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Appendices

Appendix A

Determination of Degree of Substitution

Method of calculation

Sample from method A (DS ~ 0.3)

	Normality of NaOH VS.	= 0.1526 N
	Normality of HCL VS.	= 0.0965 N
	Average residue on ignition (C)	= 5.3903
Sample1	Weight of MGS	= 0.5014 gm
	Volume of $NaOH_1$ (added first)	= 9.00 ml
	Volume of HCL used	= 14.00 ml
	Volume of $NaOH_2$ (for back titration)	= 0.4 ml

$NaOH_2$ (= excess HCL) = 0.4 x 0.1526 = 0.0610 meq.

HCL used (= total HCL – excess HCL) = (14.0x0.0965)- 0.0610 = 1.2900 meq.

Excess $NaOH_1$ (react with HCL used) = 1.2900 meq.

$NaOH_1$ used (=total $NaOH_1$ – excess $NaOH_1$) = (9.0x0.1526)- 1.2900

= 0.0834 meq

meq. Of NaOH used to react with sample 0.5014 gm = 0.0834 meq.

meq. Of NaOH used to react with sample 1.0000 gm = 0.1664meq. (M)

Calculation of degree of acid carboxymethyl substitution (A)

$$A = \frac{1150M}{7102 - 412M - 80C}$$

$$= \frac{1150(0.1664)}{7102 - (412x0.1664) - (80x5.3903)} = 0.0290$$

Calculation of sodium carboxymethyl substitution (S)

$$S = \frac{(162 + 58A)\,C}{7102 - 80C}$$

$$= \frac{(162 + 58\,(0.0290)) \times 5.3903}{7102 - 80(5.3903)} = 0.1323$$

Calculation of degree of substitution (DS)

$$DS = A + S$$

$$= 0.0290 + 0.1323 = 0.1613$$

Appendix B

Rheological of modified starches and Ultrasperse®2000 (UT)

The following formulas should be used to calculated and display the Brookfield viscometer data after each packet of data is obtained from the DV-II+

Viscosity (cP)	=	$\frac{100 \times TK \times SMC \times Torque}{RPM}$
Shear Rate (1/sec)	=	RPM x SRC
Shear Stress (dynes/cm^2)	=	TK x SMC x SRC x Torque

where :

RPM	=	Current viscometer spindle speed in rpm
TK	=	Viscometer toque constant
SMC	=	Current spindle multiplier constant
SRC	=	Current spindle shear rate constant
Torque	=	Current viscometer torque (%) expressed as number between 0 and 100.

In this study, was using Brookfield viscometer SC4-31 spindle and running at 0-10 rpm. :

RPM	=	from the example statement.
TK	=	0.09373
SMC	=	32.0
SRC	=	0.34
Torque	=	from the example statement.

For example (Table B1);

Appearance viscosity of MGS at concentration of 1.0%w/v as used SC4-31 spindle, running at 0.50 rpm and currently displaying a Torque of 4.53 % was 2819.40 cP. Applying this data to above equation yields;

Shear Rate = RPM x SRC
= 0.05 x 0.34
= 0.17 sec^{-1}

Shear Stress = TK x SMC x SMC x Torque
= 0.09373 x 32.0 x 0.34 x 0.05
= 4.6717 $dynes/cm^2$

Table B1 Raw data was for calculating rheologram and thixotropic value of 1.0%w/v.MGS dispersion

Viscosity (cps)	Speed (rpm)	% Torque	Shear rate (1/sec)	shear stress (dynes/cm^2)
0.00	0.00	0.00	0.00	0.0000
2819.40	0.50	4.53	0.17	4.6171
2440.50	1.00	7.84	0.34	7.9933
1829.61	2.00	12.20	0.68	12.4413
1703.64	2.50	14.20	0.85	14.4809
1432.19	4.00	19.10	1.36	19.4778
1343.71	5.00	22.40	1.70	22.8431
1031.78	10.00	34.40	3.40	35.0805
1031.78	10.00	34.40	3.40	35.0805
1028.78	10.00	34.30	3.40	34.9785
1031.80	10.00	34.40	3.40	35.0811
1025.98	10.00	34.21	3.40	34.8835
1020.80	10.00	34.03	3.40	34.7071
997.18	10.00	33.25	3.40	33.9042
980.79	10.00	32.70	3.40	33.3469
1253.73	5.00	20.90	1.70	21.3135
1379.71	4.00	18.40	1.36	18.7640
1595.66	2.50	13.30	0.85	13.5631
1679.64	2.00	11.20	0.68	11.4216
2509.51	1.00	8.06	0.34	8.2193
2639.44	0.50	4.40	0.17	4.4870
0.00	0.00	0.00	0.00	0.0000

Table B2 Raw data was for calculating rheologram and thixotropic value of 2.0%w/v.MGS dispersion

Viscosity (cps)	Speed (rpm)	% Torque	Shear rate (1/sec)	shear stress (dynes/cm^2)
0.00	0.00	0.00	0.00	0.0000
2979.39	0.50	4.78	0.17	4.8791
2750.21	1.00	8.83	0.34	9.0076
2314.56	2.00	14.87	0.68	15.1615
2107.59	2.50	16.92	0.85	17.2572
1877.13	4.00	24.12	1.36	24.5923
1801.66	5.00	28.93	1.70	29.5044
1469.72	10.00	47.20	3.40	48.1370
1441.18	10.00	46.29	3.40	47.2024
1421.78	10.00	45.66	3.40	46.5670
1325.72	10.00	42.58	3.40	43.4206
1325.84	10.00	42.58	3.40	43.4246
1327.14	10.00	42.62	3.40	43.4672
1329.10	10.00	42.69	3.40	43.5314
1331.72	10.00	42.77	3.40	43.6170
1631.65	5.00	26.20	1.70	26.7204
1739.63	4.00	22.35	1.36	22.7909
1855.58	2.50	14.90	0.85	15.1938
2069.56	2.00	13.29	0.68	13.5566
2489.47	1.00	8.00	0.34	8.1536
2399.49	0.50	3.85	0.17	3.9295
0.00	0.00	0.00	0.00	0.0000

Table B3 Raw data was for calculating rheologram and thixotropic value of 3.0%w/v.MGS dispersion

