm approximately and volume 15.919 L.

Because objects were cylindrical and the plastic bag had a single plane, supposing that each object had only one surface area. One WIT was attached then scanned of tag which various positions (front, back and beside) as shown in Figure 27-30 for plastic bottle, amber glass bottle, SM tank with metal case, SM plastic bag and stainless tank respectively.

Figure 26 The different type of objects for RFID tag reading distance

Figure 27 Reading position of plastic bottle and glass bottle

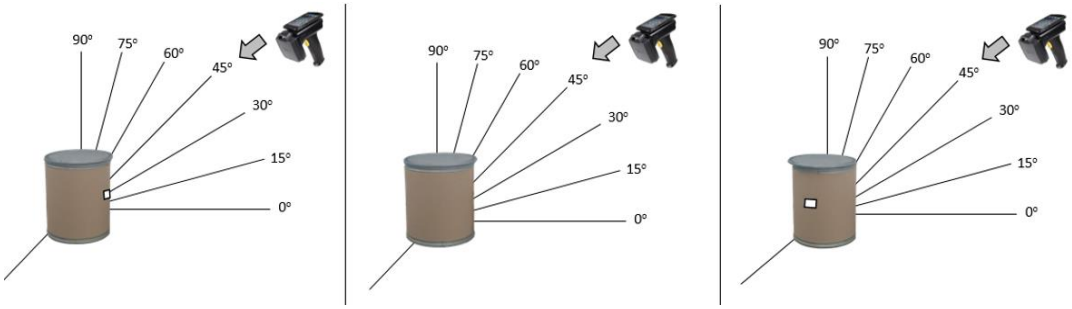


Figure 28 Reading position of SM tank with metal case

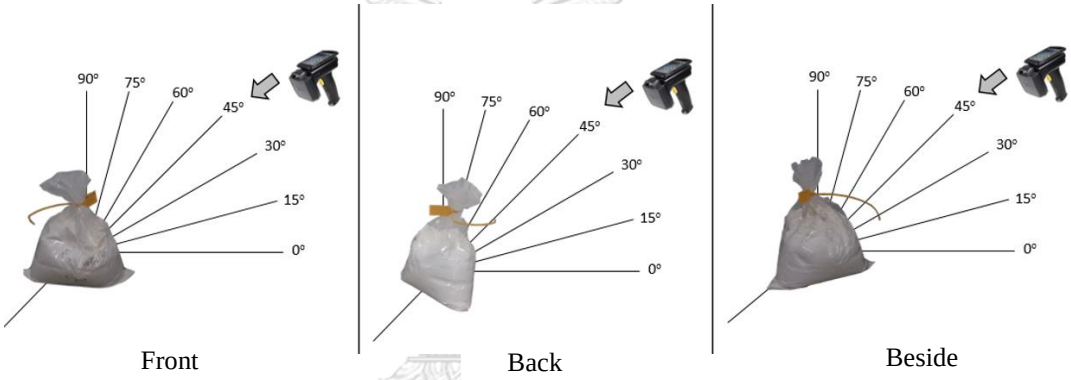


Figure 29 Reading position of SM plastic bag

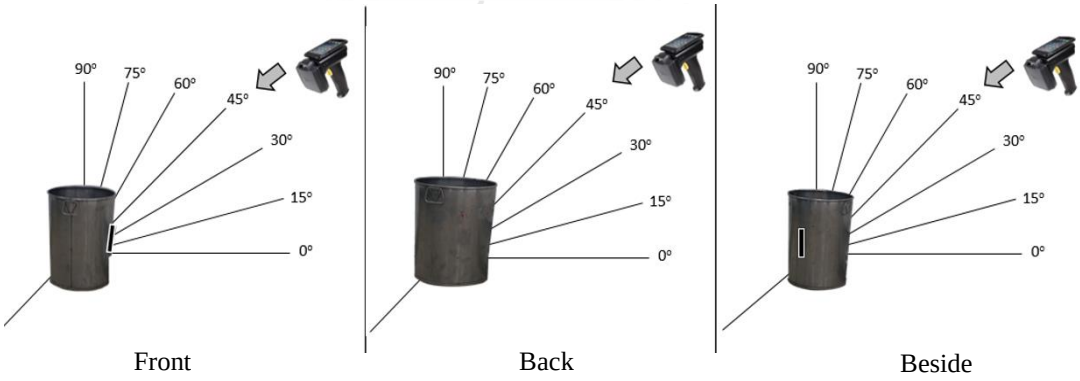


Figure 30 Reading position of stainless tank

According to Table 21, the average reading distance (cm) for a fixed tag/a movable reader which tags were tagged on objects of WIT, CTT and MTT in brief. Same as experiment C, the reading distance of each difference scanning position (front, back, beside) at reading angle as 45^{o} (which were tagged on object) were different significantly ($p<0.05$, Mann Whitney U test). Scanning positon at the front side provided the furthest reading distance for WIT was tagged on a plastic bottle (399.5 cm), amber glass bottle (33.6 cm), RM tank with metal case (252.7 cm) and for MTT was tagged on stainless tank (111.8 cm) while scanning positon at the beside provided the further reading distance for CTT was tagged on SM bag (72.0 cm). For the convenience of practical work, the researcher suggests that the WIT, CTT and MTT might be tagged on a carton and be scanned either front side or beside.

Table 21 The average reading distance (cm) for a fixed tag/a movable reader of WIT, CTT and MTT

Testing tag			**Distance of reading (cm) (A fixed tag/A movable reader at reading angle as 45^{o})**		
Tag	**Tracking on**		**Front**	**Back**	**Beside**
WIT	Plastic bottle	Avg	399.5*	396.1	351.7
		SD	1.27	1.85	0.82
	Amber glass bottle	Avg	33.6*	25.0	30.4
		SD	0.52	0.82	1.17
	RM tank with metal case	Avg	252.7*	111.6	141.6
		SD	1.57	2.27	1.35
CTT	SM bag	Avg	43.9	42.1	72.0*
		SD	0.74	1.52	2.75
MTT	Stainless tank	Avg	111.8*	72.5	69.1
		SD	1.23	0.71	3.54

* The data show the maximum value in each group

Note: WIT=wet inlay tag, CTT=cable tie tag, MTT=metal tag

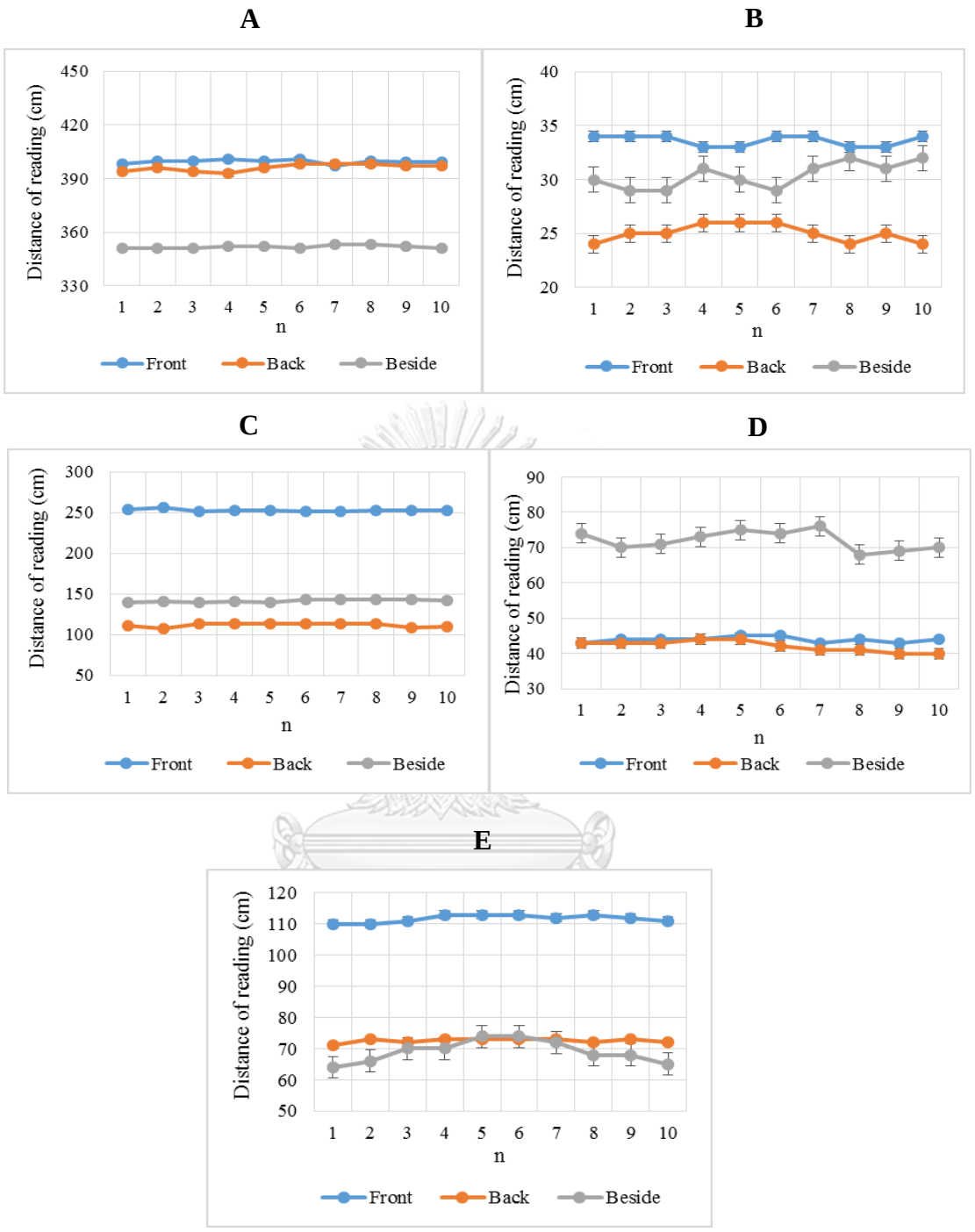


Figure 31 The reading distance (cm) of WIT on plastic bottle (A), WIT on amber glass bottle (B), WIT on SM tank with metal case (C), CTT on SM bag (D) and MTT on stainless tank (E)

From the Figure 31, the scanning position also influenced to a reading distances that the position as front side provided the further reading distance for WIT was tagged on plastic bottle, amber glass bottle and SM tank with metal case and for MTT was tagged on stainless. These results confirmed experiment C, the scanning positon at the front side provided the further reading distance for L-size carton. Moreover, this study confirmed experiment B that the WIT was tagged on amber glass bottle provided a reading distance shorter than the WIT which was tagged on the opaque material both a plastic bottle and SM tank with metal over 300 cm, these may be due to glass would less reflect on the radio frequency.

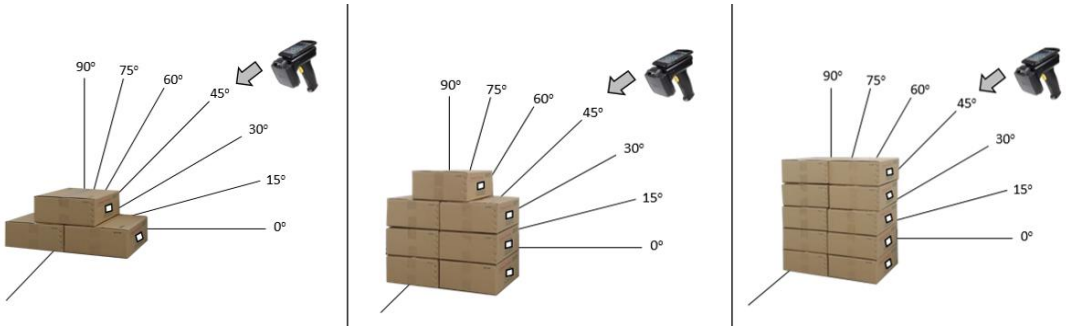
E. Result of reading distance of multiple RFID tag

According to experiment E., the group of WIT and CTT tag were measured at angles as 45^{o} of the group of object (as a result of the experiment A and B that the angle as 45^{o} provide the longest reading distances) by assuming the center of them was at origin point and scanning position of tag was on the front side (as a result of the experiment C and D, the front side provide the most suitable). Only a fixed tag/a movable reader condition was used since handheld usage in actual operation. During experiment, the reader was stopped and fully charged for 1.5-2 hours in each tag. The scale chart was installed in the laboratory (25^{o}c, 35-65%RH) which each experiment was the same operation.

Following the Figure 32, the researcher selected the installed objects to evaluate from an actual device representative in the pharmaceutical manufacturing industry were cartons (S-size: 20x24x9 cm, volume 4.32 L, thickness 3.3 mm, M-size: 27x32x12 cm, volume 10.37 L, thickness 4.22 mm and L-size: 30x37x14 cm, volume 15.54 L, thickness 3.88 mm).

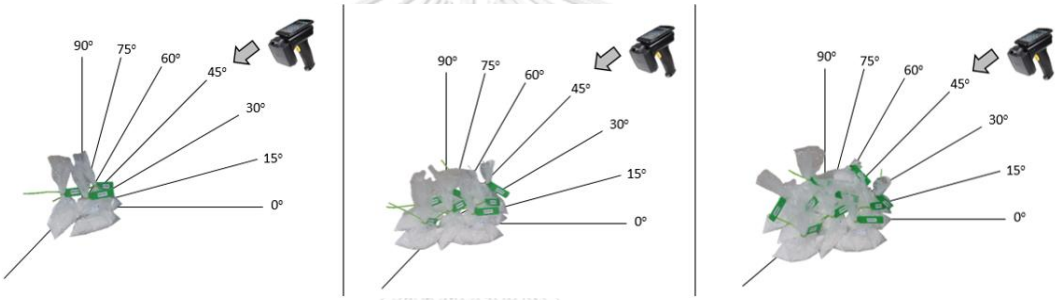
Figure 32 The different object size of overlay of object

Group of WIT was attached on cartons then they were arranged for 3, 7, 10 cartons of S, M, L-size carton as shown in Figure 33. Group of CTT was tracked on SM bag then they were stacked for 3, 7, 10 pieces as shown in Figure 34. The group of WIT and the group of CTT were measured.



