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APPENDICES

APPENDIX I

DETAILS OF POLYMERS

Carbopol 934

Carbopol 934 is a synthetic high molecular weight polymer of acrylic acid cross-linked with allylsucrose and containing 56 to 68% of carboxylic acid groups, calculated as the dry substance. The empirical formula is demonstrated below,

$$(C_3H_4O_2)x \ (-C_3H_5\text{-Sucrose})y$$
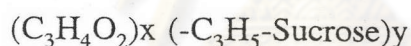
with an approximate molecular weight about $3x \ 10^6$. It is a white, fluffy, acidic, hygroscopic powder with a slight characteristic odour. Neutralised with alkali hydroxides or amines and it is soluble in water, alcohol, and glycerol.

Carbopol 934 is more commonly used in pharmaceutical liquid and semisolid dosage forms than in tablets. Carbopol is used an emulsifying agent (0.1-0.5%), and suspending agent (0.5-1.0%), and gelling agent (0.5-2.0%) in pharmaceutical and cosmatic preparations. Its wide usefulness is complimented by the lubricity it imparts to the product.

Methylcellulose

A cellulose having some of the hydroxyl groups in the from of methyl ether. The formula is long-chain substitued cellulose, ether of 50-150 anhydroglucose units containing 26-32% methoxy groups (CH_3O). Various types of methylcellulose, USP and viscosity is shown below.

Viscosity grade :

| Aproximate Viscosity of 2% Solution at 20 °C/cps.	Material	Sovent
20	Celacol M 20 GP	Water
450	Celacol M 450 GP	Water
1000	Celacol M 1000 GP	Water
2500	Celacol M 2500 GP	Water
5000	Celacol M 5000 GP	Water
10000	Celacol M 10000 CP	Water
10	Celacol MM 10 GP	Water
100	Celacol MM 100 GP	Water
20 *	Celacol M 20B PC	
450 *	Celacol M450 BPC	
15 *	Methocel A15 Premium	Water
400 *	Methocel A4 C Premium	Water
1500 *	Methocel A15 C Premium	Water
4000 *	Methocel A4M Premium	Water

* Calculated with reference to dried material.

Methycellulose is practically insoluble in hot water, dehydrated alcohol, chloroform, acetone, and ether; soluble in glacial acetic acid in a

mixture of equal volumes of alcohol and chloroform. It swells in water producing a clear to opalescent, viscous, colloidal suspension and form a colloidal solution in cold water.

Various grades of methylcellulose are use as emulsifying agents, as thickening agent for gels and creams, as dispersing and thickening agents in suspensions, as binding and disintegrating agents in tablets, and in tablet coating.

Hydroxypropylmethylcellulose

Hydroxypropylmethylcellulose is a cellulose hydroxypropylmethyl ether. The empirical formula is shown below,

$$C_8H_{15}O_6\text{-}(C_{10}H_8O_6)_n\text{-}C_8H_{15}O_5$$
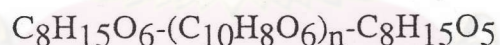
with an approximate molecular weight about 86,000. Hydroxypropyl methylcellulose is an odorless, tasteless, white or creamy-white fibrous or granular powder. It is soluble in cold water, forming a viscous colloidal solution; insoluble in alcohol, ether and chloroform; but soluble in mixtures of methyl alcohol and methylene chloride. It is available in two viscosity ranges, 50 and 4,000 cps. It undergoes a reversible transformation from sol to gel upon heating and cooling, respectively. Solutions of hydroxypropylmethylcellulose are stable at pH 3.0 - 11.0. It is incompatible with extreme pH conditions and oxidizing materials.

To prepare an aqueous solution, it is recommended to disperse and thoroughly hydrate hydroxypropylmethylcellulose in about 1/5 to 1/3 of the required amount of water at 80-90 $^{\circ}$C and add cold water or ice while it is stirring vigorously. Then add cold water to volume.

Hydroxypropylmethylcellulose is used as film former, binder, thickener, emulsifier, stabilizer, suspending agent and gelling agent in pharmaceutical preparations.

Sodium Carboxymethylcellulose

The sodium salt of a polycarboxymethyl ether of cellulose. The B.P. specifies a sodium content of 6.5 to 10.8%, and the U.S.P. 6.5 to 9.5% both calculated on the dry substance. The empirical formula is demonstrated below ,

$$[C_6H_7O_2(OH)_{3-X}(OCH_2-COONa)_X]_n$$
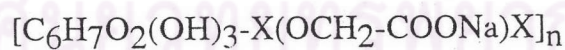
with an approximate molecular weight about 3×10^6. The degree of polymerisation affects the viscosity of solution. There are three viscosity grade; high viscosity (H.V.), medium viscosity (M.V.) and low viscosity (L.V.).

Sodium carboxymethylcellulose is a white to cream-coloured odurless or almost odourless hygroscopic powder or granuless. Easily dispersed in water forming colloidal solutions; practically insoluble in alcohol, ether and most other organic solvents.

Sodium carboxymethylcellulose is used as a suspending agent and as an emulisifying agent, it is used in the preparation of gels and is an ingredient of protective preparations used in the fitting of ileostomy and colostomy appliance. It is also used for the mechanical protection of oral and perioral lesions.

APPENDIX II

EXPERIMENTAL DATA

The vertical interaction forces between polymer patches and artificial saliva.

Formulation # (polymer)	Sample#1	Sample#2	Sample#3	Mean	SD*
1 (SCME MV)	0.0845	0.0843	0.0879	0.085567	2.0224×10^{-3}
2 (SCME MV +CP)	0.1104	0.1107	0.1092	0.1101	$7.9373 \times 10{-4}$
3 (SCMC HV)	0.1165	0.1180	0.1167	0.117067	8.1240×10^{-4}
4 (MC1500)	0.0591	0.0596	0.0588	0.059167	4.0373×10^{-4}
5 (MC1500+CP)	0.0641	0.0642	0.0641	0.064133	5.7706×10^{-5}
6 (MC4000)	0.0636	0.0642	0.0629	0.063567	6.5038×10^{-4}
7 (MC4000+CP)	0.0677	0.0697	0.0691	0.068833	1.0247×10^{-3}
8 (HPMC)	0.0611	0.0613	0.0619	0.061433	4.1593×10^{-4}
9 (MPMC+CP)	0.0697	0.0667	0.0660	0.067467	1.9647×10^{-3}
BLANK	0.0372	0.0370	0.0370	0.03707	1.1547×10^{-4}

* SD = Standard deviation

Miconazole release data of mucoadhesive patch formulation #1 using SCMC MV .

Calibration Curve Data :

Conc. (mcg/ml)	0.0712	0.1187	0.3562	0.7123	1.1872	3.5616	7.1232
Peak Area Ratio	0.0903	0.1489	0.3289	0.7004	1.5708	5.4539	10.4246

$$y = -0.1300 + 1.4948 \, x \cdot \quad r^2 = 0.9982$$

Release Run Data :

Time (min)	Run #1			Run #2			Run #3		
	Conc.1 (mcg/ml.)	Amt.2 (mcg.)	C.A.3 (mcg.)	Conc.1 (mcg/ml.)	Amt.2 (mcg.)	C.A.3 (mcg.)	Conc.1 (mcg./ml.)	Amt.2 (mcg.)	C.A.3 (mcg.)
5	1.6384	37.7064	37.7064	1.4987	36.6650	36.6650	1.1877	27.2937	27.2937
10	0.8968	20.6395	58.3459	0.9637	23.5763	60.2414	0.8940	20.5433	47.8370
20	1.9904	45.8082	104.1541	2.1290	52.0828	112.3241	1.7700	40.6740	88.5111
30	2.5523	58.7375	162.8916	2.3042	56.3690	168.6931	2.3457	53.9055	142.4165
40	1.7332	39.8879	202.7795	1.2793	31.2963	119.9894	1.9009	43.6817	186.0982
50	0.8409	19.3533	222.1328	0.7460	18.2491	218.2385	0.9018	20.7242	206.8224
60	0.5326	12.2568	234.3896	0.4914	12.0209	230.2594	0.6517	14.9753	221.7977
70	0.4009	9.2262	243.6157	0.3873	9.4746	239.7340	0.5253	12.0723	233.8700
80	0.3709	8.5368	252.1525	0.2968	7.2599	246.9938	0.6100	14.0167	247.8867
Receiver Volume(ml.)	5.8			6.1			5.7		

1. Conc. = Concentration

2. Amt. = Amount

3. C.A. = Cumulative amount

Cumulative amount released vs time plot of mucoadhesive patch
containing SCMC MV .
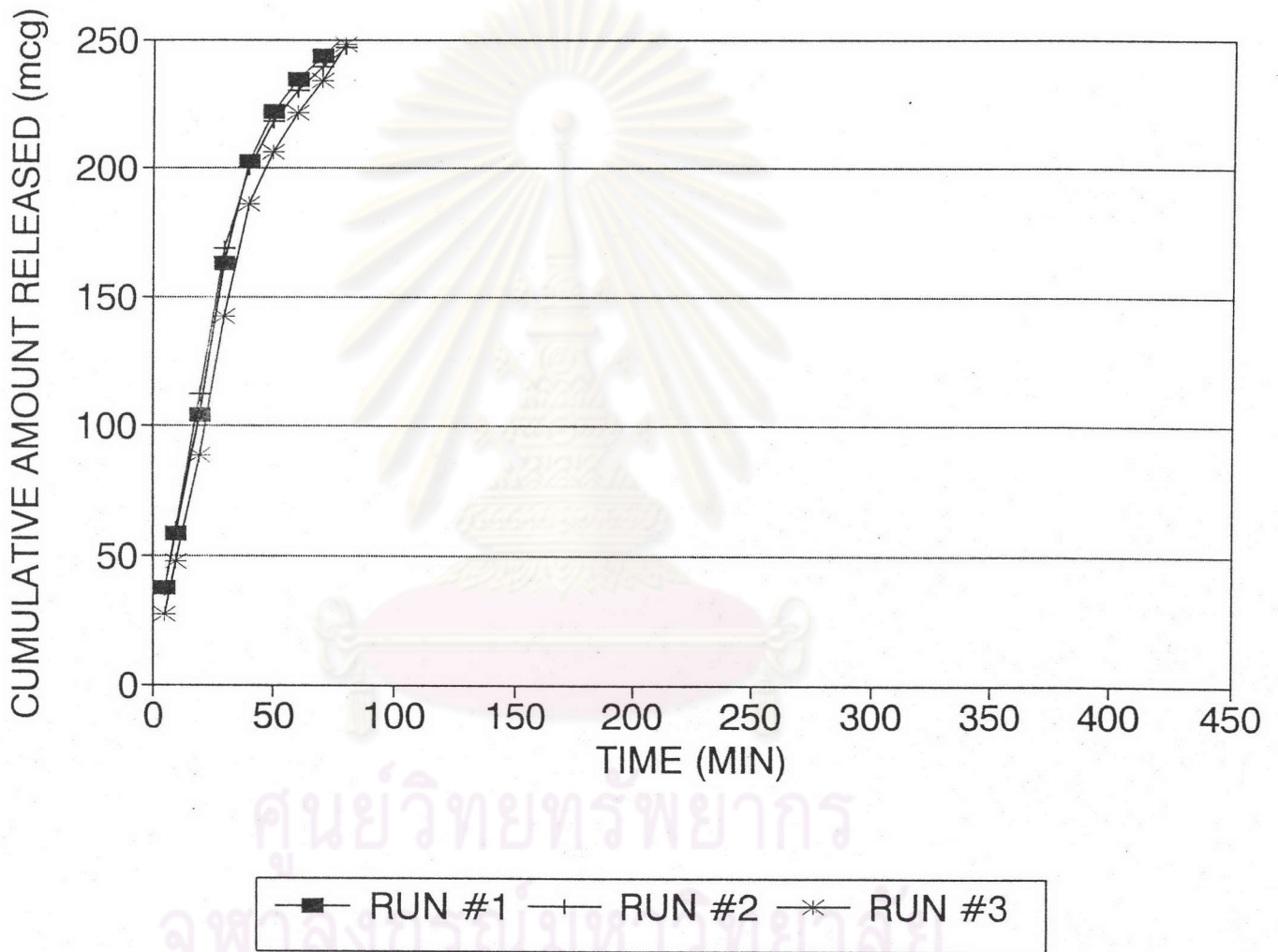
Cumulative amount released vs square root of time plot of
mucoadhesive patch containing SCMC MV .
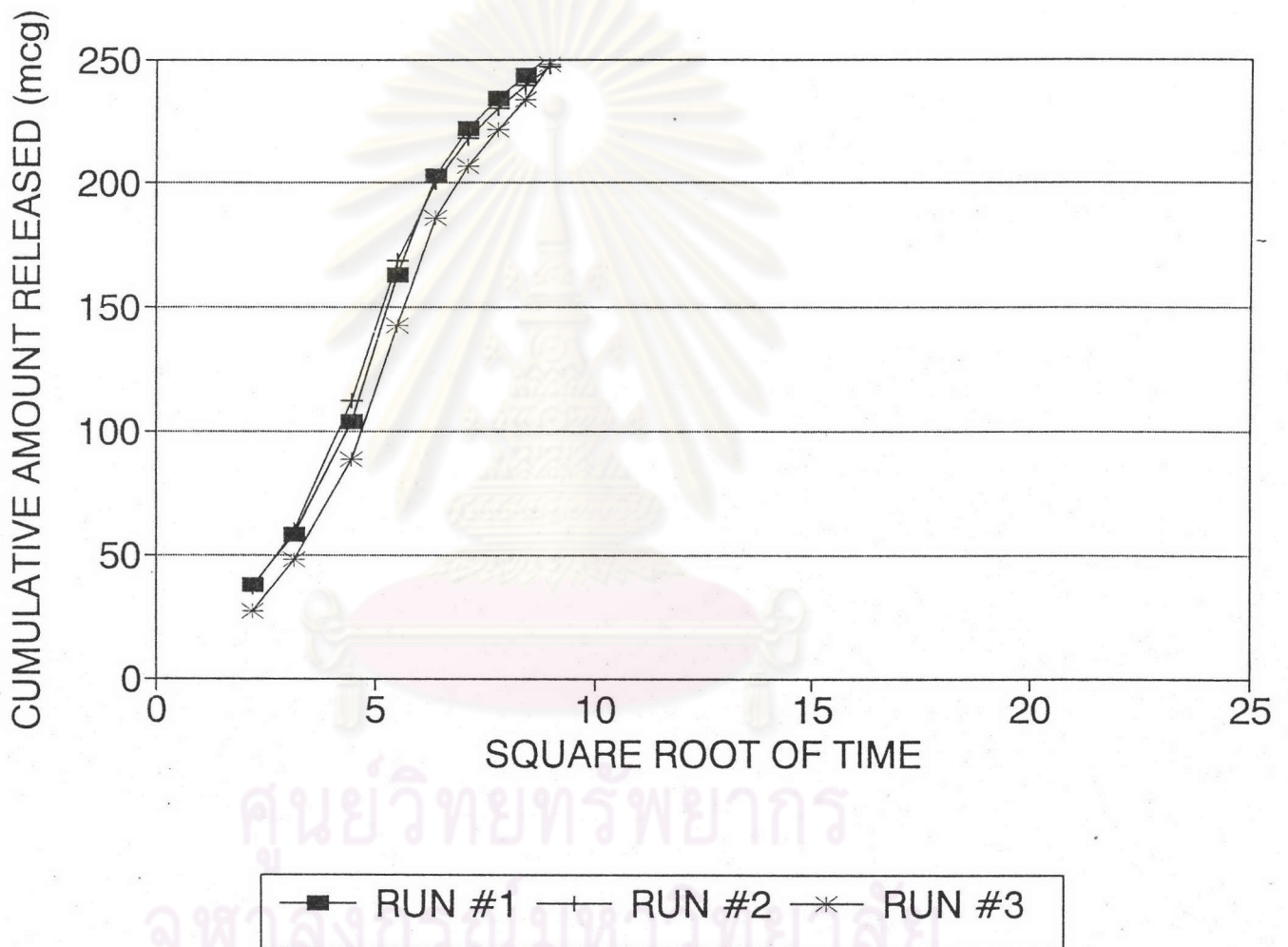
Miconazole release data of mucoadhesive patch formulation #2 using SCMC MV + CP 934.