Viscosity (cps)	Speed (rpm)	% Torque	Shear rate (1/sec)	shear stress (dynes/cm^2)
0.00	0.00	0.00	0.00	0.0000
8938.09	0.50	12.20	0.17	12.4413
6748.56	1.00	20.10	0.34	20.4976
4753.99	2.00	31.70	0.68	32.3271
4367.07	2.50	36.40	0.85	37.1201
3749.20	4.00	50.00	1.36	50.9891
3539.24	5.00	59.00	1.70	60.1672
2855.39	10.00	95.20	3.40	97.0833
2861.39	10.00	95.40	3.40	97.2872
2909.38	10.00	97.00	3.40	98.9189
2915.38	10.00	97.20	3.40	99.1228
2933.37	10.00	97.80	3.40	99.7347
2933.37	10.00	97.80	3.40	99.7347
2957.37	10.00	98.60	3.40	100.5505
2963.37	10.00	98.80	3.40	100.7545
3827.18	5.00	63.80	1.70	65.0621
4116.62	4.00	54.90	1.36	55.9861
4858.96	2.50	40.50	0.85	41.3012
5158.90	2.00	34.40	0.68	35.0805
6028.71	1.00	22.50	0.34	22.9451
7318.44	0.50	14.90	0.17	15.1948
0.00	0.00	0.00	0.00	0.0000

Table B4 Raw data was for calculating rheogram and thixotropic value of 1.0%w/v. MRS dispersion

Viscosity (cps)	Speed (rpm)	% Torque	Shear rate (1/sec)	shear stress (dynes/cm^2)
0.00	0.00	0.00	0.00	0.0000
779.86	0.50	1.25	0.17	1.2771
599.87	1.00	1.93	0.34	1.9647
479.90	2.00	3.08	0.68	3.1436
423.91	2.50	3.40	0.85	3.4710
387.42	4.00	4.98	1.36	5.0756
381.93	5.00	6.13	1.70	6.2545
280.94	10.00	9.02	3.40	9.2016
273.95	10.00	8.80	3.40	8.9726
273.76	10.00	8.79	3.40	8.9665
274.87	10.00	8.83	3.40	9.0027
274.56	10.00	8.82	3.40	8.9927
274.95	10.00	8.83	3.40	9.0054
275.94	10.00	8.86	3.40	9.0378
361.93	5.00	5.81	1.70	5.9270
374.92	4.00	4.82	1.36	4.9118
407.91	2.50	3.28	0.85	3.3400
464.90	2.00	2.99	0.68	3.0453
599.87	1.00	1.93	0.34	1.9647
779.83	0.50	1.25	0.17	1.2771
0.00	0.00	0.00	0.00	0.0000

Table B5 Raw data was for calculating rheologram and thixotropic value of 2.0%w/v. MRS dispersion

Viscosity (cps)	Speed (rpm)	% Torque	Shear rate (1/sec)	shear stress (dynes/cm^2)
0.00	0.00	0.00	0.00	0.0000
5778.55	0.50	9.28	0.17	9.4631
4298.85	1.00	13.81	0.34	14.0798
2959.16	2.00	19.01	0.68	19.3840
2755.26	2.50	22.12	0.85	22.5604
2191.93	4.00	28.16	1.36	28.7164
2003.51	5.00	32.17	1.70	32.8100
1511.66	10.00	48.55	3.40	49.5107
1502.80	10.00	48.27	3.40	49.2204
1486.30	10.00	47.74	3.40	48.6801
1466.80	10.00	47.11	3.40	48.0414
1457.30	10.00	46.80	3.40	47.7303
1450.80	10.00	46.60	3.40	47.5174
1447.80	10.00	46.50	3.40	47.4192
1445.30	10.00	46.42	3.40	47.3373
1431.70	10.00	45.98	3.40	46.8918
1877.60	5.00	30.15	1.70	30.7481
2039.56	4.00	26.20	1.36	26.7204
2467.46	2.50	19.81	0.85	20.2039
2729.42	2.00	17.53	0.68	17.8791
3719.21	1.00	11.95	0.34	12.1813
5158.90	0.50	8.28	0.17	8.4483
0.00	0.00	0.00	0.00	0.0000

Table B6 Raw data was for calculating rheologram and thixotropic value of 3.0%w/v. MRS dispersion

Viscosity (cps)	Speed (rpm)	% Torque	Shear rate (1/sec)	shear stress (dynes/cm^2)
0.00	0.00	0.00	0.00	0.0000
6838.54	0.50	10.98	0.17	11.1990
5188.89	1.00	16.67	0.34	16.9949
3944.16	2.00	25.34	0.68	25.8362
3527.25	2.50	28.32	0.85	28.8816
2916.88	4.00	37.47	1.36	38.2140
2609.44	5.00	41.90	1.70	42.7329
1987.59	10.00	63.84	3.40	65.0985
1969.69	10.00	63.26	3.40	64.5124
1954.70	10.00	62.78	3.40	64.0212
1940.70	10.00	62.33	3.40	63.5628
1937.20	10.00	62.22	3.40	63.4482
1928.20	10.00	61.93	3.40	63.1533
1900.70	10.00	61.05	3.40	62.2526
1880.58	10.00	60.40	3.40	61.5938
2473.45	5.00	39.72	1.70	40.5059
2759.41	4.00	35.45	1.36	36.1511
3335.29	2.50	26.78	0.85	27.3098
3629.23	2.00	23.31	0.68	23.7733
4828.97	1.00	15.51	0.34	15.8161
6418.63	0.50	10.31	0.17	10.5113
0.00	0.00	0.00	0.00	0.0000

Table B7 Raw data was for calculating rheologram and thixotropic value of 1.0%w/v. MTS dispersion

Viscosity (cps)	Speed (rpm)	% Torque	Shear rate (1/sec)	shear stress (dynes/cm^2)
0.00	0.00	0.00	0.00	0.0000
359.92	0.50	0.58	0.17	0.5894
269.94	1.00	0.87	0.34	0.8841
224.95	2.00	1.44	0.68	1.4735
203.96	2.50	1.64	0.85	1.6700
187.46	4.00	2.41	1.36	2.4559
179.96	5.00	2.89	1.70	2.9471
143.97	10.00	4.62	3.40	4.7154
153.68	10.00	4.94	3.40	5.0334
164.08	10.00	5.27	3.40	5.3740
172.57	10.00	5.54	3.40	5.6521
179.17	10.00	5.75	3.40	5.8683
181.17	10.00	5.82	3.40	5.9338
185.96	10.00	5.97	3.40	6.0907
239.95	5.00	3.85	1.70	3.9295
254.95	4.00	3.28	1.36	3.3400
263.94	2.50	2.12	0.85	2.1612
284.94	2.00	1.83	0.68	1.8665
389.92	1.00	1.25	0.34	1.2771
659.86	0.50	1.06	0.17	1.0806
0.00	0.00	0.00	0.00	0.0000