3 cartons 7 cartons 10 cartons

Figure 33 Arrangement of multiple scanning of WIT



3 pieces 7 pieces 10 pieces

Figure 34 Arrangement of multiple scanning of CTT

According to Table 22 and Figure 35, the average reading distance (cm) for group of WIT and CTT which were arranged in brief. The results showed the amount of tagged object influenced to the reading range that the reading distance of a group of tagged WIT carton increased when the number of tagged WIT was lessen with the same type of tag and object significantly ($p<0.05$, Mann Whitney U test), for example arranged 3 cartons with WIT of S-size (194.0 cm), M-size (202.1 cm), L-size (215.5 cm) and 3 SM bags with CTT (269.9 cm). This result showed that a reading of multiple tags which tagged on a product required a close scanning for reading all tags. Conversely, the size of tagged object also influenced to the reading range that the reading distance of a group of tagged WIT carton was raised when the size of tagged object was bigger significantly ($p<0.05$, Mann Whitney U test), for example arranged carton with WIT of L-size for 3 cartons (215.5 cm), 7 cartons (204.0 cm) and 10 carton (166.9 cm).

Table 22 The average reading distance (cm) of the arranged WIT and CTT

Tag	Tracking on	Overlay		Distance of reading (cm) (A fixed tag/A movable reader at reading angle as 45°)		
				S-size	M-size	L-size
WIT	Carton	3 pieces	Avg	194.0	202.1	215.5*
			SD	1.76	1.66	1.58
		7 pieces	Avg	169.4	186.5	204.0*
			SD	0.97	1.65	1.94
		10 pieces	Avg	143.1	162.3	166.9*
			SD	2.13	2.11	2.33
CTT	SM bag	3 pieces	Avg	269.9*		
			SD	3.60		
		7 pieces	Avg	226.5		
			SD	1.90		
		10 pieces	Avg	173.3		
			SD	4.06		

* The data show the maximum value in each group

Note: WIT=wet inlay tag, CTT=cable tie tag

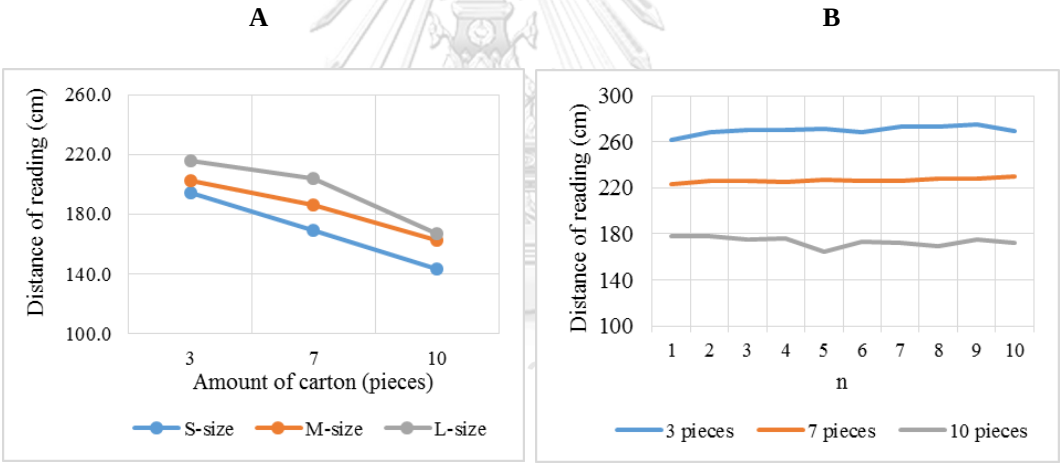


Figure 35 The average reading distance (cm) of WIT on S, M, L-size (A) and CTT (B)

F. Result of impact of overlay object.

According to experiment F, the group of WIT and CDT were measured which inside various overlay at angles as 45° of object (as a result of the experiment A and B that the angle as 45° provide the longest reading distances) by assuming the center of them was at origin point and side of tag was on the front side (as a result of the experiment C and D that the front side provide the most suitable). Only a fixed tag/a movable reader condition was used since handheld usage in actual operation. During experiment, the reader was stopped and fully charged for 1.5-2 hours in each tag. The scale chart was installed in the laboratory (25°c, 35-65%RH) which each experiment was the same operation.

Following the Figure 36, the researcher selected the installed objects to evaluate from an actual device representative in the pharmaceutical manufacturing industry. A was an amber glass bottle with aluminum screw white cap, height 81.24 mm, bottle diameter 44.68 mm, glass thickness 1.5 mm approximately and weight 73.53 g, B was a plastic bottle with plastic screw white cap, height 73.59 mm, bottle diameter 48.12 mm, plastic thickness 1.5 mm approximately and weight 16.56 g, C was cartons (S-size: 20x24x9 cm, volume 4.32 L, thickness 3.3 mm, M-size: 27x32x12 cm, volume 10.37 L, thickness 4.22 mm and L-size: 30x37x14 cm, volume 15.54 L, thickness 3.88 mm), D was a 25.5x13.5 cm brown-paper bag, thickness 0.21 mm, E was 26x20 cm fabric bag, thickness 0.75 mm, F was a 13x9.5 cm clear plastic zip bag, thickness 0.1 mm and G was a 19x13 cm thick-plastic bag, thickness 0.6 mm.

Figure 36 The object for experiment of overlay object

The WIT was attached on plastic bottle and amber glass bottle which were arranged for 4, 8, 12 pieces as shown in Figure 37 that inside overlay as S, M, L-size carton whereas the CDT which was inside overlay as clear plastic zip bag, brown-paper bag, thick-plastic bag and fabric bag, was measured one by one as shown in Figure 38.

Figure 37 Arrangement of plastic bottle and amber glass bottle for experimental of overlay object

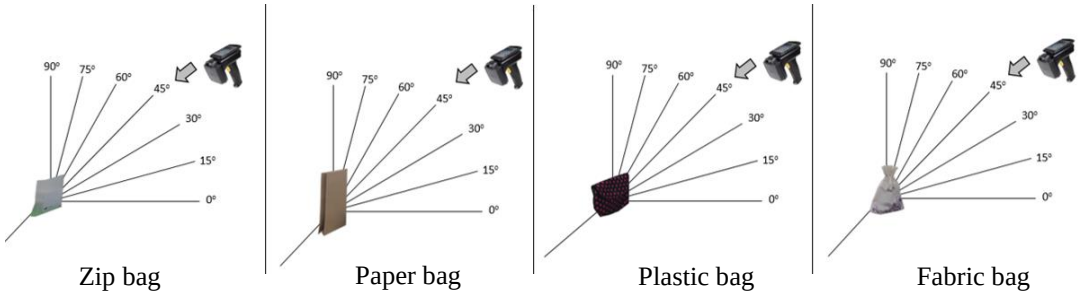


Figure 38 Impact of overlay object with CDT tag on zip bag, paper bag, plastic bag and fabric bag of CDT

According to Table 23, the average reading distance (cm) for a fixed tag/a movable reader which WIT were tagged on plastic bottle and amber glass bottle in brief and CDT was inside in various overlay in brief are shown in Table 24 whereas the average reading distance of group of WIT were tracked on plastic bottle for 4, 8, 12 bottles which were arranged in S, M, L-size cartons (A) and the average reading distance of CDT in various overlay (B) are showed as Figure 39. As experiment E, the amount of tagged object influenced to the reading range that the reading distance of a group of tagged WIT (even in the S, M, L-size carton) was decreased when the number of tagged WIT was more added. Especially the tagged WIT on an amber glass bottle, if there were lots of tagged object, the reading distance was very short with move of reader to left-right in order to reading all of tag. Furthermore, the size of overlay affected the reading distance that would not conformable if the tagged WIT on equal of a plastic bottle but were arranged in different size cartons. Especially for arranging 12 bottles in small boxes provided the shortest reading distance. Accordingly, much density of the tag would provide a shorter reading range. For CDT examination, The CDT in overlay was provided shorter reading distance than free tag and the various material (zip, paper, plastic and fabric) of overlay was provided the different reading distance significantly ($p<0.05$, Mann Whitney U test).

Table 23 The average reading distance (cm) for a fixed WIT tag/a movable reader on plastic and amber glass bottle

Tag	Tracking on	Overlay		Distance of reading (cm) (A fixed tag/A movable reader at reading angle as 45°)		
				In the carton size		
				S-size	M-size	L-size
WIT	Plastic bottle	4 pieces	Avg	184.2	204.7*	182.1
			SD	1.14	0.95	1.66
		8 pieces	Avg	114.5	199.0*	181.4
			SD	0.71	1.33	1.17
		12 pieces	Avg	35.9	134.0*	131.8
			SD	0.57	0.82	0.63
	Amber glass bottle	4 pieces	Avg	less than 10 cm (without moving of reader)*		
			SD	-	-	-
		8 pieces	Avg	less than 10 cm and less than 25 cm if moving left-right of reader		
			SD	-	-	-
		12 pieces	Avg	less than 10 cm and less than 20 cm if moving left-right of reader and chang the reading angle		
			SD	-	-	-

* The data show the maximum value in each group

Table 24 The average reading distance (cm) for a fixed CDT tag/a movable reader in various overlay

Tag	Tracking on	Overlay	Distance of reading (cm) (A fixed tag/A movable reader at reading angle as 45°)
CDT	Free tag	Avg	369.7*
		SD	1.95
	In the zipper bag	Avg	322.9
		SD	1.20
	In the paper bag	Avg	318.9
		SD	1.10
	In the plastic bag	Avg	348.1
		SD	1.52
	In the fabric bag	Avg	320.9
		SD	1.66

* The data show the maximum value in each group

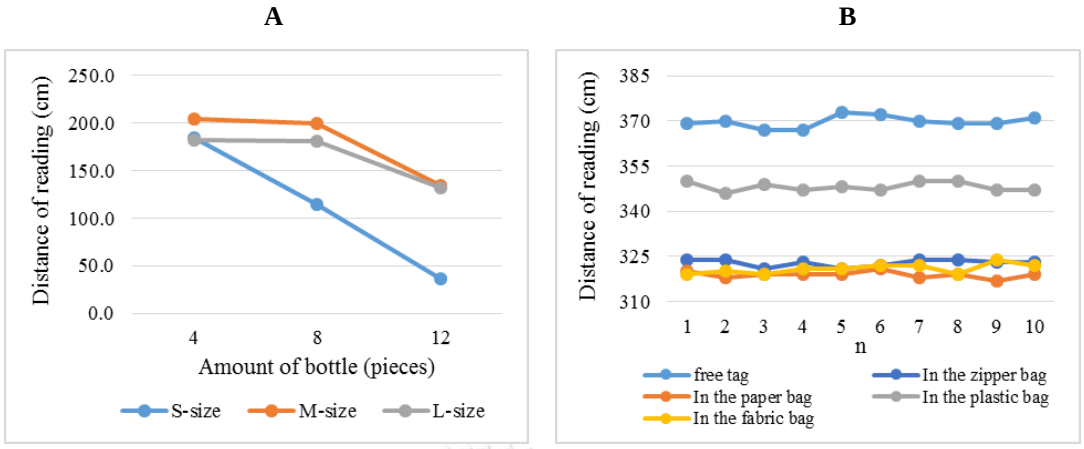


Figure 39 The average reading distance (cm) of WIT on plastic bottle in S, M, L-size (A) and the average reading distance (cm) of CDT in various overlay (B)

4.4 System verification

System verification was tested at faculty of Pharmaceutical Science, Chulalongkorn University. The Pharmaceutical Manufacturing Process Tracking System was used to track four of starting materials (SM) and five of production batches. The sample of reports were printed from system server as shown in Appendix D which were the four SM summary data and five Batch Processing Record. From the study, the Pharmaceutical Manufacturing Process Tracking System could work in according as almost of URS. Moreover, the system operation was recorded as a video clip and the system was passed of verification test and was guaranteed by the committee as the "Certification of Verification" in Appendix E.

The obvious advantages of using this system were the system can read the group of data quickly and also confirm that both type and quantity of receiving product were correctly and matched to the previous section. Furthermore, using of the cable tie tag could also prevent a material bag opening whether even though breaking and changing to a new tag during transit, receiving goods at the next section will not information available on such items, indicates that the item was certainly opened during shipping. Although the Pharmaceutical Manufacturing Process Tracking System could be worked according to URS but it had some limitation using. For example, due to the frequency range of each tag was quite wide and the tagged items were placed proximity so each tag must be labeled to record on a handheld reader correctly. For precautions, the user could not edit the information after saving, recording during operation should be done carefully.

4.5 Manufacturing site testing

A handheld reader and the selected tags were used. The certified system "The Pharmaceutical Manufacturing Process Tracking System" was also executed for site testing. The wet inlay tag was attached to SM carton, the cable tie tag was attached to material plastic bag, the card tag was used to accessing system and EAS-AM kit was

also used as double lock device for material bag. The SM of phenobarbital (19 boxes of lot no. R1-61/00006 and 7 boxes of lot no. R1-61/000284 of phenobarbital) were received and the FP of phenobarbital tablets (1 batch of phenobarbital tablets 30 mg and 6 batches of phenobarbital tablets 60 mg) were produced, batch no. as follows; F610041, F610042, F610043, F610044, F610045, F610046 and F610047. The sample of reports were printed from server as shown in Appendix G which were two SM summary data and seven batch processing records.

Because GPO concerned about the finished product would be contaminated and changed from normal, the site testing terminated tracking when the bulk products were shipped to packaging section. Packaging, shipping FP to FP-WH, analytical reporting of FP by QC and shipping FP to distribution center are not done. Therefore, the evaluators were represented by the operator from raw material section 1 and tableting section 1. They consisted of 8 persons were men and 3 persons were women who 4 persons worked for raw material section 1 and 7 persons worked for tableting section 1. It was found that 7 persons were staff, 2 persons were pharmacist and 2 persons were head of section that 4 persons had 0-5 years, 4 persons had 5-10 years, 1 persons had 10-20 years and 2 persons had more than 20 years' work experience. For a background of RFID, 8 persons were unknowing about RFID, 3 persons were slight know and no one was well knowing. All evaluator was signed as showed in Appendix F.