Calibration Curve Data :

Conc. (mcg/ml)		0.0712	0.1187	0.3562	0.7123	1.1872	3.5616	7.1232
Peak Area Ratio		0.1501	0.1841	0.6296	1.0833	1.6440	4.9916	11.1210

$$y = -0.0553 + 1.5378 x \quad r^2 = 0.9971$$

Release Run Data :

Time	Run #1			Run #2			Run #3		
(min)	Conc.1	Amt.2	C.A.3	Conc.1	Amt.2	C.A.3	Conc.1	Amt.2	C.A.3
	(mcg/ml.)	(mcg.)	(mcg.)	(mcg/ml.)	(mcg.)	(mcg.)	(mcg./ml.)	(mcg.)	(mcg.)
10	0.2548	5.8645	5.8645	0.2396	5.8620	5.8620	0.2147	4.9338	4.93
25	0.5245	12.0703	17.9348	0.5128	12.5439	18.4059	0.4001	9.1938	14.12
40	0.7940	18.2731	36.2079	0.6819	16.6819	35.0878	0.6727	15.4582	29.58
60	1.0227	23.5357	59.7436	0.8907	21.7895	56.8773	0.8467	19.4571	49.04
90	1.7549	40.3871	100.1307	1.4667	35.8810	92.7583	1.5332	35.2336	84.27
120	1.5399	35.4391	135.5700	1.6528	40.4350	133.1933	1.8303	42.0596	126.33
150	0.5406	12.4419	148.0117	0.6716	16.4303	149.6235	0.8301	19.0973	145.43
180	0.4397	10.1198	158.1315	0.4316	10.5586	160.1822	0.7489	17.2102	162.64
210	0.4108	9.4540	167.5855	0.4173	10.2078	170.3900	0.4383	10.0730	172.71
240	0.3312	7.6221	175.2076	0.3188	7.7998	178.1898	0.3301	7.5865	180.303
Receiver Volume (ml.)	5.8			6.1			5.7		

1. Conc. = Concentration

2. Amt. = Amount

3. C.A. = Cumulative amount

Cumulative amount released vs time plot of mucoadhesive patch containing SCMC MV + CP 934.
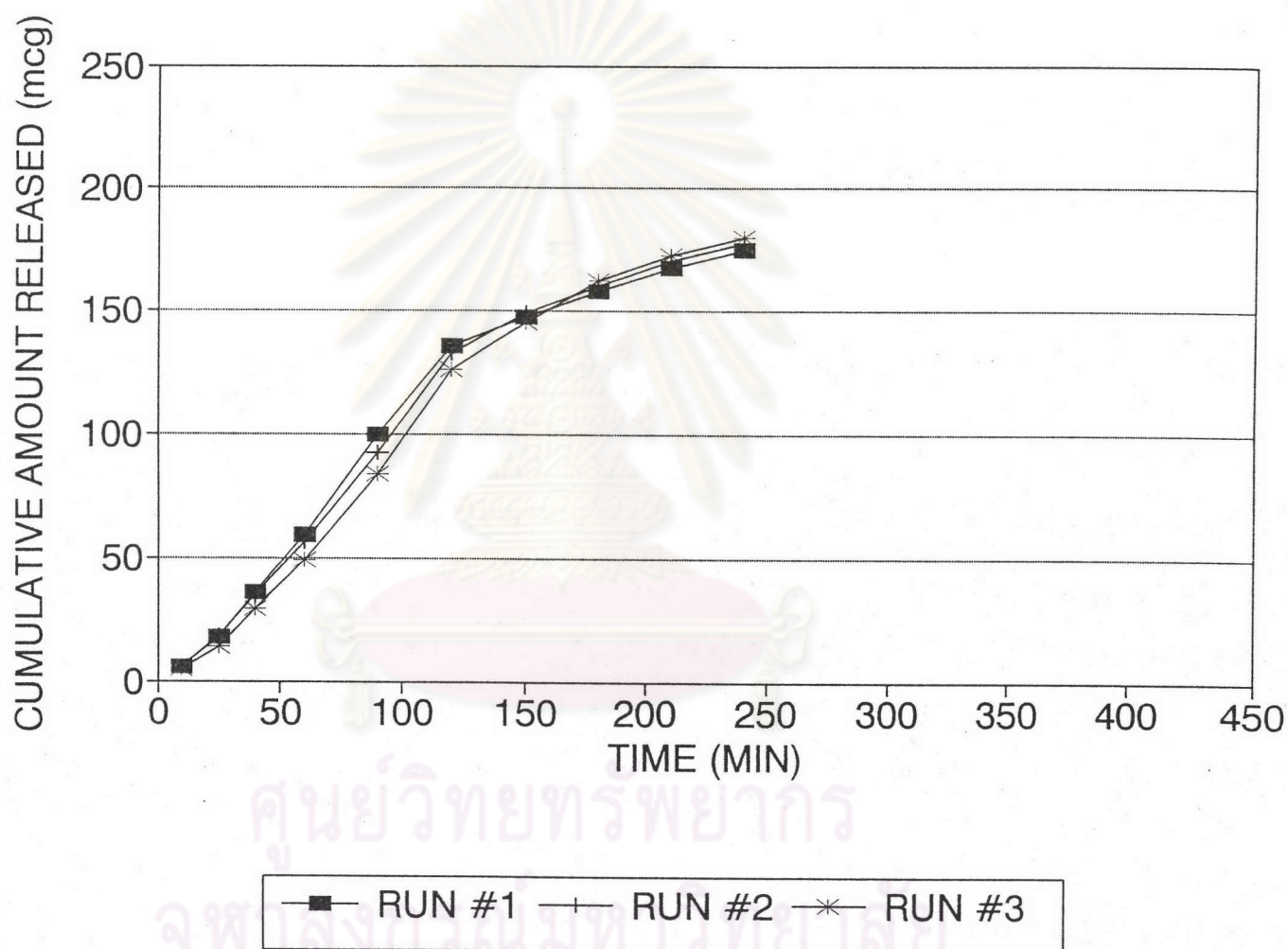
Cumulative amount released vs square root of time plot of mucoadhesive patch containing SCMC MV + CP 934.
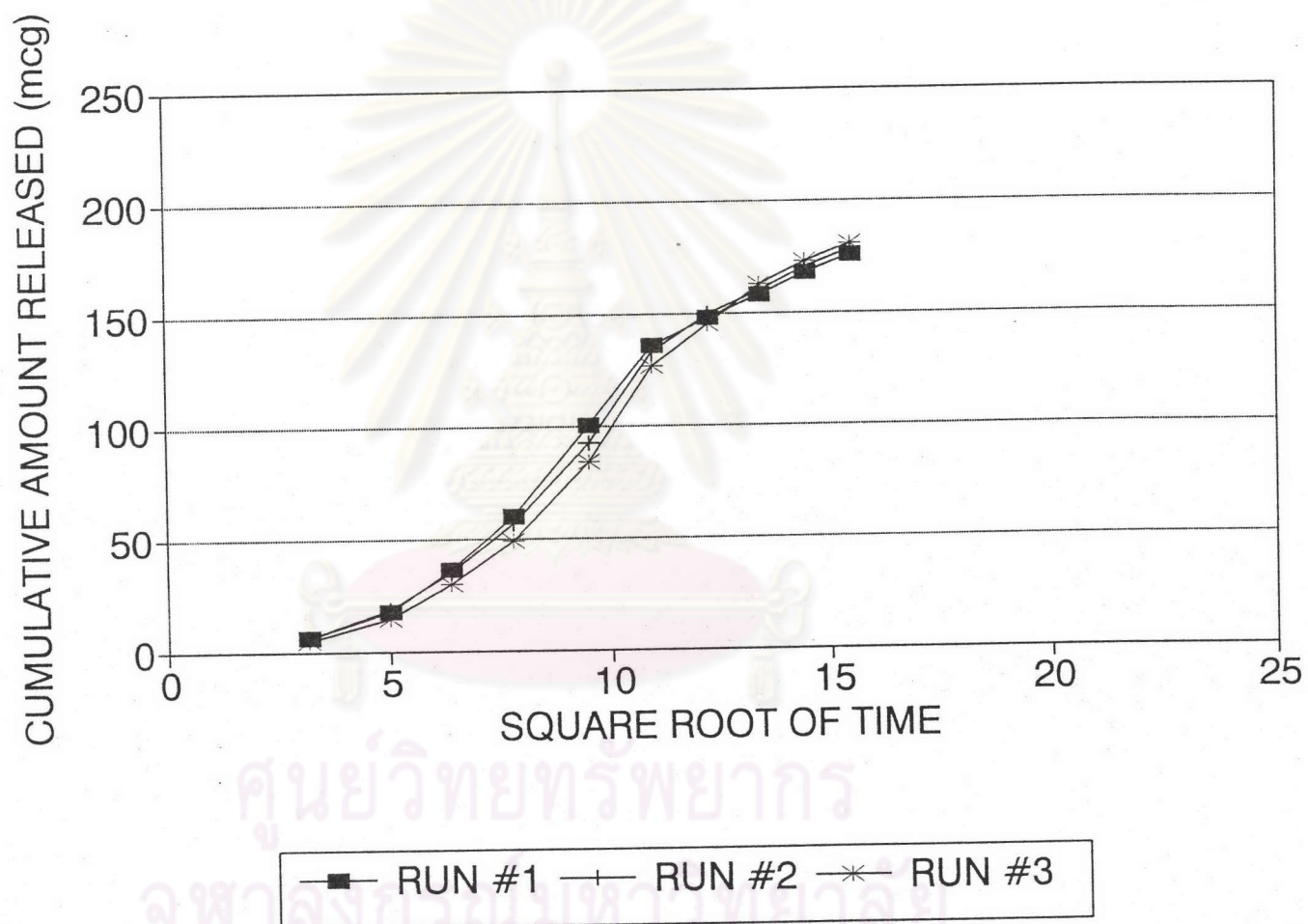
Miconazole release data of mucoadhesive patch formulation # 3 using SCMC HV.