Table B8 Raw data was for calculating rheologram and thixotropic value of 2.0%w/v. MTS dispersion

Viscosity (cps)	Speed (rpm)	% Torque	Shear rate (1/sec)	shear stress (dynes/cm^2)
0.00	0.00	0.00	0.00	0.0000
599.87	0.50	0.96	0.17	0.9824
589.88	1.00	1.89	0.34	1.9320
564.90	2.00	3.63	0.68	3.7004
542.42	2.50	4.36	0.85	4.4414
477.42	4.00	6.13	1.36	6.2547
441.93	5.00	7.10	1.70	7.2371
406.94	10.00	13.07	3.40	13.3282
387.86	10.00	12.46	3.40	12.7035
379.16	10.00	12.18	3.40	12.4185
361.16	10.00	11.60	3.40	11.8290
352.16	10.00	11.31	3.40	11.5342
345.16	10.00	11.09	3.40	11.3049
337.86	10.00	10.85	3.40	11.0658
308.93	10.00	9.92	3.40	10.1184
353.92	5.00	5.68	1.70	5.7960
355.92	4.00	4.57	1.36	4.6629
419.91	2.50	3.37	0.85	3.4383
434.91	2.00	2.79	0.68	2.8489
539.88	1.00	1.73	0.34	1.7683
544.12	0.50	0.87	0.17	0.8911
0.00	0.00	0.00	0.00	0.0000

Table B9 Raw data was for calculating rheologram and thixotropic value of 3.0%w/v. MTS dispersion

Viscosity (cps)	Speed (rpm)	% Torque	Shear rate (1/sec)	shear stress (dynes/cm^2)
0.00	0.00	0.00	0.00	0.0000
1139.76	0.50	1.83	0.17	1.8665
929.80	1.00	2.99	0.34	3.0453
859.85	2.00	5.52	0.68	5.6324
801.86	2.50	6.44	0.85	6.5657
681.37	4.00	8.75	1.36	8.9266
640.88	5.00	10.29	1.70	10.4952
543.90	10.00	17.47	3.40	17.8141
526.54	10.00	16.91	3.40	17.2455
507.54	10.00	16.30	3.40	16.6232
488.41	10.00	15.69	3.40	15.9967
479.99	10.00	15.42	3.40	15.7209
460.10	10.00	14.78	3.40	15.0694
453.20	10.00	14.56	3.40	14.8434
445.90	10.00	14.32	3.40	14.6042
531.88	5.00	8.54	1.70	8.7102
540.87	4.00	6.95	1.36	7.0860
671.86	2.50	5.39	0.85	5.5012
704.85	2.00	4.53	0.68	4.6171
869.81	1.00	2.79	0.34	2.8489
1139.76	0.50	1.83	0.17	1.8665
0.00	0.00	0.00	0.00	0.0000

Table B10 Raw data was for calculating rheologram and thixotropic value of 3.0%w/v. UT dispersion

Viscosity (cps)	Speed (rpm)	% Torque	Shear rate (1/sec)	shear stress (dynes/cm^2)
0.00	0.00	0.00	0.00	0.0000
179.96	0.50	0.30	0.17	0.3059
149.97	1.00	0.50	0.34	0.5099
119.97	2.00	0.80	0.68	0.8158
107.98	2.50	0.90	0.85	0.9178
97.48	4.00	1.30	1.36	1.3257
95.98	5.00	1.60	1.70	1.6317
74.98	10.00	2.50	3.40	2.5495
74.98	10.00	2.50	3.40	2.5495
74.98	10.00	2.50	3.40	2.5495
74.98	10.00	2.50	3.40	2.5495
74.98	10.00	2.50	3.40	2.5495
74.98	10.00	2.50	3.40	2.5495
74.98	10.00	2.50	3.40	2.5495
83.98	5.00	1.40	1.70	1.4277
82.48	4.00	1.10	1.36	1.1218
71.98	2.50	0.60	0.85	0.6119
104.98	2.00	0.70	0.68	0.7138
0.00	0.00	0.00	0.00	0.0000

Table B11 Raw data was for calculating rheologram and thixotropic value of 4.0%w/v. UT dispersion

Viscosity (cps)	Speed (rpm)	% Torque	Shear rate (1/sec)	shear stress (dynes/cm^2)
0.00	0.00	0.00	0.00	0.00
11157.62	0.50	18.60	0.17	18.9680
6448.62	1.00	21.50	0.34	21.9253
3869.17	2.00	25.80	0.68	26.3104
3155.33	2.50	26.30	0.85	26.8203
2347.00	4.00	31.30	1.36	31.9192
1991.58	5.00	33.20	1.70	33.8568
1337.71	10.00	44.60	3.40	45.4823
1302.69	10.00	43.43	3.40	44.2913
1284.69	10.00	42.83	3.40	43.6793
1261.29	10.00	42.05	3.40	42.8838
1239.89	10.00	41.34	3.40	42.1562
1222.49	10.00	40.76	3.40	41.5646
1210.49	10.00	40.36	3.40	41.1567
1208.74	10.00	40.30	3.40	41.0972
1571.66	5.00	26.20	1.70	26.7183
1687.14	4.00	22.50	1.36	22.9451
1979.58	2.50	16.50	0.85	16.8264
2129.55	2.00	14.20	0.68	14.4809
2639.44	1.00	8.80	0.34	8.9741
4019.14	0.50	6.70	0.17	6.8325
0.00	0.00	0.00	0.00	0.00

Appendix C

Calcium Carbonate Suspension

Table C1 Reconstitution time of calcium carbonate suspension

Suspending agent	%	Sample1	Sample2	Sample3	(times) Average (SD)
MGS DS 0.16	1	8.0	9.5	8.0	8.50 (0.87)
	2	11.5	10.0	10.0	10.50 (0.87)
	3	Lump*	Lump*	Lump*	Lump*
MRS DS 0.26	1	5.5	4.0	4.5	4.67 (0.76)
	2	7.5	7.5	8.0	7.67 (0.29)
	3	12.5	11.5	12.0	12.00 (0.50)
MTS DS 0.38	1	5.0	5.0	5.0	5.00 (0.00)
	2	8.5	8.0	8.0	8.17 (0.29)
	3	10.5	9.5	10.0	10.00 (0.50)
UT DS 0.10	1	1.5	1.0	1.0	1.17 (0.29)
	2	2.0	2.5	2.0	2.17 (0.29)
	3	2.5	2.5	2.5	2.50 (0.00)
	4	5.0	6.0	7.0	6.00 (1.00)

*Lump = after the shaking vigorously more than 20 times, the deposit was dispersed non-homogeneous.