From part 1 of Appendix B, eleven potential failure modes which different impact during transportation and production tracking were assessed into the RPN value of normal operation (RPN_{nor}) and operation with RFID implementation (RPN_{im}) using the FMEA tool by 11 evaluators. Following Table 25, the result shows RPN_{im} of all failure mode less than RPM_{nor}, we assume that RFID implementation could reduce risk during transportation and could track the process. The risk priority class was reduced from minor class to negligible for topic 2 - Cannot protect the opening of material container such as staff can open the bags during the transportation of materials between inter-departments, topic 5 - The counterfeit drug or a drug differing from the standard are produce, and topic 10 - The document is incorrect recording or it cannot read the handwriting document that percentage of RPN decreasing were more than 50%. For another failure mode, although the risk priority class would not change, RPN_{im} also decreased compared to RPM_{nor} for all failure mode. On the other side, most of the manufacturing process remain following GMP, therefore, the risk priority class of normal operation was negligible.

Table 25 RPN value, risk priority class and RPN decreasing of normal operation and RFID implementation for each potential failure mode and impact

no	Potential failure mode	Potential failure impact	Normal operation		RFID implementation		RPN decreasing (%)
			RPN_{nor}	Risk priority class	RPN_{im}	Risk priority class	
1	Cannot track the shipping of materials in real time.	It does not know what the current production process.	1.93	Negligible	0.66	Negligible	
		It does not know what the status of material, work in process product and finished product.	1.35	Negligible	0.46	Negligible	
		Might be arduous solve and follow the problem.	2.20	Negligible	0.88	Negligible	
2	Cannot protect the opening of material container such as staff can open the bags during the transportation of materials between inter-departments.	loss of API.	15.99	Minor	5.95	Negligible	62.79
		loss of non-API.	14.49	Minor	6.29	Negligible	56.59
		Might be produced a drug differing from the standards.	5.13	Negligible	1.83	Negligible	
3	Staff ships the materials out of the route or to the wrong department.	Might be produced a counterfeit drug.	10.94	Negligible	4.75	Negligible	
		Waste time shipping to the right department.	3.52	Negligible	2.08	Negligible	
4	Confusion with other materials or other pallets.	The materials are sent to another department or taking another material into department.	4.42	Negligible	2.03	Negligible	
		Might be produced a counterfeit drug	6.94	Negligible	2.52	Negligible	
		Waste time investigation and shipping to the right department.	5.16	Negligible	1.90	Negligible	
5	The counterfeit drug or a drug differing from the standard are produce.	If it is found immediately before the pass to sale, may have to reject the whole lot.	21.93	Minor	8.23	Negligible	62.49
		If the products are released, maybe impact on the reputation of GPO.	22.53	Minor	10.85	Negligible	51.82
6	There is no the system for checking suddenly the weight of products shipped from the previous department.	Unknowing about the cause of material loss.	6.29	Negligible	1.56	Negligible	
7	There is no the system for accessing by the operator.	The authorized pharmacist does not control transportation or production themselves.	5.68	Negligible	2.08	Negligible	
		The manufacturing is not in compliance with the Narcotics Act and Psychotropic Substances Act.	3.87	Negligible	1.30	Negligible	
8	There is no the system for approval or verification of operation by the authorized person to ensure the correct sequence of processes.	The damage is done caused by staff not working on the orders of the pharmacist.	2.68	Negligible	1.16	Negligible	
9	The signature of the authorized person on BPR may be faked by the irrelevant person.	It will be included in the forgery document.	3.91	Negligible	1.95	Negligible	
		The pharmacist or supervisor and operation time cannot be examined.	4.32	Negligible	1.80	Negligible	
10	The document is incorrect recording or it cannot read the handwriting document.	Might misconstrues in the document.	19.34	Minor	5.86	Negligible	69.70
11	Tracking back to starting material is arduous.	Waste time investigation to starting material when the problem is occurring.	5.17	Negligible	1.98	Negligible	

For part 2, the satisfaction level was divided into 5 levels as follows; very satisfied (5 score), satisfied (4 score), neither satisfied nor dissatisfied (3 score), dissatisfied (2 score) and very dissatisfied (1 score). The result was shown in Figure 40, the evaluator satisfied in topic access control (4.4%). Whereas the part of a general feature was assessed just 3.5% might be due to the letters appearing in a handheld reader does not clear, not easy to read and the font size was too small. Due to the screen size was limit (3.5") and there was plenty of information showed on screen, the letters appeared too small.

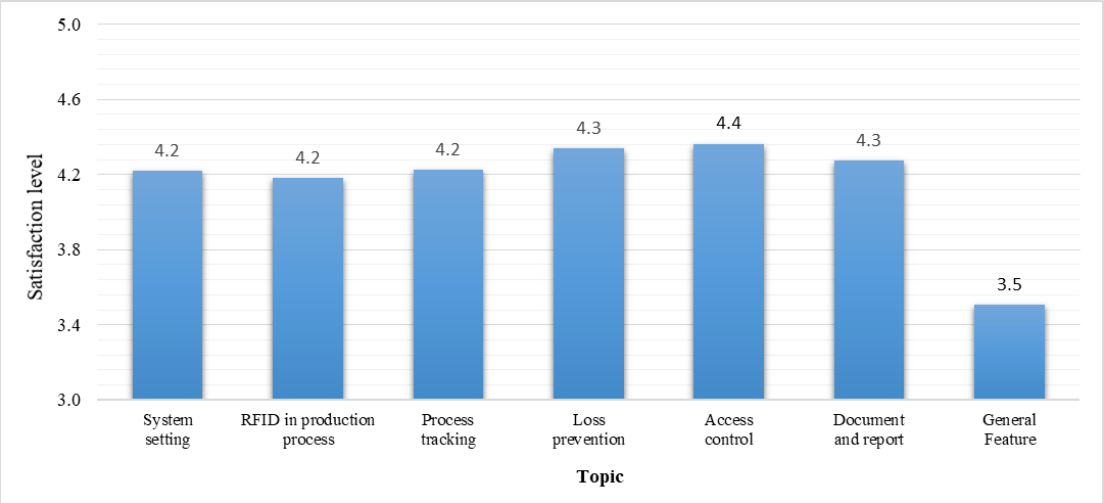


Figure 40 The satisfaction level using RFID implementation

From part 3, if the evaluator was answered at least one time of "yes", the RFID technology requires the GMP relevant for application to the manufacturing. All assessors (11 persons) considered that the system impact on system record, change, monitor, transmit or make decisions about data related to products or its components and impact the status of starting material, packaging material, work in process material, finished product in warehouse and distribution center. Most of them thought that the system support manufacturing as; transportation during inter-department protection from pharmacovigilance such as production of a drug differing from the standards document preparation and training of personnel in these activities while only one predicted that the system had impact the quality, identity, strength or purity of the product or its components. Following the result, implementation would require the GxP relevant when considering to apply RFID technology in the practical operation.

Finally, the assessors give additional suggestions from part 4 of the questionnaire such as;

- The frequency range was too wide that cause each tag might interfere with the other and the worker might be confused in operation.
- The desired tag might be chosen from many data when many tags were scanned.
- Using of software is too difficult that might not be suitable for operators who are not familiar technology.

- The scanning RFID tag was not stable because there were many tags interfering with each other
- The screen and the appeared letter were quite small might be caused by many information showing.
- Difficult to use the device
- Reduce the misunderstood of handwritten record.
- Some assessor preferred the system concept that could be developed in the existing process or large scale production. This technology is interesting solving that should apply in the future.
- Useful for manufacturing tracking that could be verified in the process of production until packaging which was more convenient.
- To prevent counterfeit information, the reference data might be additional input.

For the satisfaction in software, the evaluator satisfied in topic access control (4.4%) and all assessors considered that the RFID technology would require the GxP relevant for application to the manufacturing. It seems that the computer system need to validation. So, Computer System Validation (CSV) is to verify the software, hardware, and network (a set of a computerized system) that can be processed as intended use properly and be credible whether the developed software according to the reliable standard. The GxP standard that relevant to a computerized system for industry is GAMP 5 guideline. Good Automation Manufacturing Practice (GAMP) is a guide to achieve the proper system for demanding applications and meet to existing regulatory requirements (ISPE, 2008). “Manufacturing Process Tracking System”, the custom application to meet individual user requirement for each department, was grouped as GAMP in category 5. As the approach for a custom application, the user requirement specification, the functional requirement, the design specification and each module should be specified, then code for each module should be done, and lastly, the testing of each module, the integration testing, the functional testing, and requirement testing should be verified following Figure 41. For this research, almost of requirement according to GAMP 5 guideline have been done except for data of system life cycle that should be tested several months and trial production batch.

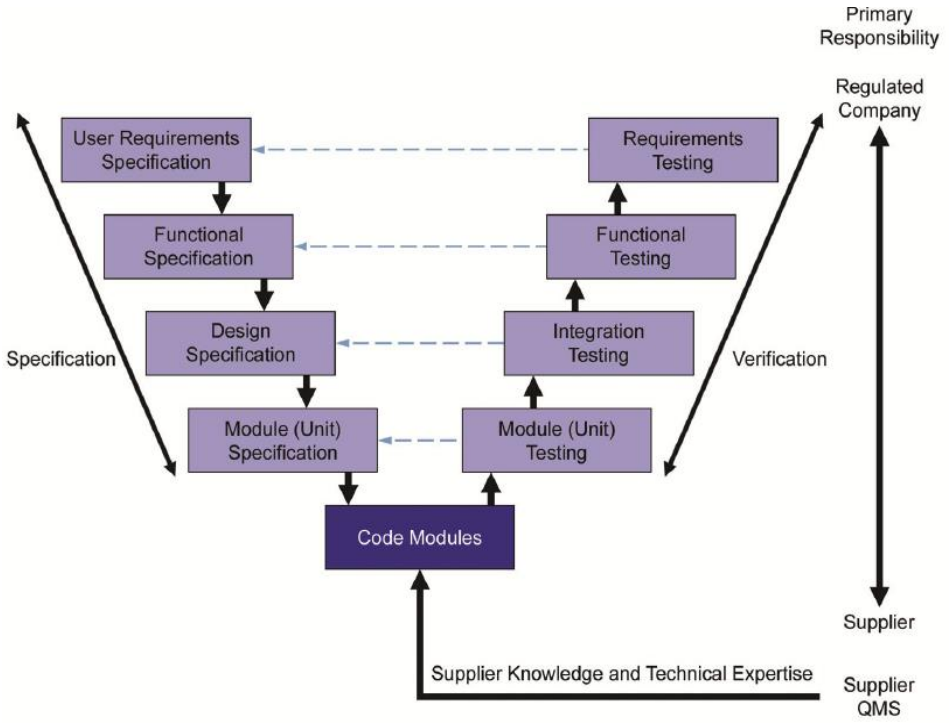


Figure 41 Approach for a custom application (category 5) according to GAMP 5

4.6 Value estimation

The fixed cost and variable cost were also determined in this research in Table 26. The total cost was not less than 200k bath per project. To compare the technology worthiness, many risks should be considered, such as the risk of manufacture problem, the risk of transportation, system and human errors, and damages due to unexpected events. The worst case is the drug manufacturing differing from standard. It will be risky to the patients and lost to the company reputation with an unacceptable expense. Therefore, it was interested to apply the RFID in the real production.

In parts of the valuation of investments, Roh J., Kunnathur A. and Tarafdar M. (2009) identified the three benefit concepts of RFID adoption as cost savings, supply chain visibility, and new process creation that each firm should describe the "scale" and "scope" of their RFID implementations. RFID benefits could be divided into two parts as a cost reduction (e.g. labor cost, inventory cost, and process cost) and a value creation (e.g. revenue increasing, and customer satisfaction increasing) (N. C. Wu, Nystrom, Lin, & Yu, 2006). However, Sarac, A., Absi, N., and Dauzère-Pérès, S. (2010) stated that a positive return-on-investment also depends on the technology costs such as the cost of tags, readers, middleware, implementation, maintenance, and service. For this research, only single drug that seven batches were produced and assessor from three departments evaluated, therefore, the return-on-investment could not be assessed completely. As the risk assessment' result, RFID could effectively reduce risk of any problem, it was interesting to apply RFID in the existing production that would benefit both supplier and customer on transferring from upstream to downstream stages straightforwardly. Following the average RPN decrease, RFID implementation should

be considered to adopt in packaging section first since the product out of tableting section until the product shipped to warehouse.

Table 26 Value estimation of research

Type of cost	Detail	Remark	For this research
Fixed cost	Software cost	By user requirement	60,xxx bath
	Set up cost	By man day	-
	Training cost	By man day	-
	Maintenance cost	By monthly or annual	-
	System administrator cost	Depends on salary	-
Variable cost	Instrument cost		
	CTT		32 bath per piece (for 500 pieces up)
	WIT		6.50 bath per piece (for 10,000 pieces up)
	CDT (reusable)		30 bath per piece (for 1,000 pieces up)
	Handheld reader	Depends on point of use and production capacity	86,xxx bath
	EAS hard tag (reusable)		25 bath per piece (for 100 pieces up)
	EAS detacher		10,000 bath per pieces
	EAS detector		
	handheld detector		10,000 bath
	door detector (if any)		30,000 bath
	Printer		-
	Connection cost	Depends on point of use	-
Total cost			Not less than 200k bath per project

Both supplier and customer would have a benefit of inventory controlling straightforwardly because of barcode modification to RFID (Chan, Choi, & Hui, 2012). Dai, H. & Tseng, M. (2012) stated that the RFID had benefits on transferring from upstream to downstream stages that different applications would incur in different investments and benefits. Moreover, Gareth R.T. White et al. (2007) encouraged the mixing RFID system with barcode. Although the hybrid system presented operational performance over the single barcode system, it was unclear whether the hybrid system cost might over the cost benefit. The barcode may possibly be replaced by RFID technology with cost increasing (Akbari et al., 2015). Due to highly investment, the system could be implemented in the selected department that risk evaluation has been done.