Calibration Curve Data

Conc. (mcg/ml)	0.0712	0.1187	0.3562	0.7123	1.1872	3.5616	7.1232
Peak Area Ratio	0.1098	0.1639	0.4863	0.8878	1.6719	5.3183	10.4391

$$y = -0.0447 + 1.4770\ x \quad r^2 = 0.9997$$

Release Run Data :

| Time (min)	Run #1			Run # 2			Run #3		
	Conc.1 (mcg/ml.)	Amt.2 (mcg.)	C.A.3 (mcg.)	Conc.1 (mcg/ml.)	Amt.2 (mcg.)	C.A.3 (mcg.)	Conc.1 (mcg./ml.)	Amt.2 (mcg.)	C.A.3 (mcg.)
10	0.1970	4.5111	4.5111	0.2535	5.8340	5.8340	0.3336	7.7353	7.73
25	0.6693	15.3252	19.8363	0.4398	10.1212	15.9552	0.4832	11.1045	18.83
40	0.5163	11.8217	31.6579	0.5717	13.1575	29.1126	0.5762	13.2421	32.08
60	0.7645	17.5038	49.1617	0.7281	16.7571	45.8698	0.9742	22.3870	54.46
90	0.9991	22.8762	72.0379	1.5362	35.3542	81.2240	1.2198	28.0318	82.50
120	1.2440	28.4830	100.5209	1.4765	33.9809	115.2049	1.3588	31.2252	113.72
150	1.8500	42.3570	142.8780	1.8961	43.6359	158.8407	1.6060	36.9054	150.63
180	1.2831	29.3774	172.2553	0.5105	11.7486	170.5894	0.7383	16.9654	167.59
220	0.7279	16.6656	188.9209	0.2819	6.4888	177.0782	0.3166	7.2751	174.87
260	0.4095	9.3767	198.2977	0.2264	5.2095	182.2876	0.2522	5.7955	180.66
Receiver Volume(ml.)	5.7			5.8			5.7		

1. Conc. = Concentration

2. Amt. = Amount

3. C.A. = Cumulative amount

Cumulative amount released vs time plot of mucoadhesive patch containing SCMC HV .
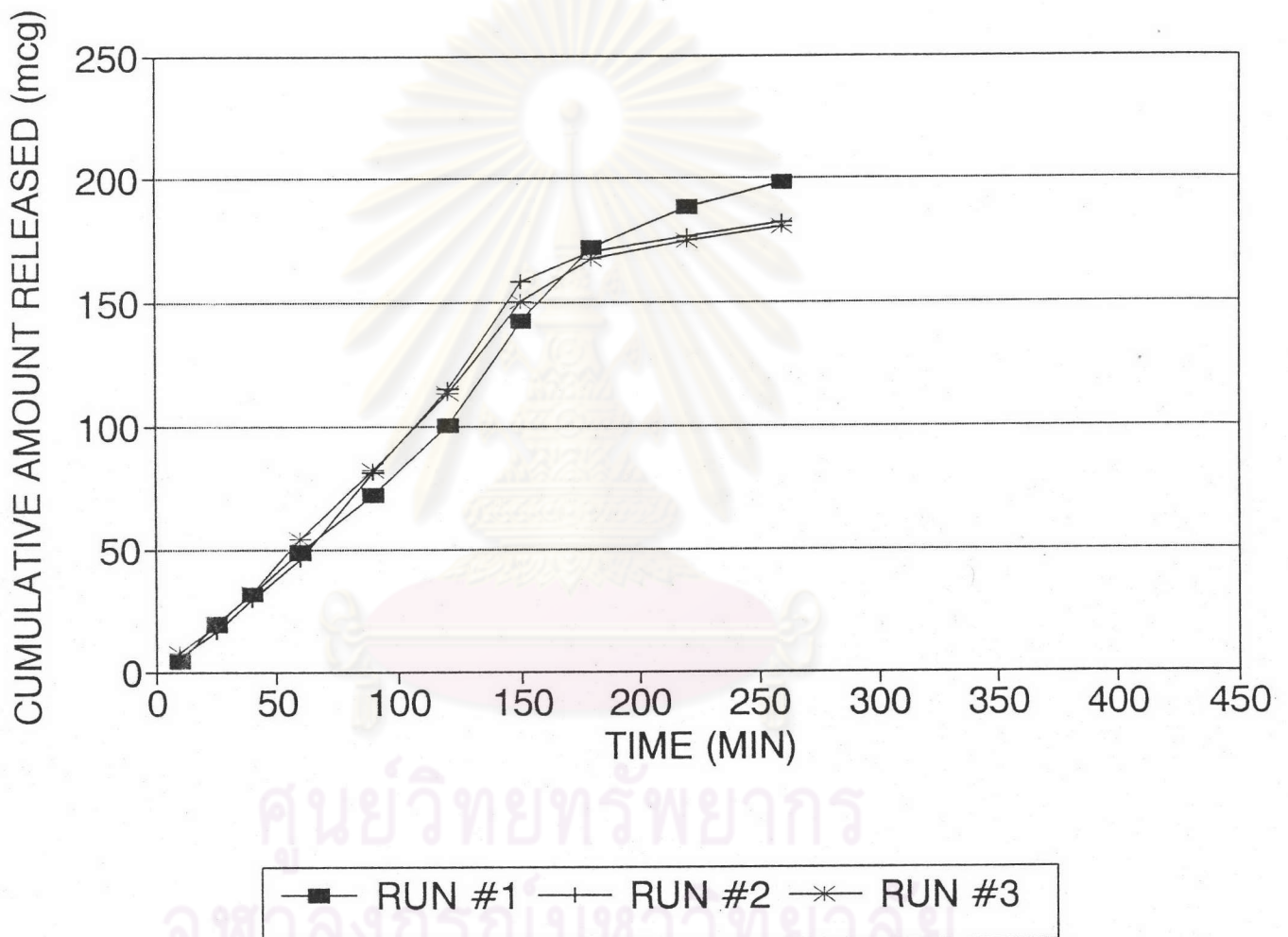
Cumulative amount released vs square root of time plot of
mucoadhesive patch containing SCMC HV .
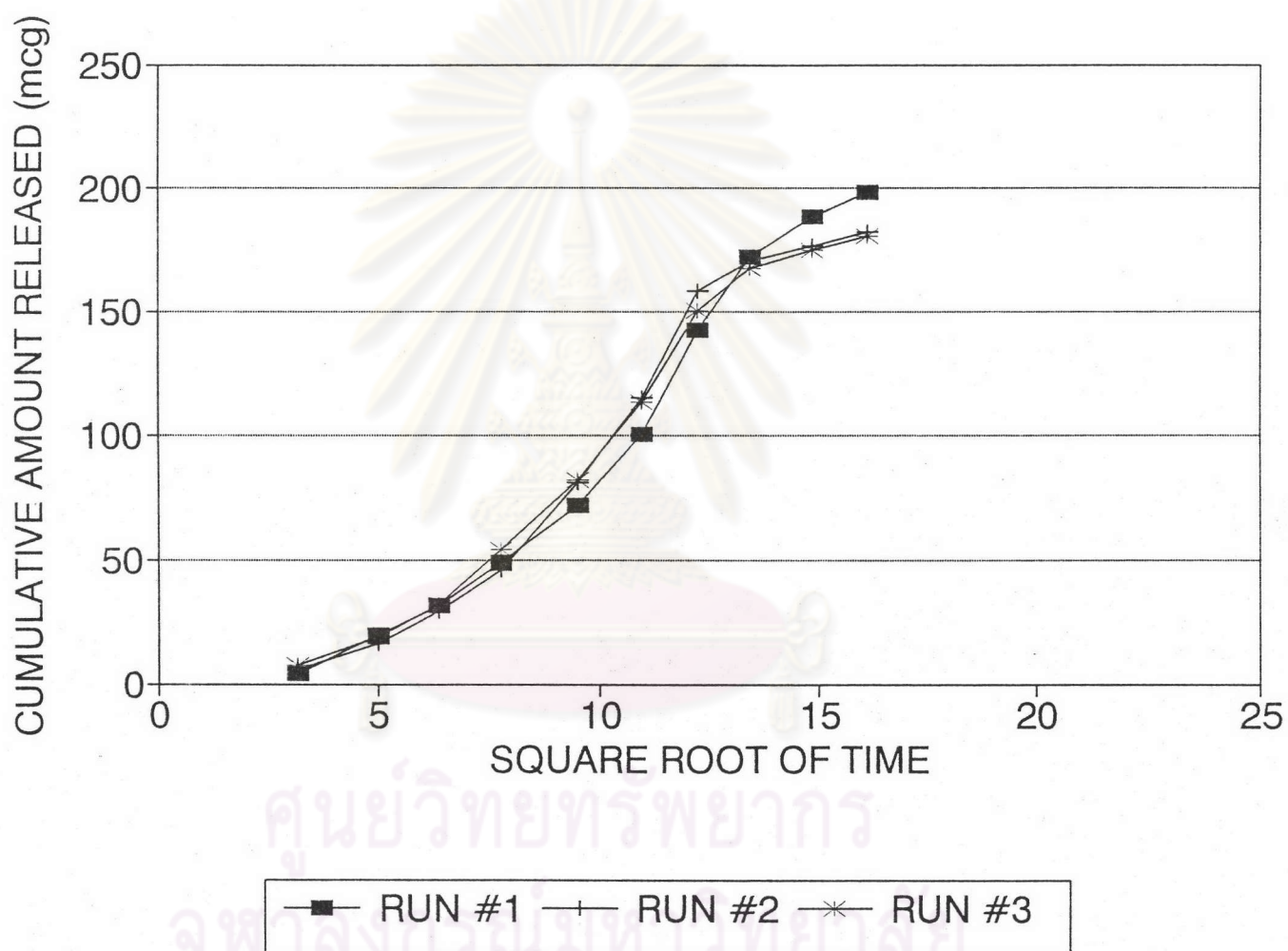
Miconazole release data of mucoadhesive patch formulation #4 using MC1500 .

Calibration Curve Data :

Conc. (mcg/ml)	0.1187	0.3562	0.7123	1.1872	2.3744	3.5616	7.1232
Peak Area Ration	0.2033	0.2707	0.9552	1.8185	3.7342	4.5528	11.0477

$$y = -0.11269 + 1.5262 x \quad r^2 = 0.9914$$

Release Run Data :

Time	Run #1			Run #2			Run #3		
(min)	Conc.1	Amt.2	C.A.3	Conc.1	Amt.2	C.A.3	Conc.1	Amt.2	C.A.3
	(mcg/ml.)	(mcg.)	(mcg.)	(mcg/ml.)	(mcg.)	(mcg.)	(mcg./ml.)	(mcg.)	(mcg.)
10.0000	0.2476	5.6697	5.6697	0.2705	6.2163	6.2163	0.2254	5.5142	5.51
25.0000	0.3338	7.6422	13.3119	0.3544	8.1437	14.3599	0.3427	8.3839	13.89
40.0000	0.4480	10.2568	23.5687	0.3974	9.1339	23.4939	0.3850	9.4195	23.31
60.0000	0.5119	11.7199	35.2886	0.5001	11.4921	34.9859	0.4678	11.4433	34.76
90.0000	0.5419	12.4083	47.6969	0.6613	15.1960	50.1819	0.6451	15.7808	50.54
120.0000	0.5735	13.1313	60.8282	0.6141	14.1117	64.2936	0.4943	12.0928	62.63
150.0000	0.5144	11.7785	72.6067	0.5943	13.6568	77.9504	0.5591	13.6770	76.31
180.0000	0.5912	13.5371	86.1439	0.5317	12.2183	90.1687	0.6148	15.0406	91.35
220.0000	0.5748	13.1594	99.3033	0.5661	13.0089	103.1776	0.5064	12.3874	103.73
260.0000	0.5200	11.9051	111.2084	0.5180	11.9040	115.0816	0.7011	17.1527	120.89
300.0000	0.5210	11.9295	123.1379	0.4943	11.3580	126.4396	0.5911	14.4599	135.35
340.0000	0.4291	9.8237	132.9617	0.4833	11.1061	137.5457	0.4910	12.0121	147.36
380.0000	0.5928	13.5727	146.5344	0.4842	11.1271	148.6728	0.4048	9.9036	157.26
420.0000	0.4624	10.5872	157.1216	0.4651	10.6892	159.3619	0.3361	8.2227	165.79
Receiver Volume(ml.)	5.7			5.7			6.1		