Table C2 Number of inversion required for redisperse calcium carbonate suspension

Suspending agent	%	7^{th} day (times) Average (SD)	14^{th} day (times) Average (SD)
MGS DS 0.16	1	6.33 (1.53)	5.67 (1.15)
	2	3.33 (0.58)	3.67 (0.58)
	3	5.67 (1.15)	6.00 (1.00)
MRS DS 0.26	1	2.33 (1.00)	5.67 (4.73)
	2	7.00 (0.58)	8.00 (3.00)
	3	10.67 (0.58)	6.00 (1.00)
MTS DS 0.38	1	3.00 (1.00)	2.00 (0.00)
	2	2.33 (0.58)	1.33 (0.58)
	3	1.00 (0.00)	2.00 (0.00)
UT DS 0.10	1	2.33 (0.58)	3.67 (0.58)
	2	2.00 (1.00)	4.33 (1.15)
	3	1.00 (0.00)	4.00 (1.00)
	4	1.00 (0.00)	2.33 (0.58)

Table C3 Sedimentation volume (Hu/Ho) of calcium carbonate suspension containing each of modified starches (MGS, MRS and MTS) and UT at suspending agents as various concentration when kept at room temperature for 14 days

Suspending agent	1	2	3	4	5	6	7	8	9	10	11	12	13	14
MGS 1.0%	1.00	0.99	0.97	0.95	0.92	0.55	0.15	0.14	0.12	0.12	0.12	0.12	0.12	0.12
MGS 2.0%	1.00	0.96	0.93	0.93	0.92	0.60	0.24	0.18	0.15	0.13	0.13	0.13	0.13	0.13
MGS 3.0%	1.00	1.00	1.00	0.90	0.88	0.86	0.84	0.73	0.66	0.58	0.50	0.41	0.28	0.16
MRS 1.0%	1.00	0.99	0.97	0.94	0.90	0.54	0.14	0.14	0.12	0.11	0.11	0.11	0.11	0.11
MRS 2.0%	1.00	0.99	0.98	0.96	0.94	0.60	0.18	0.16	0.16	0.16	0.16	0.16	0.16	0.16
MRS 3.0%	1.00	1.00	0.98	0.97	0.95	0.64	0.24	0.20	0.20	0.20	0.15	0.15	0.15	0.15
MTS 1.0%	1.00	0.84	0.78	0.76	0.75	0.74	0.73	0.71	0.70	0.70	0.70	0.70	0.70	0.70
MTS 2.0%	1.00	0.99	0.98	0.98	0.97	0.95	0.94	0.92	0.91	0.88	0.88	0.86	0.86	0.86
MTS 3.0%	1.00	1.00	1.00	0.99	0.98	0.90	0.90	0.90	0.90	0.90	0.90	0.90	0.90	0.90
UT 1.0%	1.00	0.56	0.53	0.52	0.52	0.50	0.47	0.45	0.42	0.38	0.25	0.22	0.20	0.18
UT 2.0%	1.00	0.54	0.52	0.52	0.52	0.52	0.50	0.47	0.46	0.42	0.34	0.31	0.30	0.27
UT 3.0%	1.00	0.97	0.94	0.92	0.91	0.64	0.56	0.54	0.52	0.50	0.46	0.42	0.36	0.39
UT 4.0%	1.00	1.00	1.00	1.00	0.97	0.95	0.90	0.80	0.75	0.72	0.72	0.72	0.72	0.72

Table C4 Apparent viscosity of calcium carbonate suspensions with various concentrations of\ suspending agent

Concentration (%w/v)	Apparent viscosity (cps) Average (SD)			
	MGS	MRS	MTS	UT
1.0	434.37 (21.80)	109.30 (12.18)	95.70 (4.57)	7.70 (0.62)
2.0	869.77 (40.71)	412.93 (23.30)	165.03 (9.78)	14.33 (1.00)
3.0	2419.27 (61.65)	1161.10 (49.26)	374.47 (16.80)	97.50 (6.67)
4.0	-	-	-	443.20 (20.74)