CHAPTER V
CONCLUSION AND DISCUSSION

5.1 Conclusion and discussion

"Manufacturing Process Tracking System" integrated system with RFID to track the process that consisted of seven work modules according to GMP, GDP and GSP guidelines. The non-reusable cable tie tags with a double lock accessories EAS set were used for protecting opening the SM bag during transportation. Wet inlay tag was used for tracking SM carton and card tag was used for access to the system. All information was recorded and showed via a handheld reader. Four applications including the database, web service API, android application (handheld reader) and web application were working synchronously.

The RFID devices suite for the purpose. UHF was selected to the frequency operation range with the passive tag operated for a short length that reasonable distance in a pharmaceutical process and easy to maintenance. The card tag was inexpensive and more expedient for accessed control using while the cable tie tag and wet inlay tag were appropriate for material tracking operated with UHF, lightweight, simplicity of product installation. The cable tie tag would rather prevent uncovered SM bag, while wet inlay tag might be suitable for attaching on a carton or bottle. A handheld reader was more convenient to read and write promptly and accurately. Furthermore, the RFID implementation with EAS-AM system prevented the material bag opening during shipping better than using RFID stands alone.

According to the parameter testing, it could assume that a fixed reader/a movable tag could be reading from a fixed reader whereas a fixed tag/a movable reader could be reading from handheld reader. A movable reader (or a handheld reader) is recommended using for material tracking in the pharmaceutical process. The 45^{o} angle is mostly provided the furthest reading distance while the 0^{o} angle mostly provided the nearest reading distance for all free tags and tagged tags. The estimated results that reading for each tag could be kept away from others at least 3 meters for wet inlay tag, 1.2 meter for cable tie tag, 3.7 meters for card tag and 1.3 meters for metal tag. A reading distance of different materials appeared dissimilar. This may be due to the different frequency reflection of each material, and the different scanning position at 45^{o} reading angle of each difference. Scanning positon at the front side and above could be provided the further reading distance. The researcher suggests for the convenience that wet inlay tag might be tagged and turned out to scan at the front side whereas the cable tie tag and metal tag might be tagged and scanned either front side or beside. The results also showed the reading distance of a group of tag on carton was raised when the number of tagged WIT was lessening. This means that reading of multiple tags which tagged on a product requires close scanning for reading all tags.

For the overlay, many tagged of wet inlay tag on a product which were in carton could be scanned outside for tracking without opening the carton conveniently. For card tag, it was provided shorter reading distance than free tag and the various material was provided the different reading distance. Anyway, accessing a system could be done by scanning the card tag which was in the bag. Furthermore, it was noteworthy that the wet inlay tag tagged on an amber glass bottle provided a reading distance shorter than the free wet inlay tag were tagged on carton and plastic bottle over 200 cm and SM tank with metal over 300 cm. The tagged WIT on an amber glass bottle especially arranged in the carton, the reading distance was very short with move of reader from left to right in order to reading all of tags. These may be due to glass would be less reflection on the radio frequency than other materials. It concluded that the wet inlay tag was suitable tracked on opaque material (such as plastic bottle or carton). If it is tagged on a glass bottle, tracking on the lid was suggested.

The Pharmaceutical Manufacturing Process Tracking System could be used to track materials following URS, could read the group of data quickly and confirm correctly both type and quantity of received product which matching with the previous section. The certificated software was used for site testing. The system testing was evaluated by evaluators from 2 sections; raw material section 1 and tablets section 1. The risk during transportation and production tracking were assessed by the RPN value of normal operation (RPN_{nor}) and operation with RFID implementation (RPN_{im}) using the FMEA tool. The potential failure modes were divided into the risk priority class. The result showed the risk priority class was reduced from minor class to negligible. We assumed that RFID implementation could reduce risk during transportation and could track the process. However, the risk priority class of other failure mode would not be changed. The RPN_{im} also decreased compared to RPM_{nor} for all failure mode and most of the manufacturing process following the GMP guideline. Therefore, the risk priority class of normal operation was also negligible. The GPO concerned about the finished product contamination, the process of packaging, shipping FP to FP-WH, analytical report of FP by QC, and shipping FP to distribution center were not done. The computer system was essential for validation according to Good Automation Manufacturing Practice (GAMP).

The most assessors preferred this conceptual software. It assisted for solving problems in the future, reducing the misunderstood of handwritten record, and developing the existing process or large scale production. However, this might not be suitable for older-workers who are technology unawareness. The tag might be interfered with other tags. This could be solved by separating workspace from the other at least 3 meters approximately. Moreover, the letters appearing in a handheld reader were not easy to read and the font size was too small owing to the limitation of the screen size. Thus, only specific information should be displayed on the screen. The reference data should be added to prevent counterfeit information.

In the valuation of investments of this research, only seven batches of a single drug produced and assessors from three departments evaluated were studied. Therefore, the return-on-investment could not be assessed completely. The estimated cost was not less than 200k bath per project. As the risk assessment' result, RFID could effectively reduce risk of any problem. It was interested to apply RFID in the existing production

that would benefit both supplier and customer on transferring from upstream to downstream stages. Following the average RPN decrease, RFID implementation should be considered to adopt in packaging section starting the product from tableting section until the product shipped to warehouse.

There were many factors influencing the experiment and reflecting radio frequency, such as temperature, humidity, material structure in the laboratories, and any obstruction. Therefore, the experiment should be conducted on the same day at the same time.

5.2 Suggestion

RFID has been publicized as an effective inventory management. It is a technology support of preventing the problem during transportation and producing of a drugs differing from the standards and a deteriorated drugs. However, there is no previous study regarding adoption to trace the manufacturing process in the pharmaceutical industry, especially the manufacture of narcotic drugs and psychotropic substances. This study explored the process tracking, starting material loss prevention and process traceability of the mentioned manufacturer using the developed software with RFID implementation. Leading to considering the use of appropriate RFID technology in order to trace and track the manufacturing process of such drugs in accordance to the requirements of GMP and the Narcotics and Psychotropic Substances Act. The risk assessment by FMEA tool and the RPN value of normal operation and implementation were being compared.

The finding suggested that RFID has a potential support in a pharmaceutical plant. The RFID could manage both starting material and work-in-process material. It could trace and track manufacturing process starting from receiving materials to keeping in a warehouse. It could prevent loss of material by applying with double system as EAS-AM, support the accessing system for ensuring that the authorized person shall exercise control throughout the production (more authorized person could be joined to double check for the critical process), and supporting the printed report as a quality document (Figure 42).

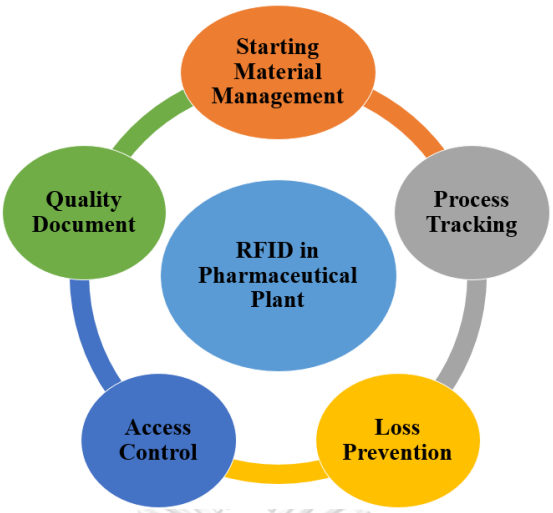


Figure 42 The relationship of RFID technology parameters in pharmaceutical plant

The system could be developed to be a tracking model for the other manufacturing materials such as controlled substances, biological products, high-risk products, or high-value products. It is a clear understanding of product and manufacturing process and understanding of risks associated with a business process lead to developing the system appropriately. It might possibly use as a managing tool for Product Quality Review in order to promote the process development, enhance capabilities of the production process, incur the value-added of product that could compete with the other pharmaceutical industry leading to the development in the international levels.

Furthermore, the collaboration between a trading partner and a manufacturer, both national and international could be linked efficiently which reduced the complexity of data transferring using the wireless technology. This same management system could be beneficially adopted in the trading partners throughout the supply chain such as warehouses, distribution centers, hospitals, or drug stores.

In the following topics should be further consider;

- Whether considering for using this technology, the system should be customized for the intended use. For example, the development of FXFO management efficiently (additional costs may be incurred), the addition of approved persons for each process step for double checking point of GMP, some warnings or unequal weight of receiving products unmatched from the previous section.

- In the present situation, the market trend of RFID technology has been growing continuously. Many firms increasingly pay attention and demand for devices. The RFID tag price is lessened and the reader has higher readability. Further studies are needed such as profitability, cost saving, cost reduction, increased

revenue, productivity, value creations i.e., a risk-reducing of transportation, a prevention of API loss, a supporting for a drug production differing from the standards and a deteriorated drugs, customer satisfaction, a benefit between upstream and downstream stage. However, the technology costs such as cost of tags, readers, middleware, implementation, maintenance, and service should be assessed necessarily.

- For protection the opening of the material container during the transportation between inter-departments causing the loss of API and the stainless container with a metal tag plus EAS lock should be redesigned.

- Combing with barcode systems requiring a closer reading range might be an alternative choice for the new system because the reading ranged from many tags might be interfering and the working area was limited,

- It appears that the wireless technology could promote better production activity, however, it will not be profitable if the operators do not perform stringently and faithfully.

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APPENDIX

APPENDIX A	**The master data**
APPENDIX B	**The software evaluation questionnaires and the FMEA assessment criteria**
APPENDIX C	**Evaluation form of device selection**
APPENDIX D	**Starting Material summary data and Batch Processing Record for software verification test**
APPENDIX E	**Certification of verification**
APPENDIX F	**Evaluation team**
APPENDIX G	**Starting Material summary data and Batch Processing Record for site testing**

Appendix A

The master data

Supplier detail		
Code	**Item no**	**Detail**
1	API-4008	DZAPI Co., LTD
2	API-5188	PBBAPI Co., LTD
3	API-4102	CODAPI Co., LTD
4	API-0981	MTDAPI Co., LTD
5	API-2019	MOPAPI Co., LTD

Starting Material detail		
Code	**Item no**	**Detail**
1	41010470	Diazepam
2	41011160	Phenobarbital
3	41020860	Codeine Phosphate
4	41022140	Methadone Hydrochloride
5	41022300	Morphine Sulphate

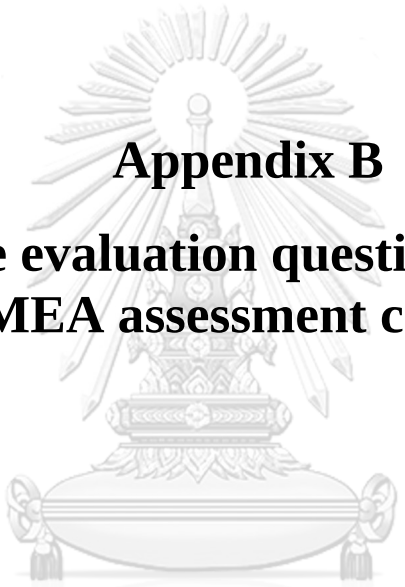
Authorized person				
Code	**Item no**	**Detail**		
		Name	**Department**	**Position**
1	101411	Somjaiyak	SM-WH	Pharmacist
2	101412	Nutthida	SM-WH	Approve
3	101413	Srisamon	Dispensing	Pharmacist
4	101414	Thanathani	Production	Pharmacist
5	101415	Rachan	Production	Pharmacist
6	101416	Kawin	Production	Pharmacist
7	101417	Ariirat	Production	Pharmacist
8	101418	Srisukjai	Packaging	Pharmacist
9	101419	Rakchart	FP-WH	Pharmacist
10	101420	Patcha	FP-WH	Approve

Product detail							
Code	Item no	Detail					
		Product name	Reg. no	Contain	GTIN	Batch size	category
1	110103210112	Diazepam tablets 2 mg	P1A9/2558	500 tab	8850678232812	1,200,000 tab	Psychotropic substances in Schedule IV
2	110103210123	Diazepam tablets 5 mg	P1A10/2558	500 tab	8850678232928	1,200,000 tab	
3	110103210132	Diazepam tablets 10 mg	P1A11/2558	1,000 tab	8850678233024	800,000 tab	
4	110107510122	Phenobarbitone tablets 30 mg	P1A7/2558	1,000 tab	8850678236612	2,400,000 tab	
5	110107510132	Phenobarbitone tablets 60 mg	P1A8/2558	1,000 tab	8850678236711	-	
6	110107620111	Codeine Phosphate tablets 15 mg	-	100 tab	8850678241418	-	Narcotics of category II
7	110107620121	Codeine Phosphate tablets 30 mg	-	100 tab	8850678242514	-	
8	110116131011	Methadone Hydrochloride tablets 5 mg	-	100 tab	8850678241210	-	

Distribution center		
Code	Item no	Detail
1	C-01	Pathum thani
2	N-01	Chiangmai
3	N-02	Phitsanulok
4	S-01	Songkhla
5	NE-01	Udonthani

Appendix B

The software evaluation questionnaires and the FMEA assessment criteria



แบบสอบถามการใช้งานซอฟแวร์

คำชี้แจง แบบประเมินนี้จัดทำขึ้นโดยมีวัตถุประสงค์เพื่อสอบถามการใช้งานซอฟแวร์ "SP Track" ซึ่งเป็นซอฟแวร์ที่ใช้เทคโนโลยี RFID ในการติดตามการผลิตยากลุ่มยาเสพติดให้โทษ และวัตถุที่ออกฤทธิ์ต่อจิตและประสาท ที่ผลิตในองค์การเภสัชกรรมเท่านั้น เพื่อใช้ในวิทยานิพนธ์ระดับปริญญาโท ภาควิชาวิทยาการเภสัชกรรมและเภสัชอุตสาหกรรม คณะเภสัชศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย ไม่มีผลต่อการเปลี่ยนแปลงการทำงานจริง และไม่มีผลต่อการทำงานต่อผู้ประเมิน ดังนั้น จึงขอความอนุเคราะห์ผู้ทำการประเมินกรอกข้อมูลตามความเป็นจริง โดยแบบประเมินนี้ แบ่งออกเป็น 4 ส่วน

ส่วนที่ 1 Risk Assessment: ประเมินความเสี่ยงระหว่างการขนส่งยาและการติดตามการผลิต ในการทำงานปกติ (ยังไม่มีการปรับปรุงงาน) และประเมินความเสี่ยงระหว่างการขนส่งยา หากมีการปรับปรุงงานโดยใช้ระบบแล้ว

ส่วนที่ 2 Satisfaction Questionnaire: แบบสอบถามความพึงพอใจในการใช้งานระบบ

ส่วนที่ 3 System Impact Assessment: ประเมินผลกระทบจากการใช้งานระบบ

ส่วนที่ 4 Recommendation: ปัญหาอื่นๆและข้อเสนอแนะ

แผนก ☐ แผนกสำรองวัตถุดิบ ☐ ศูนย์ชั่งจ่ายยา ☐ แผนกยาเม็ด 1
☐ แผนกบรรจุยาเม็ด 1 ☐ แผนกสำรองผลิตภัณฑ์

ผู้ทำประเมิน ☐ หัวหน้าแผนก ☐ เภสัชกรระดับปฏิบัติการ ☐ พนักงานผู้ปฏิบัติการ

อายุงาน ☐ 0 - 5 ปี ☐ 5 – 10 ปี ☐ 10 – 20 ปี ☐ 20 ปี ขึ้นไป

ท่านรู้จักเทคโนโลยี RFID หรือไม่ ☐ ไม่รู้จักเลย ☐ รู้จักบ้างเล็กน้อย ☐ รู้จักและเข้าใจการทำงานของระบบ

ลงชื่อ.....