1. Conc. = Concentration

2. Amt. = Amount

3. C.A. = Cumulative amount

Cumulative amount released vs time plot of mucoadhesive patch containing MC 1500 .
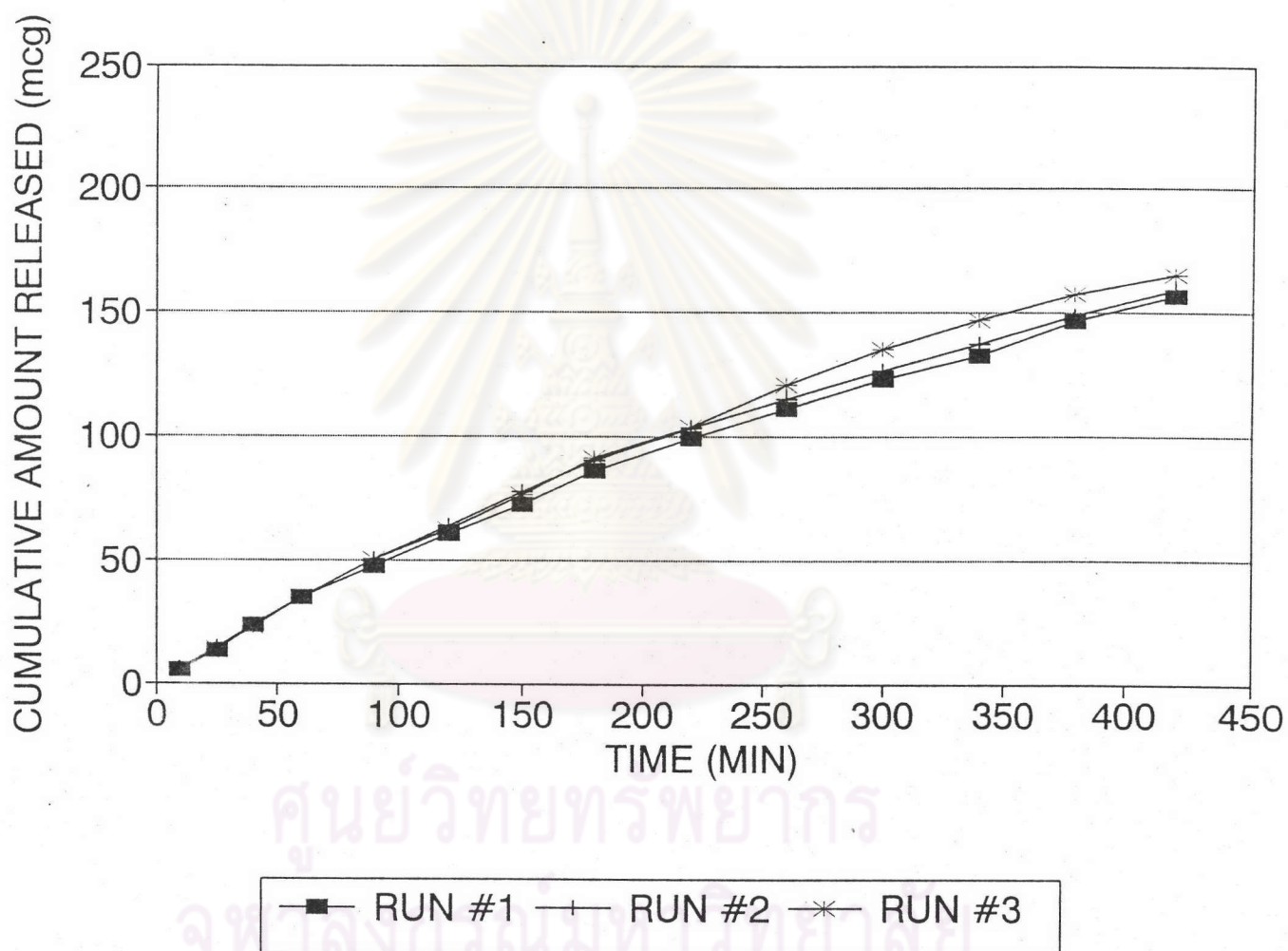
Cumulative amount released vs square root of time plot of mucoadhesive patch containing MC 1500 .
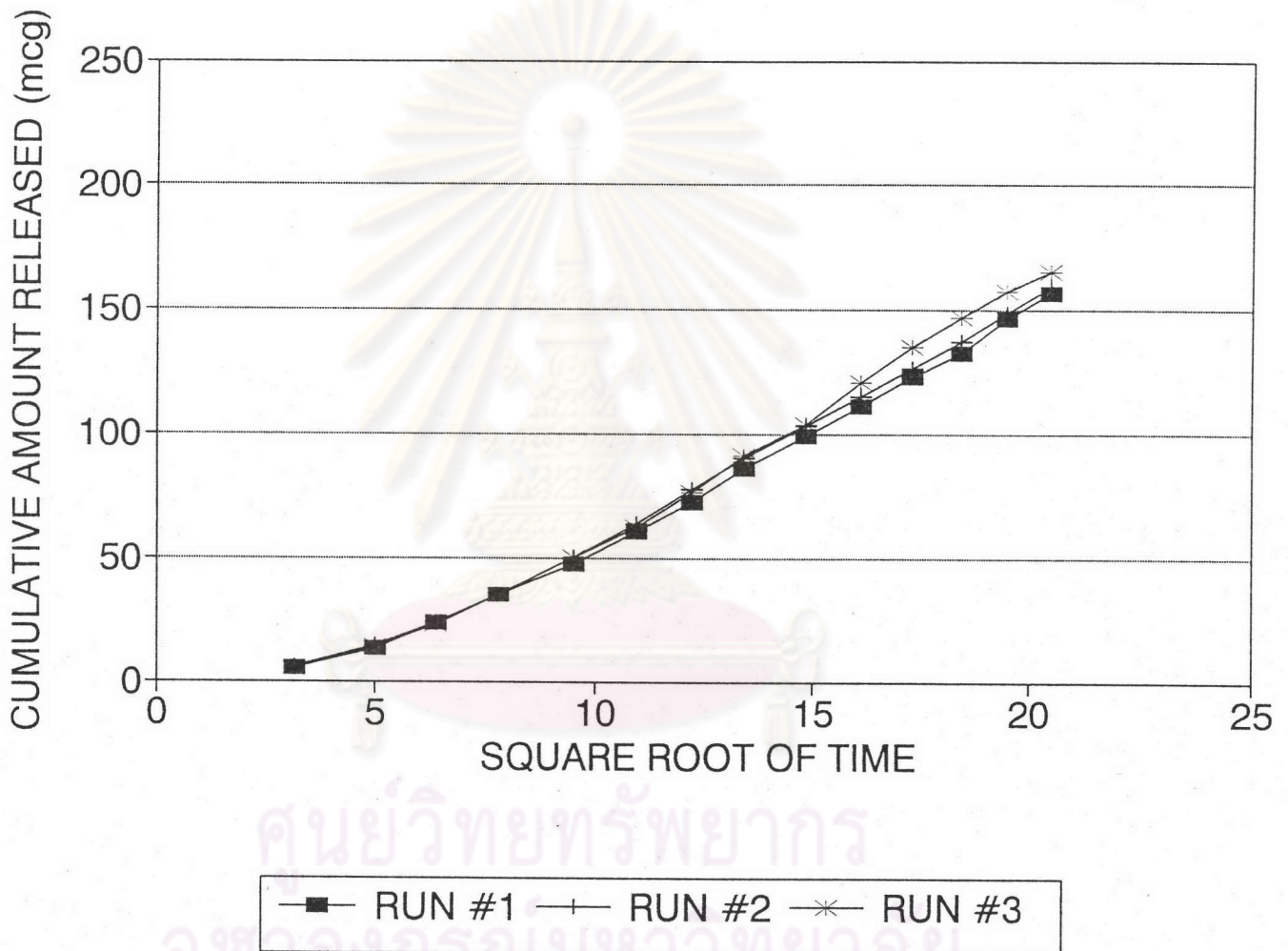
Miconazole release data of mucoadhesive patch formulation# 5 using MC1500 +CP934.

Calibration Curve Data :

Conc. (mcg/ml)	0.0712	0.1187	0.3562	0.7123	1.1872	3.5616	7.1232
Peak Area Ratio	0.1634	0.3441	0.5488	1.0574	1.8062	4.7843	11.2017

$$y = -0.0320 + 1.5331\ x \qquad r^2 = 0.9914$$

Release Run Data :

| Time (min)	Run #1			Run #2			Run #3		
	Conc.1 (mcg/ml.)	Amt.2 (mcg.)	C.A.3 (mcg.)	Conc.1 (mcg/ml.)	Amt.2 (mcg.)	C.A.3 (mcg.)	Conc.1 (mcg./ml.)	Amt.2 (mcg.)	C.A.3 (mcg.)
10	0.5403	12.3715	12.3715	0.3945	9.0792	9.0792	0.4276	9.8263	9.82(
25	0.4915	11.2540	23.6255	0.4321	9.9442	19.0233	0.3277	7.5162	17.34:
40	0.4350	9.9604	33.5859	0.3789	8.7206	27.7440	0.4148	9.5317	26.874
60	0.3689	8.4463	42.0322	0.4448	10.2364	37.9804	0.4394	10.0966	36.97(
90	0.3457	7.9159	49.9482	0.4419	10.1698	48.1502	0.4984	11.4542	48.42:
120	0.3597	8.2353	58.1835	0.4228	9.7308	57.8810	0.4750	10.9160	59.34(
150	0.3819	8.7446	66.9281	0.4297	9.8893	67.7703	0.4944	11.3621	70.70:
180	0.5853	13.4017	80.3298	0.4974	11.4478	79.2180	0.5225	12.0063	82.70!
220	0.4209	9.6378	89.9676	0.5172	11.9029	91.1209	0.5378	12.3578	95.06:
260	0.3566	8.1653	98.1329	0.4339	9.9871	101.1078	0.4157	9.5535	104.62(
300	0.2749	6.2941	104.4270	0.3568	8.2117	109.3195	0.5799	13.3268	107.94:
340	0.3752	8.5899	113.0169	0.4155	9.5622	118.8816	0.4466	10.2639	128.21
380	0.4179	9.5677	122.5846	0.5014	11.5382	130.4198	0.2133	4.9014	133.11:
420	0.3306	7.5689	130.1534	0.4039	9.2960	139.7159	0.1936	4.4497	137.56:
Receiver Volume(ml.)	5.7			5.8			5.7		

