CHAPTER IX

Conclusions

In the pharmaceutical industry, the product development is one of the best role for industrial pharmacist. Generally, one of the development of a new excipient is to achieve a better quality of product is most important. It is generally to be accepted that the full potential value of a compressed tablet is assured only when tablet dissolve rapidly, the primary action is disintegration. Therefore a development of powerful disintegrant is interesting.

The main objective of this study aimed to develop a new super disintegrant from the native starches by chemical reactions.

From the preliminary study of the native starches. It was found that it was feasible to develop tapioca starch as a new powerful disintegrant and there are a few paper to report the modification of tapioca starch as a disintegrant in pharmaceutical field.

To study the factors involved in modification process which influencing physico-chemical properties of substituted tapioca starch, a factorial design study was performed to evaluate these factors. It was found that time of reaction and temperature were the important factors influencing physico-chemical properties of carboxymethyl tapioca starch and also affected to disintegrant property of carboxymethyl tapioca starch. The most important problem of using carboxymethyl tapioca starch as disintegrant was its solubility produced viscous gel barrier around granules and tablet. To overcome this problem a crosslinking of carboxymethyl tapioca starch by suitable crosslinking agent should be done.

To achieve a good disintegrant property the optimum degree of carboxymethyl substitution and the optimum degree of phosphate crosslinking were investigated. The optimum degree of substitution and crosslinking of

crosslinked carboxymethyl tapioca starch (modified tapioca starch, MTS) which provided a good disintegrant properties were degree of substitution of 0.17 and degree of crosslinking of 0.95% phosphate.

Comparative study of physico-chemical properties of MTS and other commercial modified potato starches (Explotab^R and Primojel^R) was shown that MTS exhibited some physico-chemical properties better than modified potato starches such as water uptake, bulk swelling, hydration capacity, cold water soluble, sodium chloride content and percent compressibility while viscosity and sorption isotherm of these disintegrants more closely resembled.

Modified tapioca starch exhibited disintegrant property superior over the commercial modified potato starches in dicalcium phosphate and erythromycin stearate tablets and equivalent to Explotab^R, Primojel^R and Ac-Di-Sol^R in paracetamol tablets at the same level of concentration.

However, disintegrating capacity of modified tapioca starch was affected by granulating fluid and compression force, hence, the optimum compression force for tabletting should be considered.

In addition, moisture can affect to the tablet strength and disintegration times of paracetamol tablets and also affected to disintegrating efficiency of modified tapioca starch during storage from 0 to 12 weeks both of the low and high humidity conditions at constant temperature. In fact, moisture less affected to disintegrant efficiency of modified tapioca starch than that of Explotab^R and Primojel^R. Therefore, a suitable packaging is of importance when such a disintegrant is used in tablet.

Furthermore, it has clearly shown that modified tapioca starch can improve the disintegration of tablet containing slightly soluble tablet systems and appeared to be superior over Explotab^R and Primojel^R.

A crosslinked carboxymethyl tapioca starch (Modified Tapioca Starch, MTS) was found to be excellent disintegrant at the concentration of 4-8%.

In conclusion it breakthroughed to painstakingly develop a new super disintegrant from tapioca starch by carboxymethyl substitution and phosphate crosslinking approaches.