วันที่ทำประเมิน.....

ส่วนที่ 1 Risk Assessment: ประเมินความเสี่ยงระหว่างการขนส่งยาและการติดตามการผลิต ในการทำงานปกติ (ยังไม่มีการปรับปรุงงาน) และประเมินความเสี่ยงระหว่างการขนส่งยา หากมีการปรับปรุงงานโดยใช้ระบบแล้ว

คำชี้แจง กาเครื่องหมาย √ ในช่องว่าง และใส่หมายเลขในช่องให้ตรงกับความคิดเห็นมากที่สุดในช่อง S, O, D โดย

S (Severity) ให้ใส่เลข 1-5 สำหรับความรุนแรงของปัญหา จากระดับความรุนแรงน้อยไปมาก

O (Occurrence) ให้ใส่เลข 1-5 สำหรับโอกาสที่จะเกิดปัญหา จากโอกาสที่จะเกิดน้อยไปมาก

D (Detectability) ให้ใส่เลข 1-5 สำหรับความสามารถในการตรวจพบปัญหา จากตรวจพบได้ง่ายไปยาก

สามารถอ่านเกณฑ์การประเมินเพิ่มเติมได้ ในท้ายแบบประเมิน

ข้อ	ความเสี่ยง	ผลกระทบ	ไม่ทราบ	ไม่มีความเสี่ยง	มีความเสี่ยง							
					การทำงานปกติ				การปรับปรุงงานด้วย RFID			
					S	O	D	RPN	S	O	D	RPN
1	ไม่สามารถติดตามกระบวนการขนส่งยาหรือวัตถุดิบได้ในเวลาจริง (real time)	ไม่ทราบว่าการผลิตยาอยู่ในขั้นตอนการผลิตใดในปัจจุบัน										
		ไม่ทราบสถานะของวัตถุดิบ หรือผลิตภัณฑ์ระหว่างการผลิตหรือผลิตภัณฑ์สำเร็จรูป										
		ติดตามแก้ปัญหาไม่สะดวกและรวดเร็ว										
2	ไม่สามารถป้องกันการเปิดถุงวัตถุดิบ เช่น พนักงานขนส่งสามารถเปิดถุงวัตถุดิบได้ระหว่างการขนส่งวัตถุดิบระหว่างแผนก	API สูญหาย หรือเสียหาย										
		Non - API สูญหาย หรือเสียหาย										
		อาจเกิดการผลิตยาผิดมาตรฐาน (ตัวยาสำคัญต่ำกว่าระดับการรักษา)										
3	พนักงานขนส่งยาหรือวัตถุดิบออกนอกเส้นทางขนส่ง เช่น ส่งยาผิดชั้น ส่งยาผิดแผนก	อาจเกิดการผลิตยาปลอม (Counterfeit drug: ตัวยาสำคัญผิดความจริง)										
		เสียเวลาขนส่งยาหรือวัตถุดิบใหม่ให้ถูกต้อง										
4	เกิดความสับสนกับยาหรือวัตถุดิบอื่นๆ เช่น ยาหรือวัตถุดิบปะปนกับ pallet ยาหรือวัตถุดิบอื่น	ยาหรือวัตถุดิบถูกส่งไปแผนกอื่น หรือรับยาหรือวัตถุดิบอื่นเข้าแผนกผลิตตัวเอง										
		อาจเกิดการผลิตยาปลอม (Counterfeit drug: ตัวยาสำคัญผิดความจริง)										
		เสียเวลาตรวจสอบและขนส่งยาหรือวัตถุดิบใหม่ให้ถูกต้อง										
5	เกิดการผลิตยาปลอม (Counterfeit drug) หรือยาผิดมาตรฐาน	หากตรวจสอบพบก่อนจำหน่าย อาจต้อง reject ทั้ง lot										
		หากนำยาออกจำหน่าย เกิดผลกระทบต่อชื่อเสียงขององค์การ										
6	ไม่มีระบบการตรวจสอบน้ำหนักของผลิตภัณฑ์ที่ถูกส่งมากจากแผนกก่อนหน้าที่ดีและรวดเร็วพอ	ไม่ทราบสาเหตุการสูญหายของผลิตภัณฑ์										
7	ไม่มีระบบการเข้าถึงผู้ปฏิบัติงานที่ดีพอ	เภสัชกรผู้รับผิดชอบไม่ได้ควบคุมการขนส่งหรือการผลิตด้วยตนเอง										
		การผลิตยาไม่เป็นไปตามพรบ.ยาเสพติดฯและวัตถุออกฤทธิ์ฯ										
8	ไม่มีระบบการอนุมัติหรือตรวจสอบก่อนการทำงานหรือหลังการทำงาน เพื่อให้ลำดับการทำงานที่ถูกต้อง	เกิดความเสียหายจากการที่พนักงานไม่ทำงานตามคำสั่ง หรือทำงานก่อนคำสั่งของเภสัชกร										
9	มีการปลอมแปลงลายเซ็นเภสัชกรหรือเวลาการผลิตในเอกสารการผลิต (BPR)	เป็นการบันทึกเอกสารปลอม										
		ไม่สามารถตรวจสอบเภสัชกรผู้ควบคุมการผลิตหรือเวลาที่ใช้ในการผลิตที่ชัดเจนได้จริง										
10	บันทึกเอกสารผิดพลาด อ่านลายมือไม่ออก	เกิดความเข้าใจผิดในเนื้อความเอกสารการผลิต										
11	การตรวจสอบและสืบย้อนกลับถึงวัตถุดิบตั้งต้นเป็นไปด้วยความยากลำบาก	ทำให้เสียเวลาในการตรวจสอบวัตถุดิบตั้งต้น เมื่อเกิดปัญหาในการผลิต										

FMEA Assessment Criteria*

Severity: Categorize and identify the severity of impact of risk on the quality of the product/service as High/ Medium/ Low as defined below		
Category	**Score**	**Description of Severity (S)**
Low	1-2	- Limited or no impact on operations and quality of operational efficiency. - No impact to product quality and process robustness.
Medium	3	- Impact on operations and efficiency, but not pervasive. Management intervention required. - Noticeable impact to product quality.
High	4-5	- Very significant and catastrophic impact, significant losses and inefficiencies, necessitating immediate attention. Loss of operating capability, deterioration of efficiency. - Critical deviation from GMP requirements. - Batch failure.
Probability: Categorize and identify the probability of occurrence of risk based on the frequency as High/ Medium/ Low as defined below:		
Category	**Score**	**Probability of Occurrence**
Low	1-2	Seen every more than 3 years.
Medium	3	Seen every 1-3 years.
High	4-5	Seen to occur more than once a year.
Detectability: Categorize and identify the detectability of impact of risk based on the detection control as High/ Medium/ Low as defined below:		
Category	**Score**	**Description of Detectability (D)**
Low	4-5	- Detection controls are absent. - Low likelihood that controls will detect the failure mode or its effects.
Medium	3	- Medium likelihood that controls will detect the failure mode or its effects.
High	1-2	- High likelihood that controls will detect the failure mode or its effects.

*** Ref: ICH Q9 Annex I: Method & Tools, Annex 1.2: Failure Mode Effects Analysis (FMEA)**

ส่วนที่ 2 Satisfaction Questionnaire: แบบสอบถามความพึงพอใจในการใช้งานระบบ

คำชี้แจง กาเครื่องหมาย √ ในช่องว่างให้ตรงกับความคิดเห็นมากที่สุด

ข้อ	หัวข้อ	การทำงานของซอฟแวร์	ระดับความคิดเห็น				
			ดีมาก (5)	ดี (4)	พอใช้ (3)	ควรแก้ไข (2)	ไม่ชอบ (1)
1	System setting	อุปกรณ์ทุกตัวสามารถเชื่อมต่อกับระบบ และสามารถทำงานกันได้อย่างถูกต้อง					
2		ผู้ใช้งานสามารถอ่านและเขียน tag ได้					
3		ระบบสามารถบันทึกข้อมูลการผลิตได้อย่างถูกต้อง เช่น วัน เวลา สถานที่ ผู้ปฏิบัติงาน					
4		ผู้ใช้งานสามารถอ่านข้อมูลจาก reader ได้อย่างถูกต้อง และรวดเร็ว					
5		ระบบสามารถสามารถบันทึก ผู้รับหรือส่งของได้					
6	RFID in production process	ระบบสามารถบันทึกและแสดงข้อมูล lot ของวัตถุดิบได้					
7		ระบบสามารถบันทึกและแสดงการผลิตได้ ว่าวัตถุดิบ lot นี้ จะถูกนำไปผลิตยา batch อะไรบ้าง					
8		ระบบสามารถบันทึกและแสดงสถานะ ว่าวัตถุดิบ ผ่านการวิเคราะห์โดยแผนก QC					
9		ระบบสามารถบันทึกและแสดงการเบิกวัตถุดิบจากคลังได้ - เบิกสำหรับผลิต production batch ใด - วัน/เดือน/ปี/เวลา รับของ (received date) - ผู้รับของ (received operator) - ปริมาณวัตถุดิบที่ใช้ และปริมาณคงเหลือ (SM inventory)					
10		ระบบสามารถแสดงข้อมูลของผลิตภัณฑ์ได้ว่าเป็นวัตถุดิบอะไร มีปริมาณเท่าไหร่					
11		ระบบสามารถบันทึกข้อมูล Mfd.date และ Exp.date ในระบบ ในวันที่ทำการผสมยา					
12	Process tracking	ระบบสามารถบันทึกและแสดงข้อมูลยาที่ทำการผลิตว่าเบิกจากวัตถุดิบ lot ใด, แหล่งที่มาจากไหน โดยที่ข้อมูลเริ่มต้นยังคงถูกบันทึกตลอดกระบวนการ					
13		ระบบสามารถบันทึกและแสดงข้อมูลการผลิต ตั้งแต่รับวัตถุดิบเข้าจนบรรจุเป็นขวด ได้แก่ เวลา แผนกที่ทำการผลิต ผู้ปฏิบัติงาน อุณหภูมิ และความชื้นขณะปฏิบัติงาน					
14		ระบบสามารถเรียกดูสถานะการผลิตยา ณ เวลาปัจจุบันได้ (real time checking)					
15		ระบบสามารถใช้งานในกระบวนการผลิตที่มีขั้นตอนมากหรือน้อยกว่านี้ได้					
16	Loss prevention	ระบบมีการใช้ RFID tag ที่มีเอกลักษณ์เฉพาะ ที่สามารถป้องกันการทดแทนอุปกรณ์จากที่อื่นได้ โดยพนักงาน (มีรหัสเฉพาะตัว ไม่ซ้ำกัน ปลอมแปลงหรือทดแทนไม่ได้)					
17		ระบบมีการตรวจสอบซ้ำ (double check) ให้มั่นใจว่าน้ำหนักจากที่ส่งออกจากแผนกหนึ่งไปแผนกถัดไปถูกต้องจริง เช่น มีการบันทึกและตรวจสอบน้ำหนักในระบบ					
18		มีระบบล็อก 2 ชั้น เพื่อป้องกันการเปิด เช่น ตัวล็อกแม่เหล็ก เป็นต้น					
19		ระบบสามารถสืบย้อนกลับการสูญหายของวัตถุดิบช่วงขนส่งยาระหว่างแผนก และสามารถสืบย้อนกลับไปที่ตัวผู้ปฏิบัติงานได้					

ข้อ	หัวข้อ	การทำงานของซอฟแวร์	ระดับความคิดเห็น				
			ดีมาก (5)	ดี (4)	พอใช้ (3)	ควรแก้ไข (2)	ไม่ชอบ (1)
20	Access control	ระบบสามารถระบุผู้ที่เข้าถึงข้อมูลได้ เช่น การมี personal tag เฉพาะบุคคล					
21		ระบบสามารถเพิ่ม-ลด-แก้ไข ข้อมูลผู้ใช้งานระบบได้ และแสดงเชื่อมต่อข้อมูลบุคคลที่เข้าถึงข้อมูลได้					
22		ระบบแสดงข้อมูลการทำงานของบุคคลได้ เช่น เวลาการทำงาน แผนกที่ทำงาน					
23		ระบบสามารถกำหนดระดับการบันทึกและการเข้าถึงข้อมูลได้					
24		สามารถเพิ่มบุคคลเพื่อยืนยันการทำงานได้ (เพิ่มบุคคลเพื่อ approve)					
25	Document and report	ระบบสามารถบันทึกข้อมูลผู้ปฏิบัติงานโดยผู้ที่เข้าถึงระบบ access ทุกครั้ง					
26		ระบบสามารถสั่งพิมพ์ข้อมูล ตาม template ตามที่กำหนดได้ และสามารถนำเป็นเอกสารคุณภาพได้					
27		ระบบสามารถเรียกดูข้อมูลการผลิตยาย้อนหลัง ภายหลังสิ้นสุดกระบวนการแล้ว 5 ปี หรือจนกว่าจะลบข้อมูลออกจากระบบ					
28	ลักษณะทั่วไปของซอฟแวร์	ระบบมีการใช้งานง่าย เรียนรู้ง่าย ไม่ซับซ้อน					
29		ไม่สามารถแก้ไขข้อมูลที่บันทึกแล้วได้					
30		ตัวอักษรที่ปรากฏชัดเจน อ่านง่าย ขนาดตัวอักษรไม่เล็กจนเกินไป					
31		ระบบสามารถทำงานได้ตรงตามวัตถุประสงค์					
32		ความเป็นไปได้ในการพัฒนาต่อยอด					