1. Conc. = Concentration

2. Amt. = Amount

3. C.A. = Cumulative amount

Cumulative amount released vs time plot of mucoadhesive patch containing MC 1500 + CP 934 .
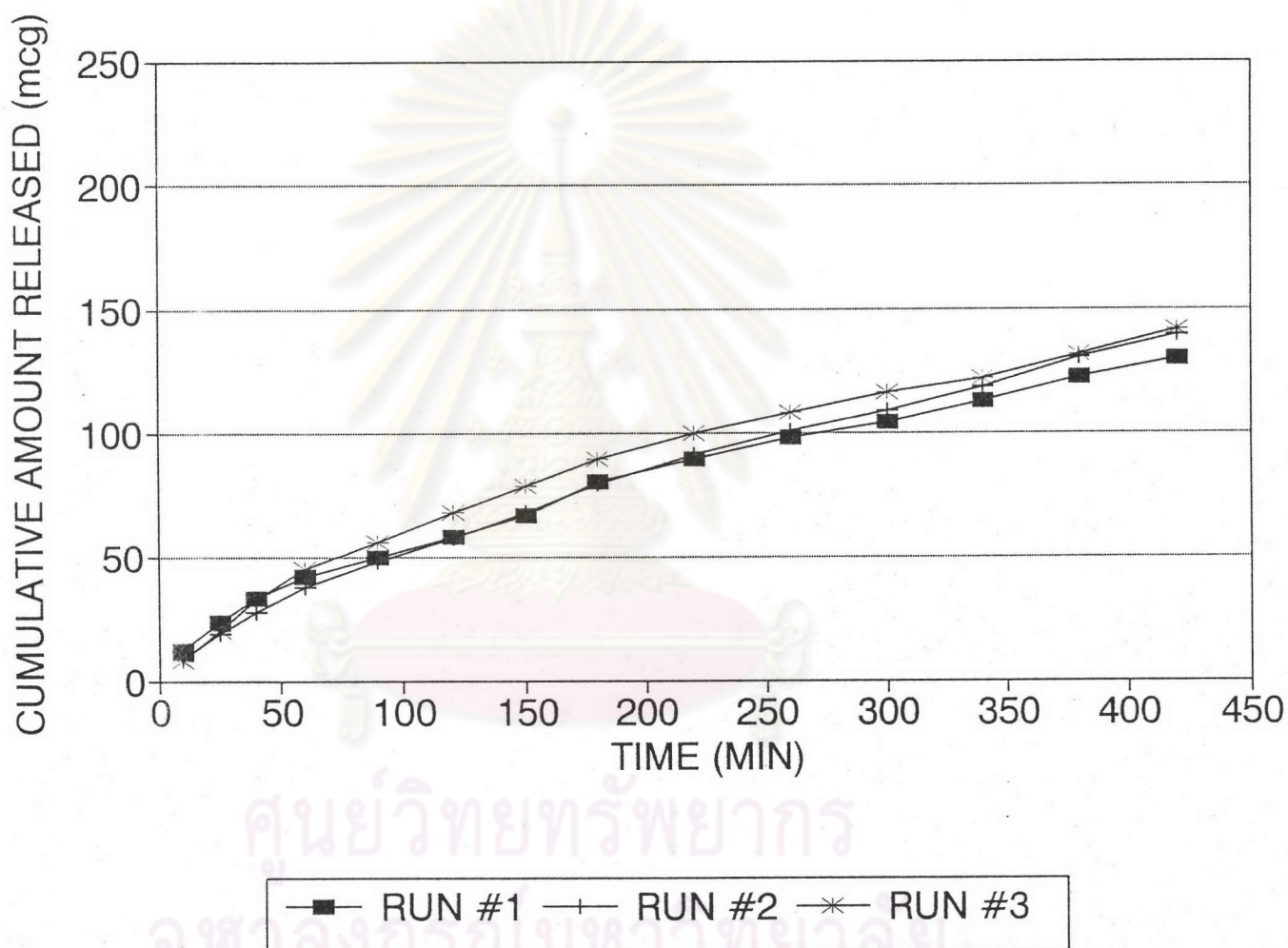
Cumulative amount released vs square root of time plot of mucoadhesive patch containing MC 1500 + CP 934 .
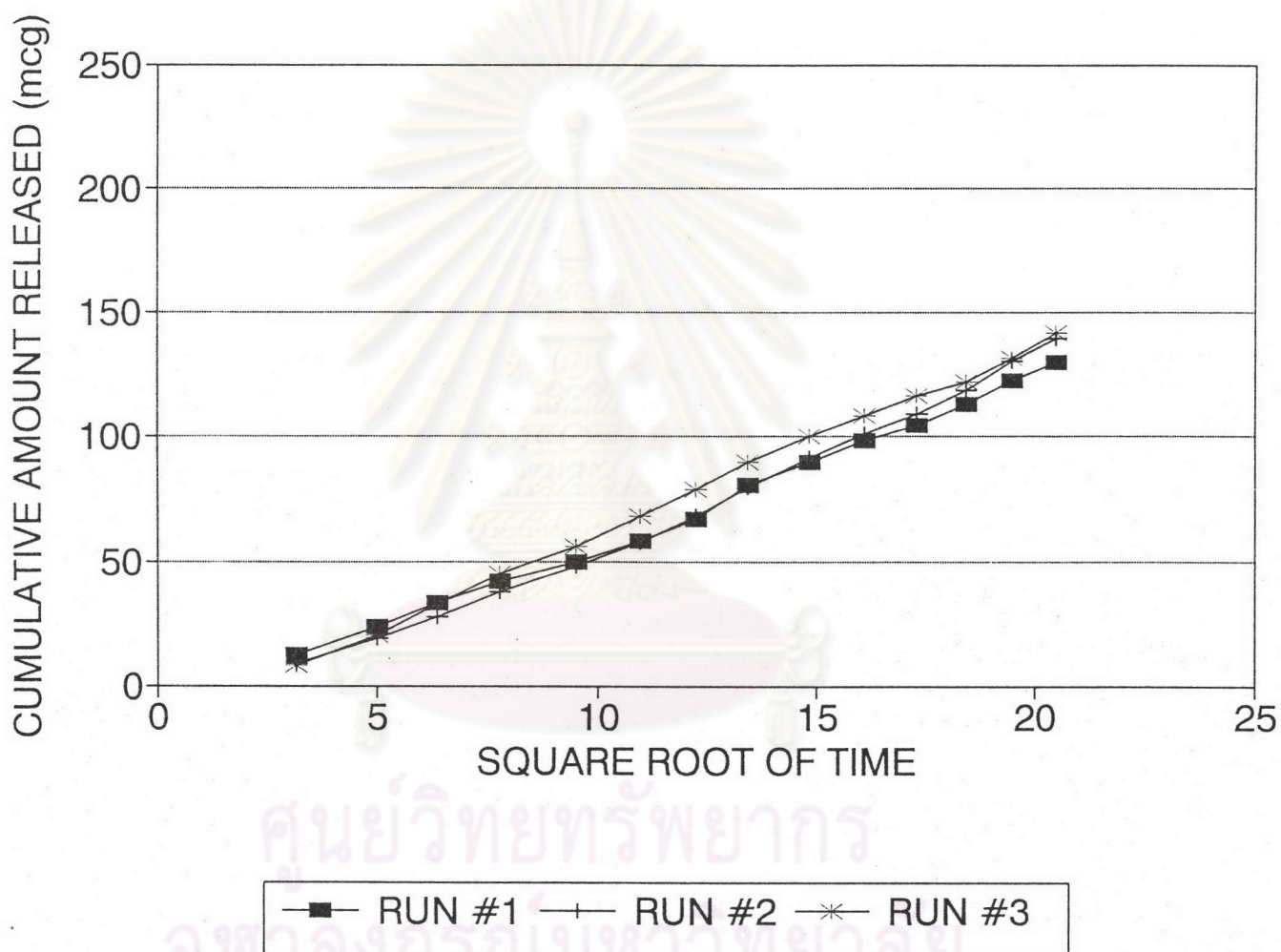
Miconazole release data of mucoadhesive patch formulation# 6 using MC4000 .

Calibration Curve Data :

Conc. (mcg/ml)		0.0712	0.1187	0.3562	0.7123	1.1872	3.5616	7.1232
Peak Area Ratio		0.0013	0.1722	0.6621	0.9977	1.6816	5.7227	10.4542

$$Y = 0.0188 \quad + \quad 1.5208X \quad r^2 = 0.9985$$

Release Run Data :

| Time	Run #1			Run #2			Run #3		
(min)	Conc.1	Amt.2	C.A.3	Conc.1	Amt.2	C.A.3	Conc.1	Amt.2	C.A.3
	(mcg/ml.)	(mcg.)	(mcg.)	(mcg/ml.)	(mcg.)	(mcg.)	(mcg./ml.)	(mcg.)	(mcg.)
10	0.1346	3.0977	3.0977	0.1402	3.2097	3.2097	0.2013	4.6259	4.62:
25	0.3074	7.0743	10.1720	0.3179	7.2794	10.4891	0.2949	6.7776	11.40:
40	0.3729	8.5810	18.7530	0.3818	8.7420	19.2310	0.2973	6.8318	18.23:
60	0.4808	11.0645	29.8175	0.4243	9.7144	28.9454	0.4401	10.1129	28.34:
90	0.4948	11.3864	41.2038	0.4639	10.6220	39.5675	0.4394	10.0969	38.44:
120	0.4169	9.5940	50.7962	0.5634	12.8990	52.4665	0.4467	10.2662	48.71:
150	0.4432	10.2006	60.9985	0.5194	11.8917	64.3582	0.5060	11.6289	60.34(
180	0.6801	15.6529	76.6515	0.6060	13.8746	78.2328	0.4970	11.4218	71.76:
220	0.5449	12.5398	89.1912	0.5020	11.4928	89.7256	0.5360	12.3169	84.07:
260	0.5001	11.5083	100.6995	0.4926	11.2792	101.0049	0.6705	15.4088	99.48:
300	0.5147	11.8461	112.5456	0.4750	10.8763	111.8811	0.4450	10.2251	109.71:
340	0.5208	11.9858	124.5314	0.4861	11.1305	123.0116	0.4139	9.4778	119.19(
Receiver Volume(ml.)	5.8			5.7			5.7		

1. Conc. = Concentration

2. Amt. = Amount

3. C.A. = Cumulative amount

Cumulative amount released vs time plot of mucoadhesive patch containing MC 4000.
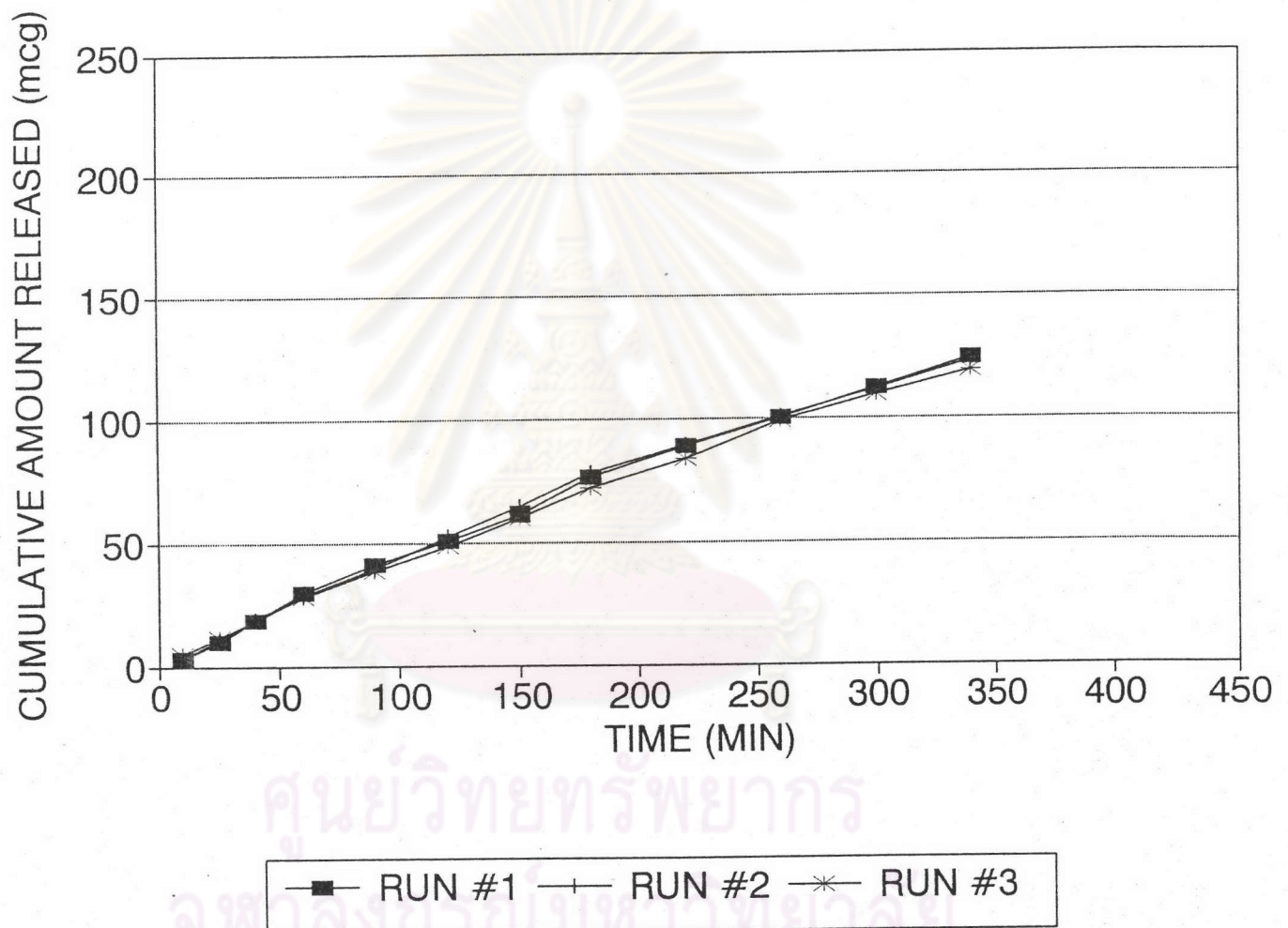
Cumulative amount released vs square root of time plot of mucoadhesive patch containing MC 4000.
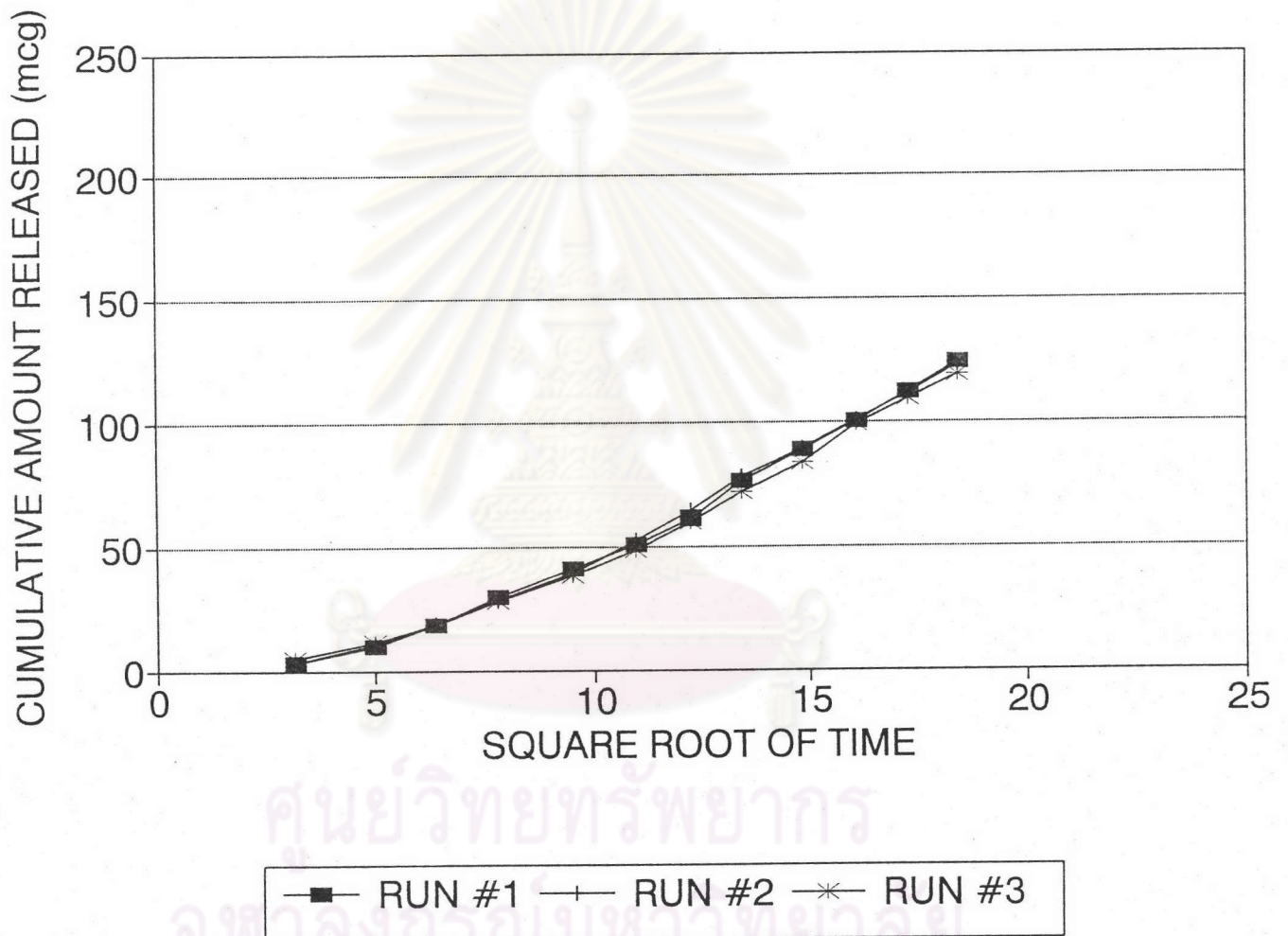
Miconazole release data of mucoadhesive patch formulation# 7 using MC4000+CP934.