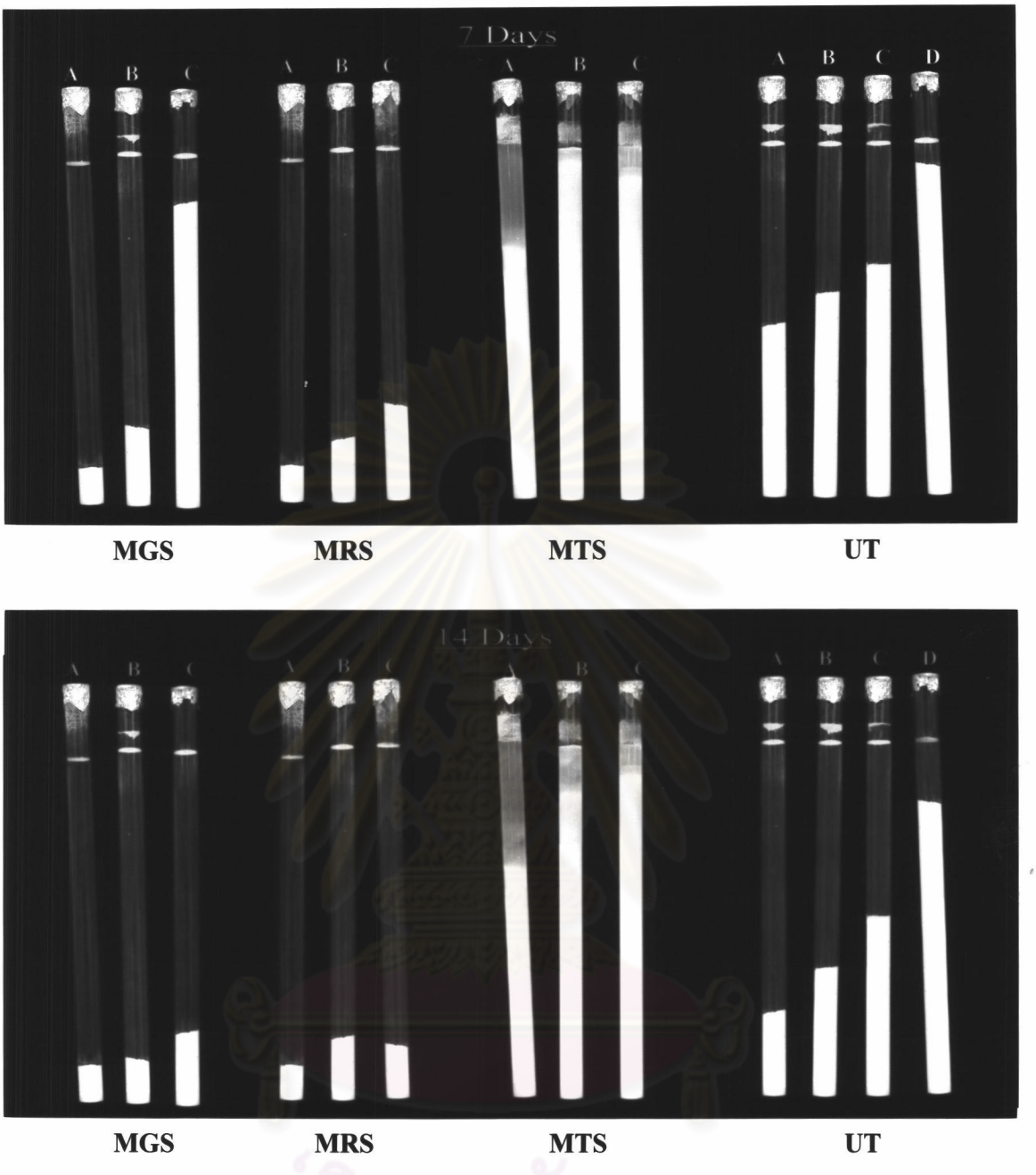


Figure C1 Photograph of calcium carbonate suspension using different types and concentrations of suspending agent, kept for 7 and 14 days

Appendix D

HPLC and Validation

Validation of HPLC Method

Method validation was performed in terms of specificity, accuracy, precision and linearity and system suitability (tailing factor, repeatability and resolutions).

1. Specificity and Accuracy

Preparation of Solution

All excipients (placebo) in amoxicillin trihydrate and cephalexin monohydrate dry syrup were determined. The percentage of ingredients were accurately weighed and used in the same formula mentioned in PartIIIA3 (spiked-placebo). The sample was weight into 10-ml volumetric flask and dissolved with distilled water. An aliquot (0.1, 0.5, or 1.0 ml) of standard stock solution was pipetted. Based on assay for cephalexin monohydrate, an internal standard solution of 0.1 ml was added to each volumetric flask before adjusting to volume with distilled water. The sample was added distilled water nearly full volume. After that, the sample was sonicated for 30 minutes and adjusted to volume with distilled water. Then, the solution was mixed thoroughly and filtered through 0.45 μm membrane filter. This final concentration was equivalent to the concentration of non-active ingredients in solution which used to assay for drug content. Final concentrations of amoxicillin trihydrate and cephalexin monohydrate in sample solutions were 0.01, 0.05 and 0.1 mg/ml, respectively. Preparation of each sample was done in triplicate.

Accuracy

Accuracy was determined by triplicate analysis. Amount of model drug within spiked-placebo at three different levels (low, medium and high) was calculated.

Specificity

Assay model drugs with in chromatographic condition used, the peak of amoxicillin and cephalexin had to be completely separated from and not to be interfered by the peak of non-active ingredients, therefore the specificity of HPLC method was evaluated. The chromatograms were evaluated by comparing with those of standard solutions of model drugs.

2. Precision

Within- Run Precision (Interday)

Six sets of standard solutions of each concentration were analyzed in the same day. The standard solutions having concentrations of 0.01, 0.05 and 0.10 mg/ml were used to analyze. The percentage coefficient of variation (% CV) of peak area and peak area ratio of each model drugs from six sets of standard solutions which having the same concentrations were determined. Amoxicillin was calculated based on peak area. Therefore, cephalexin was calculated based on peak area ratio between cephalexin and internal standard.

Between-Run Precision (Day to Day Reproducibility)

Intermediate precision study (day to day reproducibility) was conducted during routine operation of the system over a period of six consecutive days. The standard solutions having concentration of 0.01, 0.05 and 1.0 mg/ml were used. In each day, evaluate the precision determination of each concentration was done in triplicate. Statistical evaluation the percentage coefficient of variation (% CV) of peak area and peak area ratio of each model drugs from six sets of standard solutions which having the same concentrations were determined. Amoxicillin was calculated based on peak area. Therefore, cephalexin was calculated based on peak area ratio between cephalexin and internal standard.

3. Linearity

Model drug standard solutions ranking from 0.01-1.0 mg/ml were prepared and analyzed. Linear regression analysis of peak areas versus their concentrations was performed. The determination was done in triplicate.

4. System Suitability

Tailing Factor

Tailing factor was defined the ratio of the distance from the leading edge to the tailing edge of the peak, $W_{0.05}$, divided by twice the distance, f, from the peak maximum to the leading edge of the peak, the distance being measured at a point 5 % of he peak height from the baseline (USP 24).

$$T = \frac{W_{0.05}}{2f}$$

where T = tailing factor.

$W_{0.05}$ = width of peak at 5% height.

Repeatability

Repeatability expressed the precision under the same operating condition. The repeatability was displayed as the % CV and determined by multiple injection of homogeneous sample under the analytical conditions.

Resolution

The resolution was a function of column efficiency and was specified to ensure the model drugs were resolved from corresponding internal standard. The resolution (R) was determined by the following equation (USP 24)

$$R = \frac{2(t_2 - t_1)}{W_2 + W_1}$$

In which t_2 and t_1 was the retention time of the model drug and the corresponding internal standard, respectively. W_2 and W_1 were the corresponding widths at the bases of the peaks obtained by extrapolating the relatively straight sides of the peak to the baseline.

In this study, only the resolution of cephalexin monohydrate and internal standard was determined.