ส่วนที่ 3 System Impact Assessment: ประเมินผลกระทบจากการใช้งานระบบ

คำชี้แจง กาเครื่องหมาย √ ในช่องว่าง โดย

"ใช่" หากท่านคิดว่า ระบบส่งผลกระทบต่อกระบวนการผลิตที่ดี (GMP)

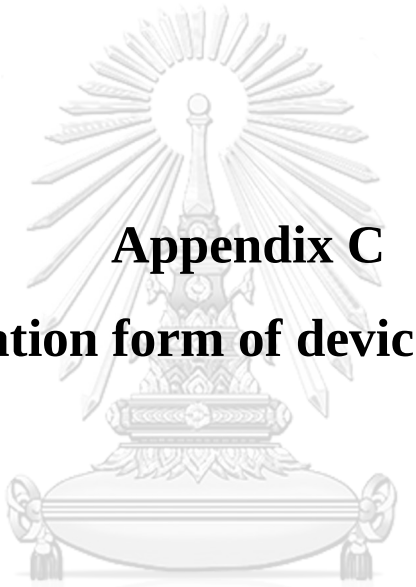
"ไม่ใช่" หากท่านคิดว่า ระบบไม่ส่งผลต่อกระบวนการผลิตที่ดี (GMP)

"ไม่ทราบ" หากท่านไม่ทราบ หรือไม่แน่ใจว่าระบบจะส่งผลกระทบต่อกระบวนการผลิตที่ดี (GMP) หรือไม่

ข้อ	รายละเอียด	ผลกระทบ		
		ใช่	ไม่ใช่	ไม่ทราบ
1	ระบบช่วยสนับสนุนการผลิต เช่น - การขนส่งวัตถุดิบระหว่างแผนก - การป้องกันจากเหตุการณ์ไม่พึงประสงค์ต่างๆ เช่น การผลิตยาปลอม หรือการผลิตยาที่ผิดมาตรฐาน - สนับสนุนการจัดทำเอกสาร - การฝึกอบรมบุคลากรในกิจกรรมที่เกี่ยวข้อง			
2	ระบบส่งผลกระทบต่อผลิตภัณฑ์และส่วนประกอบของผลิตภัณฑ์ในด้านคุณภาพ เอกลักษณ์ ความแรง หรือความบริสุทธิ์หรือไม่			
3	ระบบมีผลต่อการบันทึก การเปลี่ยนแปลง การตรวจสอบ การถ่ายทอด หรือการตัดสินใจในข้อมูลที่เกี่ยวข้องกับผลิตภัณฑ์ หรือส่งประกอบของผลิตภัณฑ์หรือไม่?			
4	ระบบที่ใช้ช่วยระบุวัตถุดิบ ส่วนประกอบที่ใช้ในการผลิต หรือบันทึกการผลิตหรือไม่?			
5	ระบบส่งผลต่อสถานะของวัตถุดิบ บรรจุภัณฑ์ ผลิตภัณฑ์ในระหว่างการผลิต หรือผลิตภัณฑ์สำเร็จรูป ทั้งก่อนและหลังการตรวจสอบ ทั้งในคลังวัตถุดิบ คลังผลิตภัณฑ์สินค้าสำเร็จรูป และศูนย์กระจายสินค้าหรือไม่?			

ส่วนที่ 4 Recommendation: ปัญหาอื่นๆและข้อเสนอแนะ

Appendix C
Evaluation form of device selection



Appendix C-1 Selection of frequencies (Fx)

Criteria	Selection		
	F1 : LF	**F2 : HF**	**F3 : UHF**
Suitable for work requiring access control.	x	√	√
A wide design of tag and reader devices.	x	x	√
Can identify objects that are moving fast.	x	x	√
Multiple objects can be identified in a short time.	x	x	√
Suitable for logistic and transportation.	√	√	√
Inexpensive	√	√	
Easy to maintenance	√	√	√
Can signal at operating range (3-5 meters)	x	x	√
Others			
Summary of the selected frequency is --> …			

Appendix C-2 Selection of RFID tag (Tx)

Criteria	Selection	
	T1 : Passive	**T2 :Active**
Can work with selected frequency (Fx)	√	√
No need to send internal energy all the time. (no need battery)	√	x
All necessary information can be recorded.	√	√
A wide design of tag devices.	√	x
The difficulty of installing the product.	√	x
Inexpensive	√	x
Easy to maintenance	√	x
Others		
Summary of the selected RFID tag is --> …		

Appendix C-3 Selection of RFID tag shape (Sx)

Criteria	Selection							
	For general process					For access control		
	S1 : Cable tie tag	S2 : High temperature metal tag	S3 : Ship tag	S4 : security tie tag	S5 : inlay tag	S6 : Card tag	S7 : Wrist band tag	S8 : Ship tag
Can work with selected frequency (Fx)	√	√	√	X	√	√	√	√
All necessary information can be recorded.	√	√	√	X	√	√	√	√
The device is lightweight.	√	√	√	√	√	√	√	√
Convenient to use the equipment.	√	√	√	√	√	√	√	X
The difficulty of installing the product.	√	√	√	√	√	-	-	-
Prevent to bag uncover of SM	√	X	X	√	X	-	-	-
Compatible with metal.	√	√	√	√	√	√	√	√
Can be installed on a carton or bottle.	X	X	X	X	√	-	-	-
Suitable for access control	-	-	-	-	-	√	√	√
Inexpensive	√	X	√	X	√	√	X	√
Reusable	X	√	√	√	X	√	√	√
Others								
Summary of the selected RFID tag shape is --> …								

Appendix C-4 Selection of RFID reader (Rx)

Criteria	Selection	
	R1 : handheld reader	**R2 : fixed reader**
Can work with selected frequency (Fx)	√	√
Can signal at operating range (3-5 meters)	√	√
Can identify objects that are moving fast.	√	√
Multiple objects can be identified in a short time.	√	√
Easy to install and maintain.	√	x
Convenient for reading and writing	√	x
Inexpensive	√	x
Others		
Summary of the selected RFIDreader is --> …		

Appendix D

Starting Material summary data and Batch Processing Record for software verification test

Starting Material Summary Data

SM Name Diazepam
Supplier Name DZAPI Co.,LTD, Bangkok
Lot No. R2-5900011
Printed date 30/12/2017 18:08
SM Status. SM-Pass

Department from - **Department to** SM warehousing **Date** 26/12/2017 15:17
Document no INVIM26122017-001 **Document type** รับเข้า **Refer to** -
Operator Sonjaiyak Yak **Approve By** -
Divided to - **Batch No.**

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
3000300833B2DDD9014000001200	499.53	25	45	0		
3000300833B2DDD9014000002200	505.11	25	45	0		
300011111111333333322221300	500.21	25	45	0		
Sum	**1504.85**			**0**		

Department from SM warehousing **Department to** Dispensing **Date** 26/12/2017 15:18
Document no INVEX26122017-001 **Document type** ส่งออก **Refer to** -
Operator Sonjaiyak Yak **Approve By** Nutthida Thida
Divided to - **Batch No.**

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
3000300833B2DDD9014000002200	474.54	25	45	30.57		
Sum	**474.54**			**30.57**		

Department from SM warehousing **Department to** Dispensing **Date** 26/12/2017 15:20
Document no INVIM26122017-002 **Document type** รับเข้า **Refer to** INVEX26122017-001
Operator Sriramon Mon **Approve By** -
Divided to - **Batch No.**

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
3000300833B2DDD9014000002200	474.54	25	45	0		
Sum	**474.54**			**0**		

Department from Dispensing **Department to** Dispensing **Date** 26/12/2017 15:21
Document no INVIMT26122017-001 **Document type** แปรรูป **Refer to** T26122017-001
Operator Sriramon Mon **Approve By** -
Divided to Diazepam tablets 2 mg **Batch No.** T6001001

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
100030000004	166.53	25	45	0	3000300833B2DDD9014000002200	166.53
Sum	**166.53**			**0**		

Department from	Dispensing	**Department to**	Dispensing	**Date**	26/12/2017 15:24
Document no	INVIMT26122017-002	**Document type**	แปรรูป	**Refer to**	T26122017-002
Operator	Srisamon Mon			**Approve By**	-
Divided to	Diazepam tablets 2 mg	**Batch No.**	T6001002		

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
100030000002	167.38	25	45	0	3000300833B2DDD9014000002200	167.38
Sum	**167.38**			**0**		

Department from	Dispensing	**Department to**	SM warehousing	**Date**	26/12/2017 15:26
Document no	INVEX26122017-004	**Document type**	ส่งออก	**Refer to**	-
Operator	Srisamon Mon			**Approve By**	-
Divided to	-	**Batch No.**			

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
3000300833B2DDD9014000002200	140.63	25	45	0		
Sum	**140.63**			**0**		

Department from	Dispensing	**Department to**	SM warehousing	**Date**	26/12/2017 15:27
Document no	INVIM26122017-003	**Document type**	รับเข้า	**Refer to**	INVEX26122017-004
Operator	Somjaiyak Yak			**Approve By**	-
Divided to	-	**Batch No.**			

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
3000300833B2DDD9014000002200	140.63	25	45	0		
Sum	**140.63**			**0**		

Department from	SM warehousing	**Department to**	Dispensing	**Date**	26/12/2017 15:56
Document no	INVEX26122017-010	**Document type**	ส่งออก	**Refer to**	-
Operator	Somjaiyak Yak			**Approve By**	Nutthida Thida
Divided to	-	**Batch No.**			

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
3000111111113333333322221300	460.86	25	45	39.35		
3000300833B2DDD9014000002200	140.63	25	45	0		
Sum	**601.49**			**39.35**		

Department from	SM warehousing	**Department to**	Dispensing	**Date**	26/12/2017 15:57
Document no	INVIM26122017-011	**Document type**	รับเข้า	**Refer to**	INVEX26122017-010
Operator	Srisamon Mon			**Approve By**	-
Divided to	-	**Batch No.**			

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
3000111111113333333322221300	460.86	25	45	0		
3000300833B2DDD9014000002200	140.63	25	45	0		
Sum	**601.49**			**0**		

Department from	Dispensing	**Department to**	Dispensing	**Date**	26/12/2017 15:59
Document no	INVIMT26122017-006	**Document type**	แปรรูป	**Refer to**	T26122017-006
Operator	Srisamon Mon			**Approve By**	-
Divided to	Diazepam tablets 5 mg	**Batch No.**	T6002001		

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
100030000034	180	25	45	0	3000300833B2DDD9014000002200	140.63
100030000034	180	25	45	0	3000111111113333333322221300	39.37
Sum	**360.00**			**0**		

Department from	Dispensing	**Department to**	SM warehousing	**Date**	26/12/2017 16:01
Document no	INVEX26122017-012	**Document type**	ส่งออก	**Refer to**	-
Operator	Srisamon Mon			**Approve By**	-
Divided to	-	**Batch No.**			

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
3000111111113333333322221300	421.49	25	45	0		
Sum	**421.49**			**0**		

Department from	Dispensing	**Department to**	SM warehousing	**Date**	26/12/2017 17:01
Document no	INVIM26122017-012	**Document type**	รับเข้า	**Refer to**	INVEX26122017-012
Operator	Somjaiyak Yak			**Approve By**	-
Divided to	-	**Batch No.**			

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
3000111111113333333322221300	421.49	25	45	0		
Sum	**421.49**			**0**		

Batch Processing Record

Product Name	Diazepam tablets 2 mg
RegNo	P1A 9/2558
Batch No.	T6001001
Contain	500 tab
GTIN	8850678232812
BatchSize	1,200,000 tablets
Print date	31/12/2017 10:39
Category	Psychotropic substances in Schedule IV
Status	FP pass

Department from	Dispensing	Department to	Dispensing	Date	26/12/2017 15:21
Document no	INVIMT26122017-001	Document type	แปรรูป	Refer to	T26122017-001
Operator	Srisamon Mon			Approve By	-
MDF Date		EXP Date			
Divided to	Diazepam tablets 2 mg	Batch No.	T6001001	Distribution Center	

Tag code	Weight	Temperature	Humidity	Sampl	Divided tag code	Divided Weight
100030000004	166.53	25	45	0	3000300833B2DDD9014000002200	166.53
Sum	166.53			0		

Department from	Dispensing	Department to	Production1	Date	26/12/2017 15:22
Document no	INVEX26122017-002	Document type	ส่งออก	Refer to	
Operator	Srisamon Mon			Approve By	-
MDF Date		EXP Date			
Divided to		Batch No.	T6001001	Distribution Center	

Tag code	Weight	Temperature	Humidity	Sampl	Divided tag code	Divided Weight
100030000004	166.53	25	45	0		
Sum	166.53			0		

Department from	Dispensing	Department to	Production1	Date	26/12/2017 15:29
Document no	INVIM26122017-004	Document type	รับเข้า	Refer to	INVEX26122017-002
Operator	Thanathani Thani			Approve By	-
MDF Date		EXP Date			
Divided to		Batch No.	T6001001	Distribution Center	

Tag code	Weight	Temperature	Humidity	Sampl	Divided tag code	Divided Weight
100030000004	166.53	25	45	0		
Sum	166.53			0		