Calibration Curve Data :

Conc. (mcg/ml)	0.0712	0.1187	0.3562	0.7123	1.1872	3.5616	7.1232
Peak Area Ratio	0.0013	0.1722	0.6621	0.9977	1.6816	5.7227	10.4542

$$Y = 0.0188 + 1.5208X \quad r^2 = 0.9985$$

Release Run Data :

| Time	Run #1			Run #2			Run #3		
(min)	Conc.1 (mcg/ml.)	Amt.2 (mcg.)	C.A.3 (mcg.)	Conc.1 (mcg/ml.)	Amt.2 (mcg.)	C.A.3 (mcg.)	Conc.1 (mcg./ml.)	Amt.2 (mcg.)	C.A.3 (mcg.)
10	0.3113	7.1274	7.1274	0.3427	8.3833	8.3833	0.2188	5.0291	5.02
25	0.3955	9.0561	16.1836	0.3467	8.4814	16.8647	0.3124	7.1785	12.20
40	0.4049	9.2702	25.4538	0.4035	9.8701	26.7348	0.3027	6.9562	19.16
60	0.3949	9.0423	34.4961	0.3780	9.2474	35.9822	0.3895	8.9515	28.11
90	0.4176	9.5607	44.0568	0.4082	9.9861	45.9683	0.4127	9.4833	37.59
120	0.4200	9.6166	53.6734	0.3940	9.6385	55.6068	0.4096	9.4116	47.01
150	0.4112	9.4143	63.0877	0.3367	8.2379	63.8443	0.4171	9.5851	56.59
180	0.4165	9.5351	72.6228	0.3621	8.8583	72.7026	0.4228	9.7150	66.31
220	0.4847	11.0986	83.7213	0.4714	11.5321	84.2347	0.5270	12.1094	78.41
260	0.5004	11.4567	95.1781	0.5029	12.3021	96.5368	0.5184	11.9130	90.33
300	0.4885	11.1851	106.3632	0.4967	12.1504	108.6872	0.5284	12.1419	102.47
340	0.4708	10.7795	117.1427	0.4602	11.2576	119.9448	0.4973	11.4288	113.90
Receiver Volume(ml.)	5.7			6.1			5.7		

1. Conc. = Concentration

2. Amt. = Amount

3. C.A. = Cumulative amount

Cumulative amount released vs time plot of mucoadhesive

patch containing MC 4000 + CP 934.
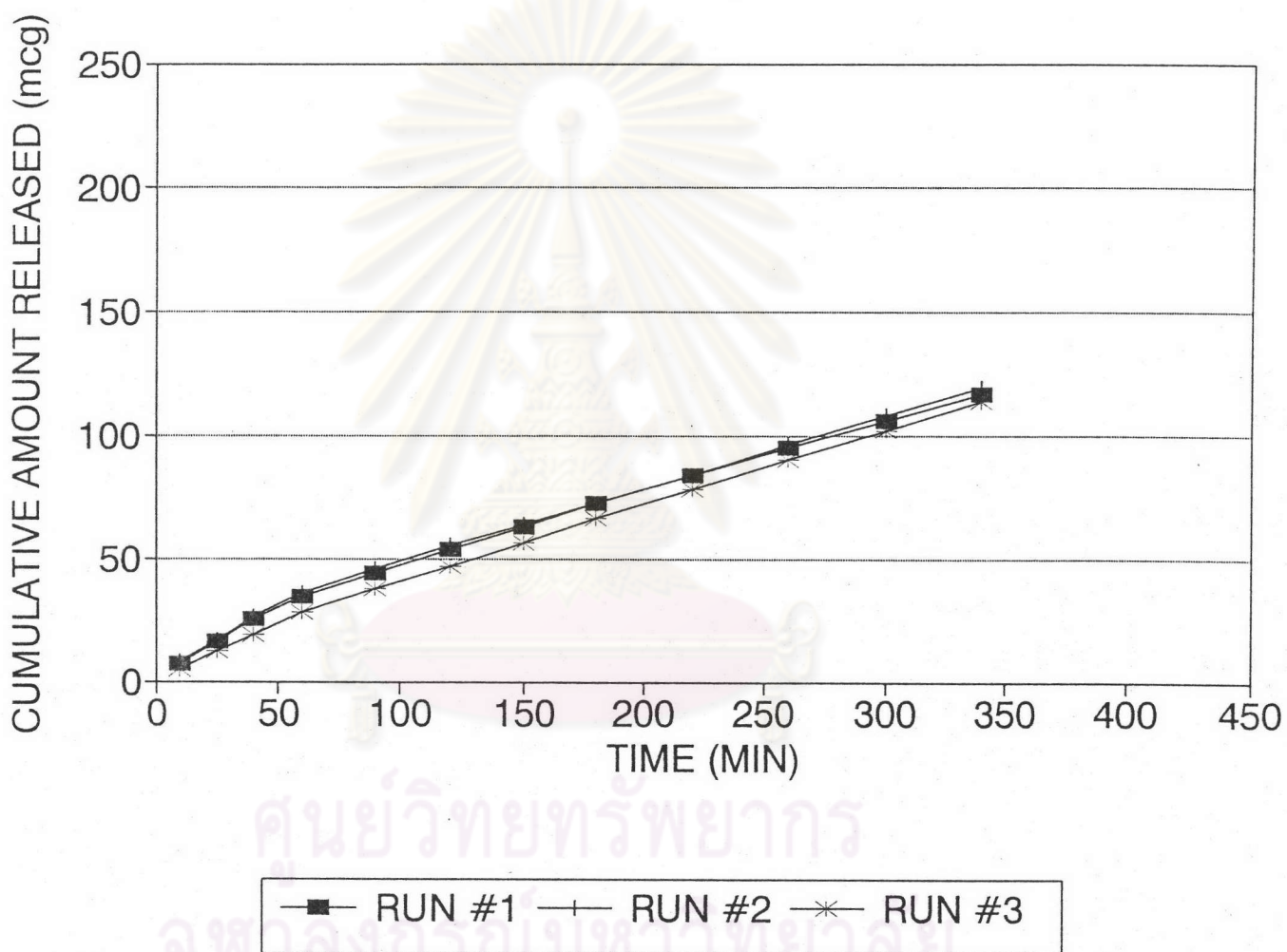
Cumulative amount released vs square root of time plot of mucoadhesive patch containing MC 4000 + CP 934.
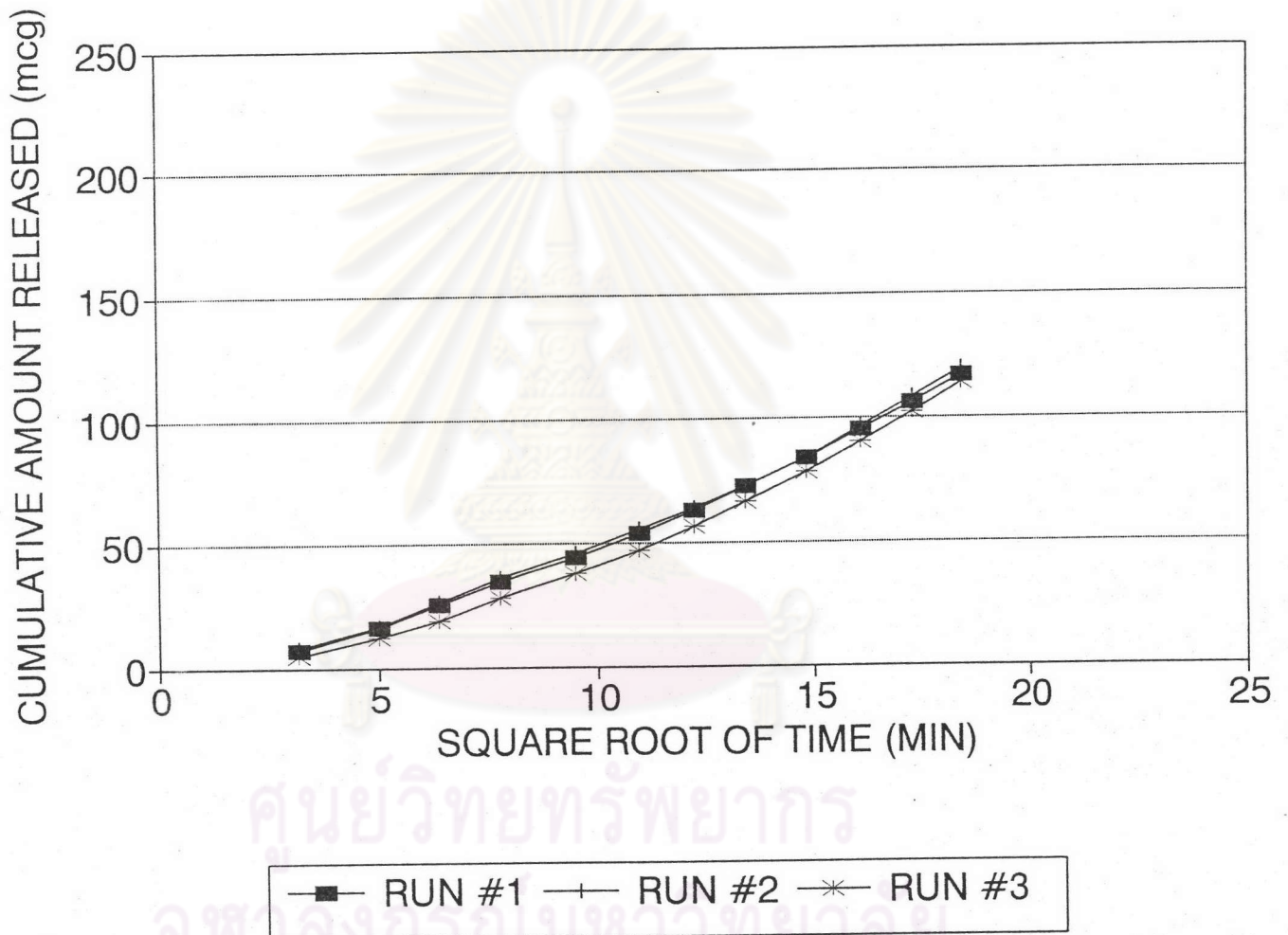
Miconazole release data of mucoadhesive patch formulation #8 using HPMC .

Calibration Curve Data :

Conc. (mcg/ml)	0.0712	0.1187	0.3562	0.7123	1.1872	3.5616	7.1232
Peak Area Ratio	0.1634	0.3441	0.5488	1.0574	1.8062	4.7843	11.2017

$$Y = 0.0320 + 1.5331X \quad r^2 = 0.9942$$

Release Run Data :

| Time	Run #1			Run #2			Run #3		
(min)	Conc.1	Amt.2	C.A.3	Conc.1	Amt.2	C.A.3	Conc.1	Amt.2	C.A.3
	(mcg/ml.)	(mcg.)	(mcg.)	(mcg/ml.)	(mcg.)	(mcg.)	(mcg./ml.)	(mcg.)	(mcg.)
10	0.2871	6.5728	6.5728	0.1363	3.1366	3.1366	0.1215	2.9717	2.97
25	0.2332	5.3391	11.9119	0.2638	6.0720	9.2092	0.2578	6.3071	9.27
40	0.2485	5.6899	17.6018	0.2794	6.4306	15.6392	0.2743	6.7113	15.99
60	0.4147	9.4956	27.0974	0.3882	8.9330	24.5722	0.3954	9.6726	25.66
90	0.4808	11.0081	38.1055	0.3841	8.8393	33.4116	0.5246	12.8345	38.49
120	0.5702	13.0564	51.1619	0.4448	10.2359	43.6475	0.5171	12.6504	51.14
150	0.4571	10.4647	61.6266	0.4977	11.4551	55.1026	0.4767	11.6625	62.81
180	0.5051	11.5644	73.1910	0.5002	11.5124	66.6150	0.4754	11.6304	74.44
220	0.4784	10.9529	84.1439	0.7469	17.1889	83.8039	0.4986	12.1983	86.63
260	0.5172	11.8427	95.9866	0.5125	11.7950	95.5989	0.4739	11.5938	98.23
300	0.3916	8.9672	104.9489	0.4429	10.1921	105.7910	0.4063	9.9396	108.17
340	0.3388	7.7578	112.7114	0.3791	8.7240	114.5150	0.4127	10.0962	118.26
380	0.3210	7.3507	120.0622	0.3325	7.6513	122.1681	0.3896	9.5311	127.79
420	0.2733	6.2573	126.3196	0.3143	7.2324	129.4005	0.4680	11.4483	139.24
Receiver Volume(ml.)	5.7			5.8			6.1		