Table D1 Percentage of drug remaining of determination accuracy

Formulation	Actual concentration (μ/ml)	Analytical concentration (Percentage of label amount)					
		n1	n2	n3	Average	SD	%CV
Amoxicillin	10	101.3513	100.3615	100.2654	100.6594	0.6011	0.5972
and	50	99.0316	101.5234	99.1562	99.9037	1.4041	1.4054
MGS	100	102.0315	100.2654	100.2197	100.8389	1.0331	1.0245
Amoxicillin	10	101.2654	101.0265	99.5135	100.6018	0.9500	0.9444
and	50	102.0725	101.2645	101.1693	101.5021	0.4962	0.4889
MRS	100	101.5761	101.2364	101.4065	101.4063	0.1699	0.1675
Amoxicillin	10	100.2645	102.2315	100.6990	101.0650	1.0333	1.0224
and	50	101.2301	102.1356	99.5553	100.9737	1.3091	1.2965
MTS	100	101.9050	102.9138	100.5546	101.7911	1.1837	1.1629
Amoxicillin	10	100.9046	102.1365	101.2613	101.4341	0.6339	0.6249
and	50	103.2597	100.6132	101.3029	101.7253	1.3729	1.3496
UT	100	101.6682	100.6707	101.9945	101.4445	0.6896	0.6798
Cephalexin	10	99.1352	99.1365	100.1274	99.4664	0.5725	0.5756
and	50	102.8019	101.6815	101.3815	101.9550	0.7487	0.7343
MGS	100	100.5555	103.2297	100.8946	101.5600	1.4560	1.4336
Cephalexin	10	101.2653	99.6453	99.5365	100.1490	0.9682	0.9668
and	50	102.6488	100.2505	100.4312	101.1102	1.3355	1.3209
MRS	100	101.8939	102.5682	100.4191	101.6271	1.0991	1.0815
Cephalexin	10	101.0326	100.6253	99.3111	100.3230	0.8997	0.8968
and	50	103.0663	102.3612	99.7612	101.7296	1.7408	1.7112
MTS	100	101.2651	102.5266	100.7915	101.5277	0.8969	0.8834
Cephalexin	10	99.8653	102.3612	99.4564	100.5610	1.5724	1.5636
and	50	99.3626	101.3265	99.2327	99.9739	1.1732	1.1735
UT	100	100.8765	103.4687	100.7629	101.7027	1.5304	1.5048

Table D2 The precision of amoxicillin trihydrate (within-day)

amoxicillin concentration (μg/ml)	Calculated concentration from calibration curve (μg/ml)								
	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6	Average	SD	%CV
10	10.14	10.11	10.18	10.20	10.01	10.12	10.13	0.07	0.68
50	50.15	50.17	50.20	50.08	50.12	50.06	50.13	0.05	0.11
100	100.43	100.43	100.81	100.22	101.15	101.30	100.72	0.44	0.43

Table D3 The precision of amoxicillin trihydrate (day-to-day)

amoxicillin concentration (μg/ml)	Calculated concentration from calibration curve (μg/ml)								
	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6	Average	SD	%CV
10	10.14	10.20	10.17	10.17	10.19	10.11	10.16	0.03	0.34
50	50.15	49.87	49.98	50.16	50.06	50.17	50.06	0.12	0.24
100	100.43	101.34	101.07	100.58	100.30	101.03	100.79	0.41	0.41

Table D4 The precision of cephalexin monohydrate (within-day)

cephalexin concentration (μg/ml)	Calculated concentration from calibration curve (μg/ml)								
	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6	Average	SD	%CV
10.00	10.15	10.07	10.16	10.09	10.05	10.12	10.11	0.05	0.45
50.00	49.54	49.55	49.39	49.44	49.63	49.21	49.46	0.15	0.30
100.00	100.38	100.64	100.83	101.03	100.19	100.22	100.55	0.34	0.34

Table D5 The precision of cephalexin monohydrate (day-to-day)

cephalexin concentration (μg/ml)	Calculated concentration from calibration curve (μg/ml)								
	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6	Average	SD	%CV
10.00	10.15	10.11	10.16	10.05	10.17	10.15	10.13	0.05	0.45
50.00	49.54	49.55	49.45	49.32	49.64	49.21	49.45	0.16	0.32
100.00	100.38	100.67	101.03	101.25	100.26	100.22	100.64	0.43	0.42

Table D6 The Linearity of assay amoxicillin trihydrate

amoxicillin concentration (μg/ml)	Calculated concentration from calibration curve (μg/ml)								
	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6	Average	SD	%CV
10	117,573	117,253	118,141	118,362	116,078	117,369	117,462.67	806.37	0.69
30	348,951	350,236	347,589	349,698	347,789	349,127	348,898.33	1,042.00	0.30
50	589,460	589,712	590,142	588,663	589,147	588,478	589,267.00	632.87	0.11
70	816,172	817,569	815,251	816,472	818,001	816,325	816,631.67	999.07	0.12
100	1,182,530	1,182,547	1,186,973	1,179,996	1,190,986	1,192,789	1,185,970.17	5,136.23	0.43

Table D7 The Linearity of assay cephalexin monohydrate

cephalexin concentration (μg/ml)	Calculated concentration from calibration curve (μg/ml)								
	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6	Average	SD	%CV
10.00	0.5069	0.5027	0.5073	0.5037	0.5014	0.5054	0.5046	0.0024	0.47
30.00	1.5176	1.5214	1.5121	1.5001	1.5136	1.5176	1.5137	0.0074	0.49
50.00	2.5592	2.5593	2.5514	2.5536	2.5639	2.5417	2.5549	0.0078	0.31
70.00	3.6173	3.6214	3.6022	3.6289	3.6199	3.6211	3.6185	0.0089	0.24
100.00	5.2079	5.2214	5.2311	5.2415	5.1977	5.1993	5.2165	0.0178	0.34