Department from	Production1	**Department to**	Production1	**Date**	26/12/2017 15:32
Document no	INVIMT26122017-003	**Document type**	แปรรูป	**Refer to**	T26122017-003
Operator	Thanathani Thani			**Approve By**	-
MDF Date	26/12/2017 15:32	**EXP Date**	26/12/2019 15:32		
Divided to	Diazepam tablets 2 mg	**Batch No.**	T6001001	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampl	Divided tag code	Divided Weight
100030000003	176.34	25	45	0	100030000004	166.53
100030000005	180.76	25	45	0		
100030000010	190.23	25	45	0		
Sum	547.33			**0**		

Department from	Production1	**Department to**	Production2	**Date**	26/12/2017 15:33
Document no	INVEX26122017-005	**Document type**	ส่งออก	**Refer to**	
Operator	Thanathani Thani			**Approve By**	-
MDF Date	26/12/2017 15:32	**EXP Date**	26/12/2019 15:32		
Divided to		**Batch No.**	T6001001	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampl	Divided tag code	Divided Weight
100030000003	176.34	25	45	0		
100030000005	180.76	25	45	0		
100030000010	190.23	25	45	0		
Sum	547.33			**0**		

Department from	Production1	**Department to**	Production2	**Date**	26/12/2017 15:34
Document no	INVIM26122017-005	**Document type**	รับเข้า	**Refer to**	INVEX26122017-005
Operator	Rachan Chan			**Approve By**	-
MDF Date	26/12/2017 15:32	**EXP Date**	26/12/2019 15:32		
Divided to		**Batch No.**	T6001001	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampl	Divided tag code	Divided Weight
100030000003	176.34	25	45	0		
100030000005	180.76	25	45	0		
100030000010	190.23	25	45	0		
Sum	547.33			**0**		

Department from	Production2	**Department to**	Production2	**Date**	26/12/2017 17:10
Document no	INVIMT26122017-007	**Document type**	แปรรูป	**Refer to**	T26122017-007
Operator	Rachan Chan			**Approve By**	-
MDF Date	26/12/2017 15:32	**EXP Date**	26/12/2019 15:32		
Divided to	Diazepam tablets 2 mg	**Batch No.**	T6001001	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampl	Divided tag code	Divided Weight
100030000013	213.98	25	45	0	100030000003	176.34
100030000014	212.19	25	45	0	100030000005	180.76
100030000016	226.53	25	45	0	100030000010	190.23
Sum	652.70			0		

Department from	Production2	**Department to**	Production3	**Date**	26/12/2017 17:34
Document no	INVEX26122017-013	**Document type**	ส่งออก	**Refer to**	
Operator	Rachan Chan			**Approve By**	-
MDF Date	26/12/2017 15:32	**EXP Date**	26/12/2019 15:32		
Divided to		**Batch No.**	T6001001	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampl	Divided tag code	Divided Weight
100030000013	213.98	25	45	0		
100030000014	212.19	25	45	0		
100030000016	226.53	25	45	0		
Sum	652.70			0		

Department from	Production2	**Department to**	Production3	**Date**	26/12/2017 18:09
Document no	INVIM26122017-018	**Document type**	รับเข้า	**Refer to**	INVEX26122017-013
Operator	Kawin Win			**Approve By**	-
MDF Date	26/12/2017 15:32	**EXP Date**	26/12/2019 15:32		
Divided to		**Batch No.**	T6001001	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampl	Divided tag code	Divided Weight
100030000013	213.98	25	45	0		
100030000014	212.19	25	45	0		
100030000016	226.53	25	45	0		
Sum	652.70			0		

Department from	Production3	**Department to**	Production3	**Date**	26/12/2017 18:11
Document no	INVIMT26122017-013	**Document type**	แปรรูป	**Refer to**	T26122017-013
Operator	Kawin Win			**Approve By**	-
MDF Date	26/12/2017 15:32	**EXP Date**	26/12/2019 15:32		
Divided to	Diazepam tablets 2 mg	**Batch No.**	T6001001	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampl	Divided tag code	Divided Weight
100030000012	420.12	25	45	0	100030000013	213.98
100030000019	387.36	25	45	0	100030000014	212.19
100030000032	401.32	25	45	0	100030000016	226.53
Sum	**1208.80**			**0**		

Department from	Production3	**Department to**	Packaging	**Date**	26/12/2017 18:11
Document no	INVEX26122017-019	**Document type**	ส่งออก	**Refer to**	
Operator	Kawin Win			**Approve By**	-
MDF Date	26/12/2017 15:32	**EXP Date**	26/12/2019 15:32		
Divided to		**Batch No.**	T6001001	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampl	Divided tag code	Divided Weight
100030000012	420.12	25	45	0		
100030000019	387.36	25	45	0		
100030000032	401.32	25	45	0		
Sum	**1208.80**			**0**		

Department from	Production3	**Department to**	Packaging	**Date**	26/12/2017 18:13
Document no	INVIM26122017-019	**Document type**	รับเข้า	**Refer to**	INVEX26122017-019
Operator	Srisukjai Jai			**Approve By**	-
MDF Date	26/12/2017 15:32	**EXP Date**	26/12/2019 15:32		
Divided to		**Batch No.**	T6001001	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampl	Divided tag code	Divided Weight
100030000012	420.12	25	45	0		
100030000019	387.36	25	45	0		
100030000032	401.32	25	45	0		
Sum	**1208.80**			**0**		

Department from	Packaging	**Department to**	Packaging	**Date**	26/12/2017 18:15
Document no	INVIMT26122017-014	**Document type**	แปรรูป	**Refer to**	T26122017-014
Operator	Srisukjai Jai			**Approve By**	-

MDF Date	26/12/2017 15:32	**EXP Date**	26/12/2019 15:32		
Divided to	Diazepam tablets 2 mg	**Batch No.**	T6001001	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampl	Divided tag code	Divided Weight
3000300833B2DDD9014000000003	1	25	45	0	100030000012	420.12
3000300833B2DDD9014000000004	1	25	45	0	100030000019	387.36
3000300833B2DDD9014000000009	1	25	45	0	100030000032	401.32
3000300833B2DDD9014000000010	1	25	45	0		
3000300833B2DDD9014000000012	1	25	45	0		
Sum	**5.00**			**0**		

Department from	Packaging	**Department to**	FPwarehousing	**Date**	26/12/2017 18:16
Document no	INVEX26122017-020	**Document type**	ส่งออก	**Refer to**	
Operator	Srisukjai Jai			**Approve By**	-
MDF Date	26/12/2017 15:32	**EXP Date**	26/12/2019 15:32		
Divided to		**Batch No.**	T6001001	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampl	Divided tag code	Divided Weight
3000300833B2DDD9014000000003	1	25	45	0		
3000300833B2DDD9014000000004	1	25	45	0		
3000300833B2DDD9014000000009	1	25	45	0		
3000300833B2DDD9014000000010	1	25	45	0		
3000300833B2DDD9014000000012	1	25	45	0		
Sum	**5.00**			**0**		

Department from	Packaging	**Department to**	FPwarehousing	**Date**	26/12/2017 18:48
Document no	INVIM26122017-025	**Document type**	รับเข้า	**Refer to**	INVEX26122017-020
Operator	Rakchart Chart			**Approve By**	-
MDF Date	26/12/2017 15:32	**EXP Date**	26/12/2019 15:32		
Divided to		**Batch No.**	T6001001	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampl	Divided tag code	Divided Weight
3000300833B2DDD9014000000003	1	25	45	0		
3000300833B2DDD9014000000004	1	25	45	0		
3000300833B2DDD9014000000009	1	25	45	0		
3000300833B2DDD9014000000010	1	25	45	0		
3000300833B2DDD9014000000012	1	25	45	0		
Sum	**5.00**			**0**		

Department from	FP warehousing	**Department to**	Distribution center	**Date**	26/12/2017 18:50
Document no	INVEX26122017-026	**Document type**	ส่งออก	**Refer to**	
Operator	Rakchart Chart			**Approve By**	Patcha Cha
MDF Date	26/12/2017 15:32	**EXP Date**	26/12/2019 15:32		
Divided to		**Batch No.**	T6001001	**Distribution Center**	Pathum thani

Tag code	Weight	Temperature	Humidity	Sampl	Divided tag code	Divided Weight
3000300833B2DDD9014000000003	1	25	45	0		
3000300833B2DDD9014000000004	1	25	45	0		
3000300833B2DDD9014000000009	1	25	45	0		
3000300833B2DDD9014000000010	1	25	45	0		
3000300833B2DDD9014000000012	1	25	45	0		
Sum	**5.00**			**0**		

Appendix E

Certification of verification

Certification of Verification
"SP Track" program

"We guarantee that "SP Track" program was pass the verification test"

At
Faculty of Pharmaceutical Science
Chulalongkorn University

Committee

(Phanphen Wattanaarsakit) Advisor — Date 5/1/2018.

(Asst. Prof.Anuchai Theeraroungchaisri) Co-Advisor — Date 5/1/2018

(Natapol Pornputtapong) Co-Advisor — Date 5/1/61

(Weerayut Chirarutsami) Expert of Pharmaceutical industry — Date 5/1/61

(Methee Roengcharas) Expert of RFID system — Date 6/1/61

(Pramoul Thongplew) Programmer — Date 6/1/61

(Punlert Piyathamrongrat) Witness — Date 4/1/61

(Arnas Lakhiew) Witness — Date 4/1/61

Appendix F

Evaluation team

Evaluation team				
No.	**Name**	**Position**	**Department**	**Sign/date**
1	Sasinij Chokrongthuamb	Head of section	Raw Material 1	23 มค. 61
2	Pisit-orn Chaivongnarong	Pharmacist	Raw material 1	23 มกราคม 61
3	Thanongsak Jitsue	STAFF	Raw material 1	23 ม.ค. 61
4	Teerawat Sangsuliyachaya	staff	Raw Material 1	23 ม.ค. 61
5	PARN SUPCHAIT	staff	Tablet 1	
6	WALLOP PHUENGPHO	staff	Tablet 1	3/2/18
7	SUTHAT TIRAWANITCHAWONG	staff	Tablet 1	02/02/61
8	OH JANMAN	STAFF	TABLET	2/2/61
9	Natthaphon Klahan	Staff	Tablet 1	2/2/61
10	Janthima Khaiman	Pharmacist	Tablet 1	2/2/18
11	Kittipon Sumthongplanich	Head of section	Tablet 1	6/2/18
12	Arpawadee Suvannus	Head of Section	Tablets-packing Sec.-I	21/12/18
13	Tinanan Manceerat	Pharmacist	Tablets Packing Section 1	21/12/18
14	Rathaya Tambingngoun	Staff	Tablets Packing Sec.	21/12/18
15	Thanandorn Inta	Pharmacist	Tablets Packing Section 1	21/02/18
16				
17				
18				

Appendix G

Starting Material summary data and Batch Processing Record for site testing

Starting Material Summary

SM Name	Phenobarbital
Supplier Name	PBBAPI Co.,LTD, Samut Prakan
Lot No.	R1-61/00006
Printed date	21/2/2018 19:52
SM Status.	SM-Pass

Department from	SM warehousing	Department to	SM warehousing	Date	17/1/2018 14:25
Document no	INVIM17012018-001	Document type	รับเข้า	Refer to	
Operator	Todsawat Sang			Approve By	-
Divided to		Batch No.			

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
3000300833B2DDD9014000000220	25.00	26	55	0		
3000300833B2DDD9014000000440	25.00	26	55	0		
3000300833B2DDD9014000003100	25.00	26	55	0		
3000300833B2DDD9014000000550	25.00	26	55	0		
3000300833B2DDD9014000000330	25.00	26	55	0		
3000300833B2DDD9014000002000	25.00	26	55	0		
3000300833B2DDD9014000001900	25.00	26	55	0		
3000300833B2DDD9014000002100	25.00	26	55	0		
3000300833B2DDD9014000001600	25.00	26	55	0		
3000300833B2DDD9014000003000	25.00	26	55	0		
3000300833B2DDD9014000002800	25.00	26	55	0		
3000300833B2DDD9014000002200	25.00	26	55	0		
3000300833B2DDD9014000002300	25.00	26	55	0		
3000300833B2DDD9014000001100	25.00	26	55	0		
3000300833B2DDD9014000002600	25.00	26	55	0		
3000300833B2DDD9014000001800	25.00	26	55	0		
3000300833B2DDD9014000002500	25.00	26	55	0		
3000300833B2DDD9014000001500	1.49	26	55	0		
3000300833B2DDD9014000000110	25.00	26	55	0		
Sum	451.49			0		

Department from	SM warehousing	Department to	Dispensing	Date	17/1/2018 14:31
Document no	INVEX17012018-001	Document type	ส่งออก	Refer to	
Operator	Todsawat Sang			Approve By	Pisitorn Chai
Divided to		Batch No.			