1. Conc. = Concentration

2. Amt. = Amount

3. C.A. = Cumulative amount

Cumulative amount released vs time plot of mucoadhesive

patch containing HPMC.
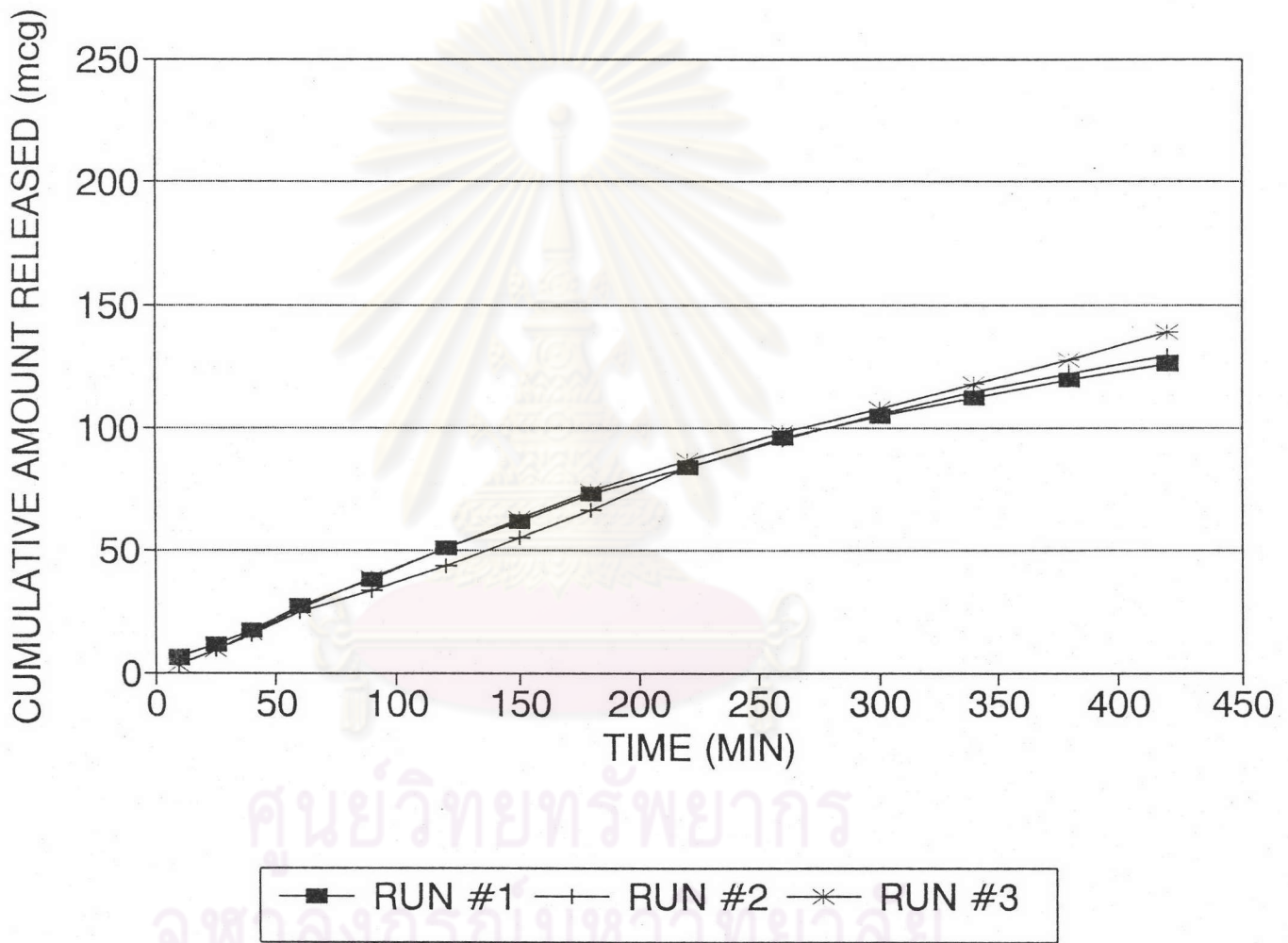
Cumulative amount released vs square root of time plot of mucoadhesive patch containing HPMC .
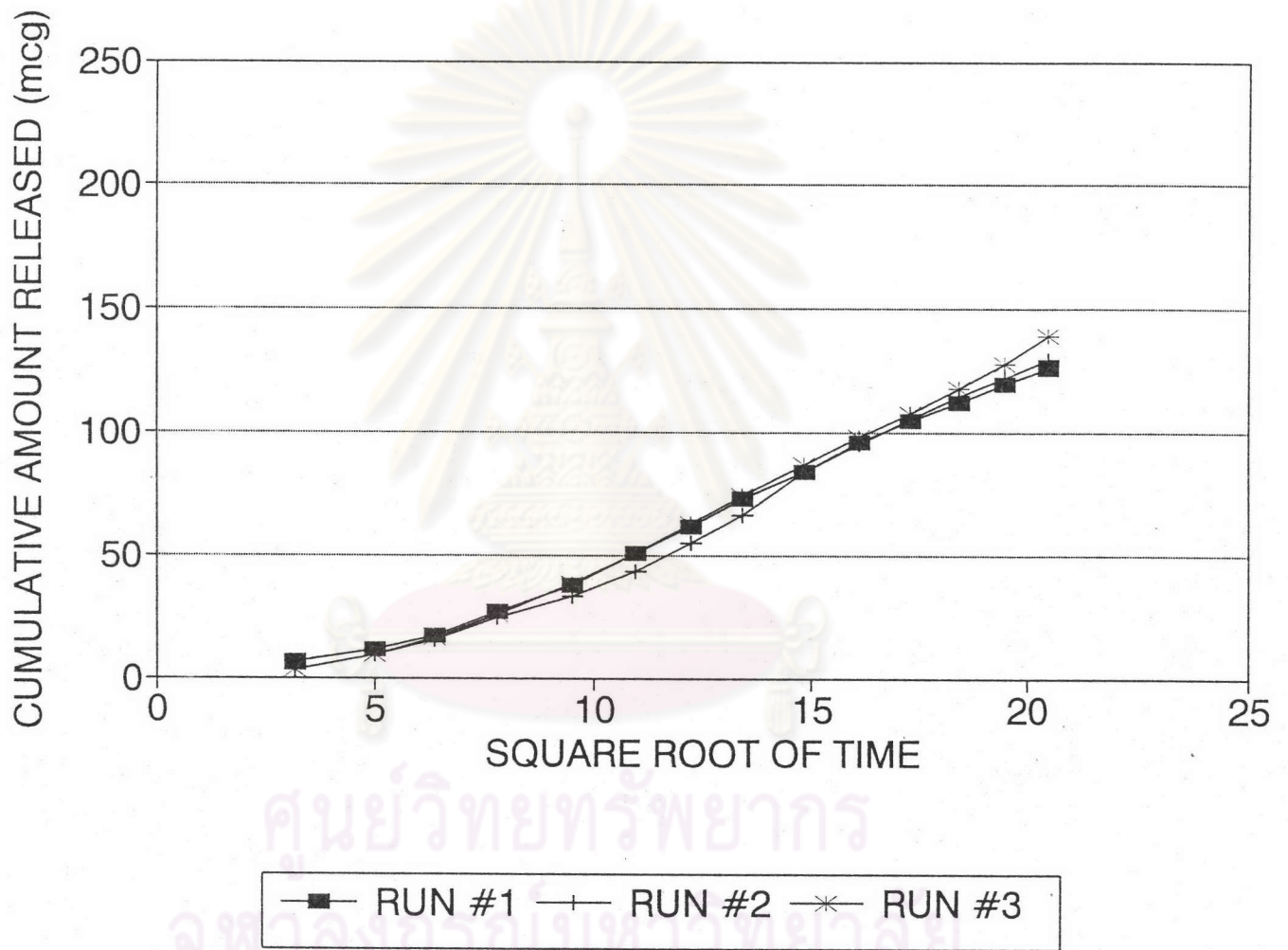
Miconazole release data of mucoadhesive patch formulation #9 using HPMC +CP934.

Calibration Curve Data :

Conc. (mcg/ml)	0.0712	0.1187	0.3562	0.7123	1.1872	3.5616	7.1232
Peak Area Ratio	0.1501	0.1841	0.6296	1.0833	1.644	4.9916	11.121

$$Y = -0.0553 + 1.5378X \quad r^2 = 0.9971$$

Release Run Data :

| Time (min)	Run #1			Run #2			Run #3		
	Conc.1 (mcg/ml.)	Amt.2 (mcg.)	C.A.3 (mcg.)	Conc.1 (mcg/ml.)	Amt.2 (mcg.)	C.A.3 (mcg.)	Conc.1 (mcg./ml.)	Amt.2 (mcg.)	C.A.3 (mcg.)
10	0.1339	3.0669	3.0669	0.1510	3.6941	3.6941	0.1087	2.4974	2.49
25	0.1845	4.2232	7.2901	0.1579	3.8624	7.5566	0.1578	3.6270	6.12
40	0.2738	6.2698	13.5599	0.1714	4.1940	11.7506	0.2434	5.5938	11.71
60	0.2463	5.6383	19.1982	0.3251	7.9528	19.7034	0.2755	6.3321	18.05
90	0.3300	7.5548	26.7530	0.2781	6.8036	26.5070	0.2873	6.6012	24.65
120	0.3232	7.3969	34.1527	0.3421	8.3680	34.8751	0.3671	8.4371	33.08
150	0.3307	7.5709	41.7236	0.3645	8.9170	43.7920	0.3586	8.2407	41.32
180	0.2934	6.7179	48.4415	0.3841	9.3959	53.1879	0.3719	8.5474	49.87
220	0.3333	7.6321	56.0736	0.3542	8.6663	61.8542	0.3794	8.7489	58.59
260	0.3242	7.4220	63.4955	0.3540	8.6616	70.5185	0.3921	9.0100	67.60
300	0.3854	8.8234	72.3190	0.4007	9.8028	80.3186	0.3960	9.1006	76.70
340	0.4381	10.0298	82.3488	0.3755	9.1859	89.5045	0.4773	10.9685	87.67
380	0.3597	8.2354	90.5842	0.3512	8.5928	98.0973	0.3860	8.8698	96.54
420	0.4267	9.7703	100.3545	0.2819	6.8954	104.9927	0.3807	8.7475	105.291
Receiver Volume(ml.)	5.7			6.1			5.7		