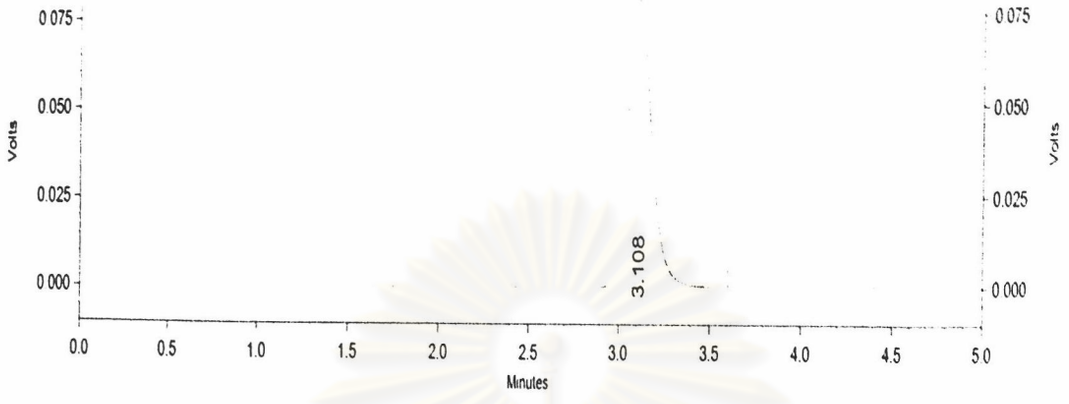


Figure D1 HPLC chromatogram of standard solution of amoxicillin trihydrate

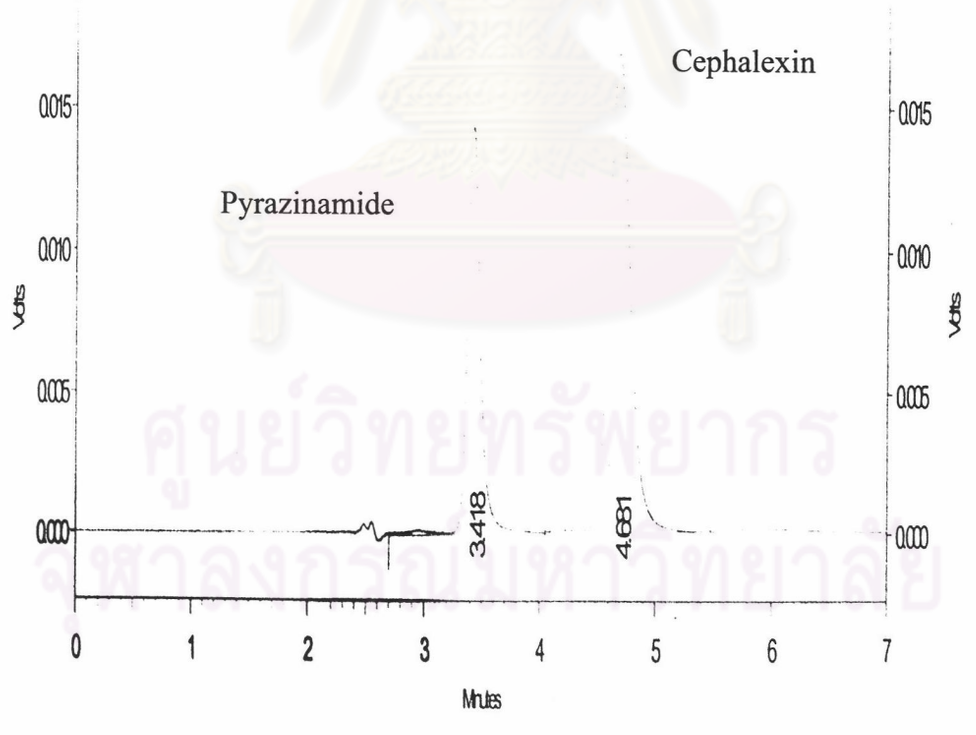


Figure D2 HPLC chromatogram of standard solution of cephalexin monohydrate and pyrazinamide as internal standard

Table D8 Peak area of amoxicillin trihydrate assay by HPLC method

Concentration (on dry basic) (μg/ml)	Peak area
10.00	117,573
30.00	348,951
50.00	589,460
70.00	816,172
100.00	1,182,530

Correlation coefficient (r^2) = 0.9999

Slope = 11,794

Intercept = -1971.4

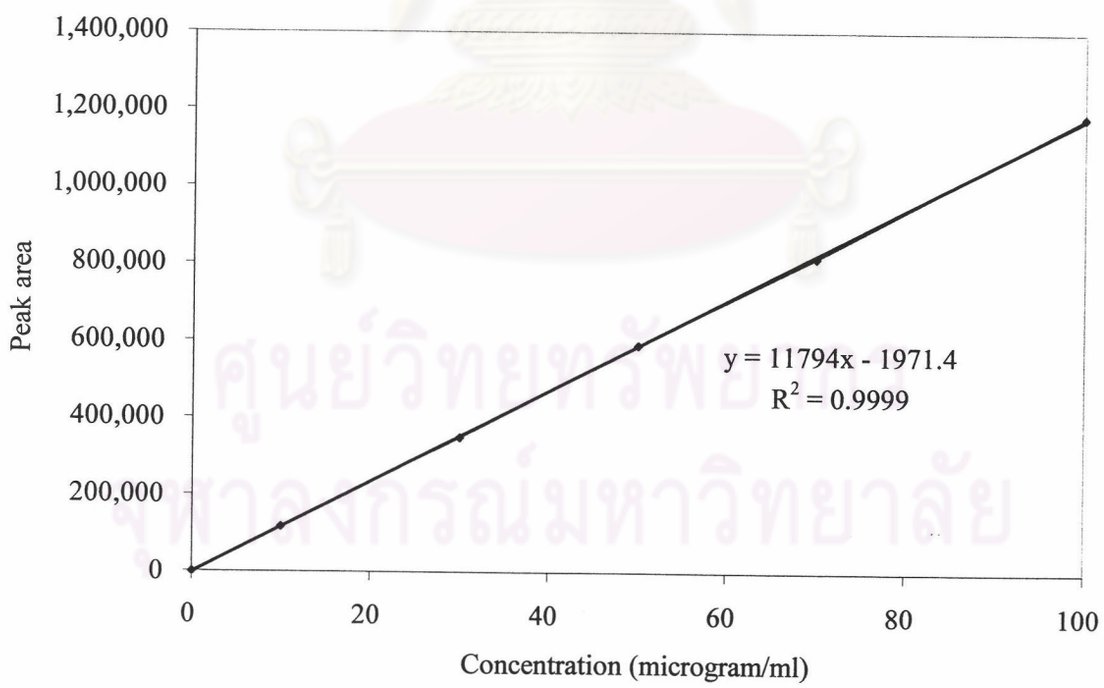


Figure D3 Calibration curve of amoxicillin trihydrate standard solution by HPLC method

Table D9 Peak area ratio of cephalexin monohydrate to pyrazinamide assay by HPLC method

Concentration (on dry basic) (μg/ml)	Peak area ratio
10.00	0.5069
30.00	1.5176
50.00	2.5592
70.00	3.6173
100.00	5.2079