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
3000300833B2DDD9014000003100	25.00	25.5	55	0		
3000300833B2DDD9014000000330	25.00	25.5	55	0		
3000300833B2DDD9014000001900	25.00	25.5	55	0		
3000300833B2DDD9014000001100	25.00	25.5	55	0		
3000300833B2DDD9014000000440	25.00	25.5	55	0		
3000300833B2DDD9014000000220	25.00	25.5	55	0		
3000300833B2DDD9014000000550	25.00	25.5	55	0		
3000300833B2DDD9014000002000	25.00	25.5	55	0		
3000300833B2DDD9014000002800	25.00	25.5	55	0		
3000300833B2DDD9014000003000	25.00	25.5	55	0		
3000300833B2DDD9014000002200	25.00	25.5	55	0		
3000300833B2DDD9014000002300	25.00	25.5	55	0		
3000300833B2DDD9014000001600	25.00	25.5	55	0		
3000300833B2DDD9014000002600	25.00	25.5	55	0		
3000300833B2DDD9014000002500	25.00	25.5	55	0		
3000300833B2DDD9014000001500	1.49	25.5	55	0		
3000300833B2DDD9014000000110	25.00	25.5	55	0		
3000300833B2DDD9014000001800	25.00	25.5	55	0		
3000300833B2DDD9014000002100	25.00	25.5	55	0		
Sum	451.49			0		

Department from	SM warehousing	**Department to**	Dispensing	**Date**	18/1/2018 9:03
Document no	INVIM18012018-001	**Document type**	จ่ายเข้า	**Refer to**	INVEX17012018-001
Operator	Nutthaphon Kla			**Approve By**	-
Divided to		**Batch No.**			

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
3000300833B2DDD9014000002300	25.00	20.8	56	0		
3000300833B2DDD9014000000440	25.00	20.8	56	0		
3000300833B2DDD9014000000550	25.00	20.8	56	0		
3000300833B2DDD9014000002600	25.00	20.8	56	0		
3000300833B2DDD9014000002800	25.00	20.8	56	0		
3000300833B2DDD9014000001900	25.00	20.8	56	0		
3000300833B2DDD9014000002100	25.00	20.8	56	0		
3000300833B2DDD9014000000220	25.00	20.8	56	0		
3000300833B2DDD9014000002500	25.00	20.8	56	0		

3000300833B2DDD9014000002200	25.00	20.8	56	0
3000300833B2DDD9014000001100	25.00	20.8	56	0
3000300833B2DDD9014000001600	25.00	20.8	56	0
3000300833B2DDD9014000000330	25.00	20.8	56	0
3000300833B2DDD9014000003000	25.00	20.8	56	0
3000300833B2DDD9014000002000	25.00	20.8	56	0
3000300833B2DDD9014000001800	25.00	20.8	56	0
3000300833B2DDD9014000003100	25.00	20.8	56	0
3000300833B2DDD9014000001500	1.49	20.8	56	0
3000300833B2DDD9014000000110	25.00	20.8	56	0
Sum	**451.49**			**0**

Department from	Dispensing	**Department to**	Dispensing	**Date**	23/1/2018 13:52
Document no	INVIMT23012018-001	**Document type**	แปรรูป	**Refer to**	T23012018-001
Operator	Nutthaphon Kla			**Approve By**	-
Divided to	Phenobarbitone tablets 30 mg	**Batch No.**	F610041		

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
100030000004	36.00	19.4	59	0	3000300833B2DDD9014000003100	25.00
100030000028	36.00	19.4	59	0	3000300833B2DDD9014000000550	25.00
					3000300833B2DDD9014000002200	22.00
Sum	**72.00**			**0**		

Department from	Dispensing	**Department to**	Dispensing	**Date**	23/1/2018 13:58
Document no	INVIMT23012018-002	**Document type**	แปรรูป	**Refer to**	T23012018-002
Operator	Nutthaphon Kla			**Approve By**	-
Divided to	Phenobarbitone tablets 60 mg	**Batch No.**	F610042		

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
100030000049	45.00	19	59	0	3000300833B2DDD9014000001600	25.00
100030000020	45.00	19	59	0	3000300833B2DDD9014000001800	25.00
					3000300833B2DDD9014000002600	25.00
					3000300833B2DDD9014000000110	15.00
Sum	**90.00**			**0**		

Department from	Dispensing	**Department to**	Dispensing	**Date**	23/1/2018 14:02
Document no	INVIMT23012018-003	**Document type**	แปรรูป	**Refer to**	T23012018-003
Operator	Nutthaphon Kla			**Approve By**	-
Divided to	Phenobarbitone tablets 60 mg	**Batch No.**	F610043		

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
100030000006	45.00	19.5	59	0	3000300833B2DDD9014000002000	25.00
100030000047	45.00	19.5	59	0	3000300833B2DDD9014000000330	25.00
					3000300833B2DDD9014000001100	25.00
					3000300833B2DDD9014000002100	15.00
Sum	**90.00**			**0**		

Department from	Dispensing	**Department to**	Dispensing	**Date**	23/1/2018 14:05
Document no	INVIMT23012018-004	**Document type**	แปรรูป	**Refer to**	T23012018-004
Operator	Nutthaphon Kla			**Approve By**	-
Divided to	Phenobarbitone tablets 60 mg	**Batch No.**	F610044		

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
100030000035	45.00	19	59	0	3000300833B2DDD9014000002500	25.00
100030000034	45.00	19	59	0	3000300833B2DDD9014000001900	25.00
					3000300833B2DDD9014000002300	25.00
					3000300833B2DDD9014000000220	15.00
Sum	**90.00**			**0**		

Department from	Dispensing	**Department to**	Dispensing	**Date**	23/1/2018 14:09
Document no	INVIMT23012018-005	**Document type**	แปรรูป	**Refer to**	T23012018-005
Operator	Nutthaphon Kla			**Approve By**	-
Divided to	Phenobarbitone tablets 60 mg	**Batch No.**	F610045		

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
100030000009	30.00	19	59	0	3000300833B2DDD9014000003000	25.00
100030000043	30.00	19	59	0	3000300833B2DDD9014000002100	10.00
100030000019	30.00	19	59	0	3000300833B2DDD9014000000110	5.00
					3000300833B2DDD9014000002800	25.00
					3000300833B2DDD9014000000440	25.00
Sum	**90.00**			**0**		

Department from	Dispensing	**Department to**	Dispensing	**Date**	23/1/2018 14:16
Document no	INVIMT23012018-006	**Document type**	แปรรูป	**Refer to**	T23012018-006
Operator	Nutthaphon Kla			**Approve By**	-
Divided to	Phenobarbitone tablets 60 mg	**Batch No.**	F610046		

Tag code	Weight	Temperatur	Humidity	Sampling	Divided tag code	Divided Weight
100030000041	30.00	19	59	0	3000300833B2DDD9014000000220	10.00
100030000044	30.00	19	59	0	3000300833B2DDD9014000000110	5.00
100030000015	30.00	19	59	0	3000300833B2DDD9014000001500	1.49
					3000300833B2DDD9014000002200	3.00
Sum	**90.00**			**0**		

Batch Processing Record

Product Name	Phenobarbitone tablets 60 mg
RegNo	P1A 8/2558
Batch No.	F610042
Contain	1,000 tab
GTIN	8850678236711
BatchSize	1,500,000 tablets
Print date	21/2/2018 19:56
Category	Psychotropic substances in Schedule IV
Status	SM pass

Department from	Dispensing	**Department to**	Dispensing	**Date**	23/1/2018 13:58
Document no	INVIMT23012018-002	**Document type**	แปรรูป	**Refer to**	T23012018-002
Operator	Nutthaphon Kla			**Approve By**	-
MDF Date		**EXP Date**			
Divided to	Phenobarbitone tablets 60 mg	**Batch No.**	F610042	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampling	Divided tag code	Divided Weight
100030000020	45.00	19	59	0	3000300833B2DDD9014000000110	15.00
100030000049	45.00	19	59	0	3000300833B2DDD9014000001600	25.00
					3000300833B2DDD9014000001800	25.00
					3000300833B2DDD9014000002600	25.00
Sum	**90.00**			**0**		

Department from	Dispensing	**Department to**	Production1	**Date**	23/1/2018 14:26
Document no	INVEX23012018-003	**Document type**	ส่งออก	**Refer to**	
Operator	Nutthaphon Kla			**Approve By**	-
MDF Date		**EXP Date**			
Divided to		**Batch No.**	F610042	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampling	Divided tag code	Divided Weight
100030000020	45.00	19	59	0		
100030000049	45.00	19	59	0		
Sum	**90.00**			**0**		

Department from	Dispensing	**Department to**	Production1	**Date**	25/1/2018 8:56
Document no	INVIM25012018-001	**Document type**	รับเข้า	**Refer to**	INVEX23012018-003
Operator	Ao Chan			**Approve By**	-
MDF Date		**EXP Date**			
Divided to		**Batch No.**	F610042	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampling	Divided tag code	Divided Weight
100030000020	45.00	21.5	65	0		

100030000049		45.00	21.5	65	0		
Sum		**90.00**			**0**		

Department from Production1 **Department to** Production1 **Date** 26/1/2018 15:46

Document no INVIMT26012018-001 **Document type** แปรรูป **Refer to** T26012018-001

Operator Ao Chan **Approve By** -

MDF Date 25/1/2018 15:45 **EXP Date** 25/1/2020 15:45

Divided to Phenobarbitone tablets 60 mg **Batch No.** F610042 **Distribution Center**

Tag code	Weight	Temperature	Humidity	Sampling	Divided tag code	Divided Weight
3000300833B2DDD9014000000001	99.55	23.8	59	0	100030000020	45.00
3000300833B2DDD9014000000009	100.20	23.8	59	0	100030000049	45.00
Sum	**199.75**			**0**		

Department from Production1 **Department to** Production2 **Date** 26/1/2018 15:47

Document no INVEX26012018-001 **Document type** ส่งออก **Refer to**

Operator Ao Chan **Approve By** -

MDF Date 25/1/2018 15:45 **EXP Date** 25/1/2020 15:45

Divided to **Batch No.** F610042 **Distribution Center**

Tag code	Weight	Temperature	Humidity	Sampling	Divided tag code	Divided Weight
3000300833B2DDD9014000000001	99.55	23.8	59	0		
3000300833B2DDD9014000000009	100.20	23.8	59	0		
Sum	**199.75**			**0**		

Department from Production1 **Department to** Production2 **Date** 27/1/2018 10:15

Document no INVIM27012018-001 **Document type** รับเข้า **Refer to** INVEX26012018-001

Operator Janthima Khai **Approve By** -

MDF Date 25/1/2018 15:45 **EXP Date** 25/1/2020 15:45

Divided to **Batch No.** F610042 **Distribution Center**

Tag code	Weight	Temperature	Humidity	Sampling	Divided tag code	Divided Weight
3000300833B2DDD9014000000001	99.55	23.8	59	0		
3000300833B2DDD9014000000009	100.20	23.8	59	0		
Sum	**199.75**			**0**		

Department from Production2 **Department to** Production2 **Date** 27/1/2018 10:16

Document no INVIMT27012018-001 **Document type** แปรรูป **Refer to** T27012018-001

Operator Janthima Khai **Approve By** -

MDF Date 25/1/2018 15:45 **EXP Date** 25/1/2020 15:45

Divided to Phenobarbitone tablets 60 mg **Batch No.** F610042 **Distribution Center**

Tag code	Weight	Temperature	Humidity	Sampling	Divided tag code	Divided Weight
30000098024C1301302000016C5C	199.75	23.5	59	0	3000300833B2DDD9014000000001	99.55
					3000300833B2DDD9014000000009	100.20
Sum	199.75			0		

Department from	Production2	**Department to**	Production3	**Date**	27/1/2018 10:17
Document no	INVEX27012018-001	**Document type**	ส่งออก	**Refer to**	
Operator	Janthima Khai			**Approve By**	-
MDF Date	25/1/2018 15:45	**EXP Date**	25/1/2020 15:45		
Divided to		**Batch No.**	F610042	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampling	Divided tag code	Divided Weight
30000098024C1301302000016C5C	199.75	23.5	59	0		
Sum	199.75			0		

Department from	Production2	**Department to**	Production3	**Date**	27/1/2018 11:17
Document no	INVIM27012018-007	**Document type**	รับเข้า	**Refer to**	INVEX27012018-001
Operator	Parn Sud			**Approve By**	-
MDF Date	25/1/2018 15:45	**EXP Date**	25/1/2020 15:45		
Divided to		**Batch No.**	F610042	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampling	Divided tag code	Divided Weight
30000098024C1301302000016C5C	199.75	20	55	0		
Sum	199.75			0		

Department from	Production3	**Department to**	Production3	**Date**	30/1/2018 10:02
Document no	INVIMT30012018-001	**Document type**	แปรรูป	**Refer to**	T30012018-001
Operator	Parn Sud			**Approve By**	-
MDF Date	25/1/2018 15:45	**EXP Date**	25/1/2020 15:45		
Divided to	Phenobarbitone tablets 60 mg	**Batch No.**	F610042	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampling	Divided tag code	Divided Weight
100030000003	39.00	18	56	0	30000098024C1301302000016C5C	199.75
100030000005	41.48	18	56	0		
100030000007	36.40	18	56	0		
100030000017	36.78	18	56	0		
100030000026	42.28	18	56	0		
Sum	195.94			0		

Department from	Production3	**Department to**	Packaging	**Date**	30/1/2018 10:03
Document no	INVEX30012018-001	**Document type**	ส่งออก	**Refer to**	
Operator	Parn Sud			**Approve By**	-

MDF Date	25/1/2018 15:45	**EXP Date**	25/1/2020 15:45		
Divided to		**Batch No.**	F610042	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampling	Divided tag code	Divided Weight
100030000003	39.00	18	62	0		
100030000005	41.48	18	62	0		
100030000007	36.40	18	62	0		
100030000017	36.78	18	62	0		
100030000026	42.28	18	62	0		
Sum	**195.94**			**0**		

Department from	Production3	**Department to**	Packaging	**Date**	21/2/2018 10:18
Document no	INVIM21022018-007	**Document type**	รับเข้า	**Refer to**	INVEX30012018-001
Operator	Tiwanan Man			**Approve By**	-
MDF Date	25/1/2018 15:45	**EXP Date**	25/1/2020 15:45		
Divided to		**Batch No.**	F610042	**Distribution Center**	

Tag code	Weight	Temperature	Humidity	Sampling	Divided tag code	Divided Weight
100030000003	39.00	25	65	0		
100030000005	41.48	25	65	0		
100030000007	36.40	25	65	0		
100030000017	36.78	25	65	0		
100030000026	42.28	25	65	0		
Sum	**195.94**			**0**		

VITA

Ms. Jesdaporn Rachivong was born on October 22, 1987 in Yasothon, Thailand. She received a Bachelor's degree in Pharmaceutical Science from Mahidol University, in 2011 in Bangkok. After graduation, she has worked as a quality assurance pharmacist at Government Pharmaceutical Organization for 3 years. She has experience in manufacturing process, good manufacturing standard and quality assurance procedures. She got a scholarship from the workplace to study in the Department of Pharmaceutics and Industrial Pharmacy, Faculty of Pharmaceutical Sciences, Chulalongkorn University. In 2017-present, she still works as a quality assurance officer at Government Pharmaceutical Organization.