1. Conc. = Concentration

2. Amt. = Amount

3. C.A. = Cumulative amount

Cumulative amount released vs time plot of mucoadhesive

patch containing HPMC + CP 934.
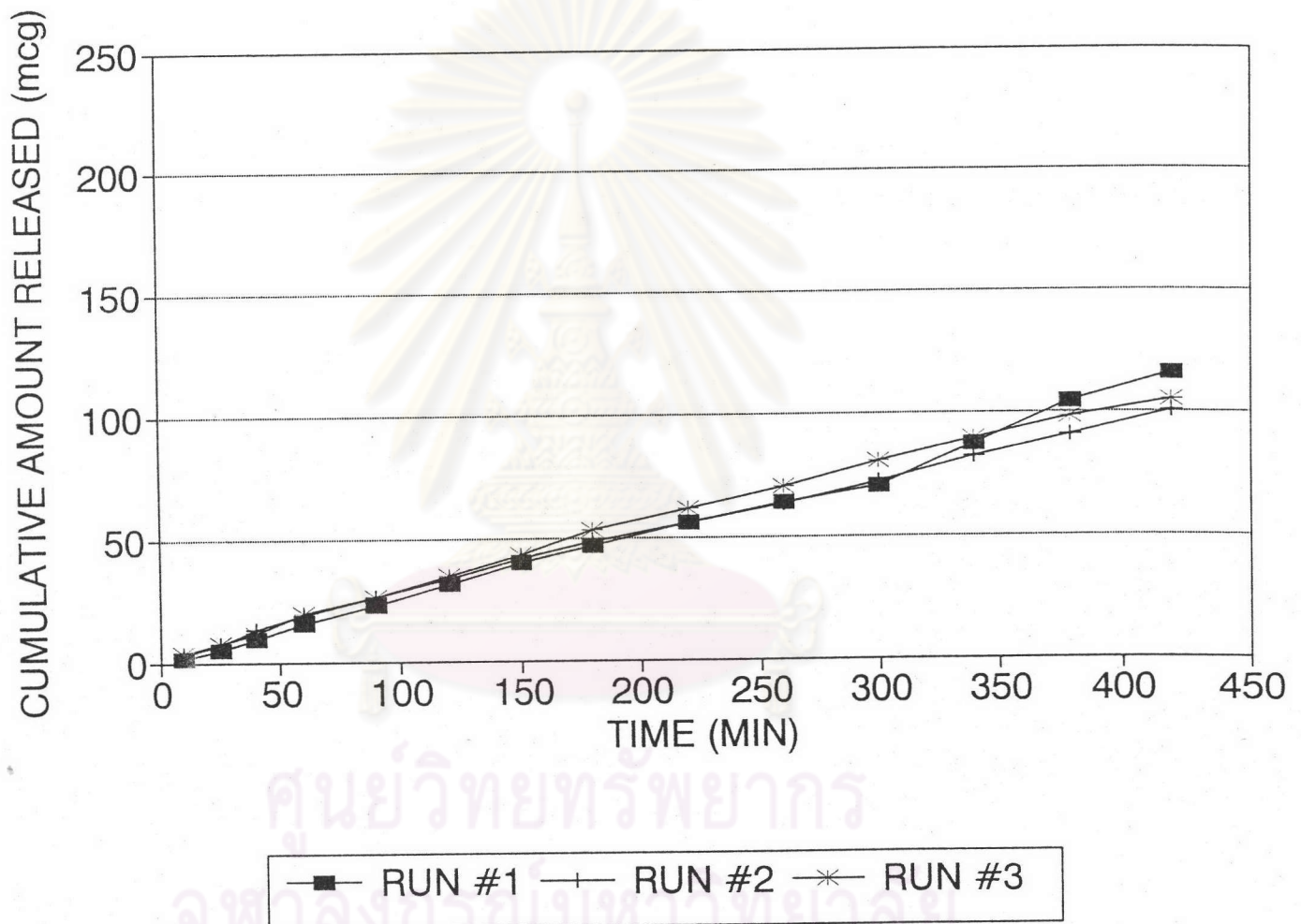
Cumulative amount released vs square root of time plot of mucoadhesive patch containing HPMC +CP 934.
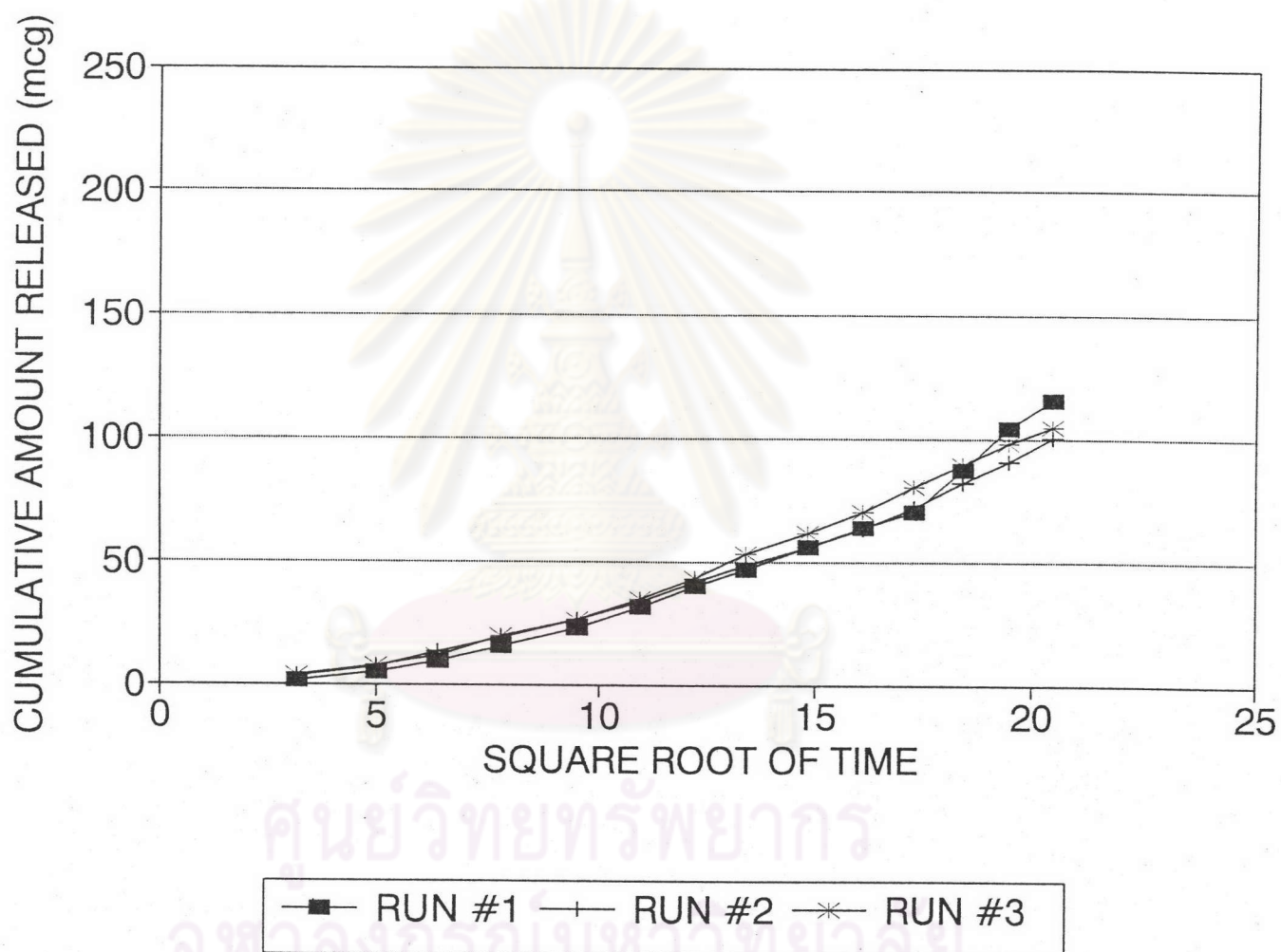
Amount of miconazole in mucoadhesive patches before storage.

Calibration Curve Data:

Conc. (mcg/ml)	0.0712	0.1187	0.3562	0.7123	1.1872	3.5616	7.1232
Peak Area Ratio	0.0155	0.0846	0.3814	0.8465	1.3921	4.1741	7.6256

$$Y = 0.0381 + 1.0855 X \qquad r^2 = 0.9976$$

Stability Test Data : Before Storage

Formulation # (Polymer)	Sample #1			Sample #2			Sample #3		
	Wt. 1 (mg)	Conc.2 (mcg/ml.)	Amt.3 (mcg.)	Wt.1 (mg)	Conc.2 (mcg/ml.)	Amt.3 (mcg.)	Wt.1 (mg)	Conc.2 (mcg/ml.)	Amt.3 (mcg.)
1 (SCMC MV)	12.4	2.4814	248.1416	14.1	2.7504	275.0370	13.5	2.6517	265.1713
2 (SCMC MV+CP)	14.4	2.9409	294.0854	14.8	2.9145	291.4470	15.1	2.9750	297.5049
3 (SCMC HV)	14.6	2.8320	283.2013	13.6	2.7122	271.2154	14.1	2.8032	280.3196
4 (MC 1500)	15.7	3.1140	311.1412	15.4	3.1228	312.2769	12.3	2.4531	245.3054
5 (MC 1500+CP)	14.5	2.9454	294.5365	17.2	3.3672	336.7187	12.6	2.5222	252.2160
6 (MC 4000)	16.3	3.2762	327.6166	15.6	3.1976	319.7591	14.4	2.8702	287.0244
7 (MC 4000+CP)	14.0	2.7744	377.4400	14.2	2.9487	294.8667	15.4	3.0315	303.1505
8 (HPMC)	14.7	2.9234	292.3440	13.4	2.7350	273.4959	15.2	3.1680	316.7969
9 (HPMC+CP)	18.4	3.6696	266.9619	17.7	3.4960	349.6044	14.9	3.0914	309.1366

1. Wt   = Weight of miconazole mucoadhesive patch

2. Conc. = Concentration

3. Amt. = Amount

Amount = Conc. x Dilution factor

Dilution factor = 100

Amount of miconazole in mucoadhesive patches after storage

Calibration Curve Data:

Conc. (mcg/ml)	0.0712	0.1187	0.3562	0.7123	1.1872	3.5616	7.1232
Peak Area Ratio	0.1108	0.1395	0.4117	0.9644	1.6576	4.8567	9.4150

$$Y = 0.170 + 1.3280 X \qquad r^2 = 0.9996$$

Stability Test Data : After Storage

Formulation # (Polymer)	Sample #1			Sample #2			Sample #3		
	Wt. 1 (mg)	Conc.2 (mcg/ml.)	Amt.3 (mcg.)	Wt.1 (mg)	Conc.2 (mcg/ml.)	Amt.3 (mcg.)	Wt.1 (mg)	Conc.2 (mcg/ml.)	Amt.3 (mcg.)
1 (SCMC MV)	15.2	2.8205	282.0544	15.7	2.7768	277.6823	15.4	2.6773	267.7285
2 (SCMC MV+CP)	14.5	2.5056	250.5615	14.7	2.7344	273.4357	16.1	2.7384	273.8364
3 (SCMC HV)	13.5	2.5910	259.1007	15.2	2.7713	277.1276	13.3	2.4917	249.1667
4 (MC 1500)	14.6	2.8454	284.5431	14.8	2.9840	298.3952	14.1	2.7094	270.9357
5 (MC 1500+CP)	15.8	2.6999	269.9925	15.5	2.9011	290.1148	16.8	3.0443	304.4342
6 (MC 4000)	16.2	3.2289	322.8851	13.4	2.7466	274.6622	14.7	2.8107	281.0672
7 (MC 4000+CP)	13.7	2.4362	243.6229	14.0	2.7589	275.8945	15.6	3.0771	307.7100
8 (HPMC)	16.5	3.2214	322.1409	16.1	3.1850	318.4961	13.5	2.7038	270.3772
9 (HPMC+CP)	14.3	2.8219	282.1947	14.6	2.7754	277.5383	16.0	3.1483	314.8337

1. Wt = Weight of miconazole mucoadhesive patch

2. Conc. = Concentration

3. Amt. = Amount

Amount = Conc. x Dilution factor

Dilution factor = 100

APPENDIX III

STATISTICS

1. ### Mean $(\overline{x})$

$$\overline{x} = \frac{\sum x}{N}$$

2. ### Standard Deviation (SD).

$$S.D. = \sqrt{\frac{\sum(x-\overline{x})^2}{N-1}}$$

3. ### Testing the Difference of Two Means, Student's t-test is used.

μ_1, μ_2 = Population means

x_1, x_2 = Sample means

σ_1, σ_2 = Polulation variances

N_1, N_2 = Sample size

The null hypothesis H_0 : $\mu_1 = \mu_2$

The alternative hypothesis H_a : $\mu_1 \neq \mu_2$

$$t = \frac{(\overline{x}_1 - \overline{x}_2) - (\mu_1 - \mu_2)}{S_p}$$

3.1 If $\sigma_1^2 \neq \sigma_2^2$

$$t = \frac{\overline{x}_1 - \overline{x}_2}{S_p}$$

where S_p^2 = pooled variance

$$S_p^2 = \frac{(S_1)^2}{N_1} + \frac{(S_2)^2}{N_2}$$

with the degree of freedom, df :

$$df = \left[s_1^2 / N_1 + s_2^2 / N_2 \right]^2 / \left[\left(s_1^2 / N_1 \right)^2 / (N_1 - 1) + \left(s_2^2 / N_2 \right)^2 / (N_2 - 1) \right]$$

3.2 If $\sigma_1^2 = \sigma_2^2$

$$t = \frac{\overline{x}_1 - \overline{x}_2}{S_p}$$

$$S_p^2 = \left[\frac{1}{N_1} + \frac{1}{N_2} \right] \left[\frac{(N_1 - 1) S_1^2 + (N_2 - 1) S_2^2}{N_1 + N_2 - 2} \right]$$

with the degree of freedom, df :

$$T_{.j} \quad = \quad \sum_{i=1}^{n_j} x_{ij}$$

$$X_{.j} \quad = \quad \frac{T_{.j}}{n_j}$$

$$T_{..} \quad = \quad \sum_{j=1}^{k} T_{.j}$$

$$X_{..} \quad = \quad \frac{T_{..}}{N}$$

$$N \quad = \quad \sum_{j=1}^{k} n_j$$

In this study "k"   represents number of formulations studied

"N"   represents total number of samples

The V.R. value is compared with the critical value, F, which is obtained from the table at degree of freedom (k-1) and (N-k).

If $F > F_{(tab)}$, the null hypothesis that $\mu_1 = \mu_2 = \mu_3 = ... = \mu_k$ is rejected and the alternative hypothesis is accepted. If F is not significant, the null hypothesis stands.

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5. Duncan's New Multiple Range Test.

If the alternative hypothesis from 4 is accepted, Duncan's New Multiple Range Test is used to test the difference between means of two formulations.

$$S_{\overline{x}} = \sqrt{MS_{within} / n}$$

with the degree of freedom, df = N-k

$$LSR = SSR \times S_{\overline{x}}$$

where LSR = Least significant range

SSR = Significant studentized range,

obtained from the table at df = N-k

The means of all formulations are ranked from minimum to maximum, and then they were compared. If the difference between two means of each pair of formulations is more than LSR, this pair is decided to be significantly different.

VITAE

Miss Pornpen Werawatganone was born on 8th May 1968, in Bangkok, Thailand. She graduated the Bachelor of Science in Pharmacy with a second class honor in 1990 from Faculty of Pharmaceutical Sciences, Chulalongkorn University, Bangkok, Thailand. Following graduation, she worked as a hospital pharmacist at Kaedam Hospital, in Mahasarakarm, Thailand for two years before attending the Master's Degree programme in Pharmaceutical sciences at Chulalongkorn University in 1992.