Correlation coefficient (r^2) = 0.9999

Slope = 0.0521

Intercept = -0.022

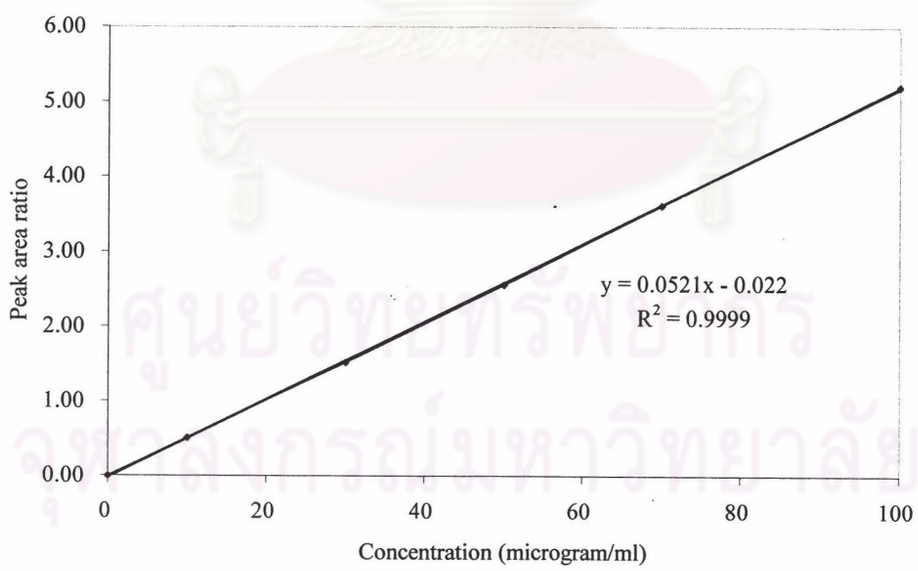


Figure D4 Calibration curve of cephalexin in aqueous solution by HPLC method

Table D9 Peak area ratio of cephalexin monohydrate to pyrazinamide assay by HPLC method

Concentration (on dry basic) (μg/ml)	Peak area ratio
10.00	0.5069
30.00	1.5176
50.00	2.5592
70.00	3.6173
100.00	5.2079

Correlation coefficient (r^2) = 0.9999

Slope = 0.0521

Intercept = -0.022

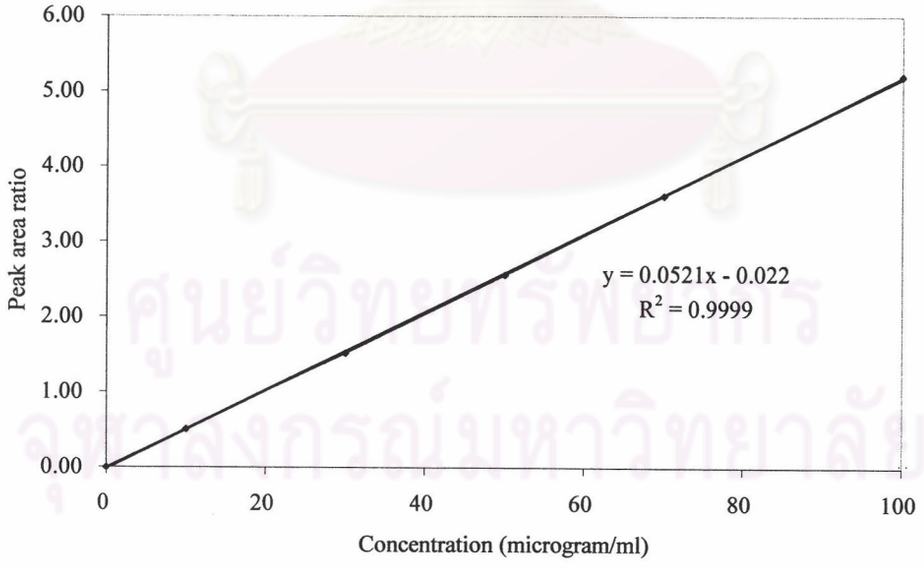


Figure D4 Calibration curve of cephalexin in aqueous solution by HPLC method

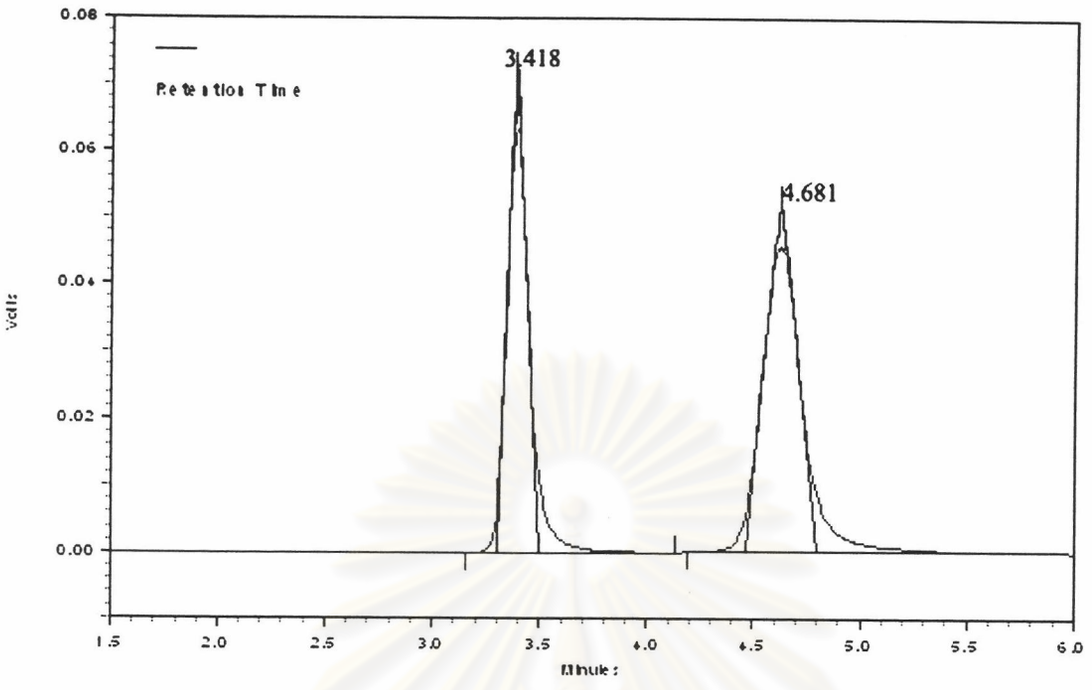


Table D11 Tailing factor and resolution factor of cephalexin and pyrazinamide

Name	Retention Time	Area	Resolution	Asymmetry	Asymmetry (10%)
pyrazinamide	3.418	603913	0.00	1.41	1.21
cephalexin	4.681	116817	6.40	1.29	1.60

Table D12 The repeatability of peak areas of amoxicillin trihydrate and peak area ratio of cephalexin monohydrate and pyrazinamide

Sample No.	Peak area	Peak area ratio
	Amoxicillin trihydrate	Cephalexin monohydrate and pyrazinamide
1	816,172	2.5592
2	815,639	2.5593
3	816,954	2.5514
4	817,459	2.5536
5	818,693	2.5639
6	817,994	2.5417
Average	817,151.83	2.5549
SD	1,137.25	0.0078
%CV	0.14	0.31

Table D13 The analytical method validation parameter of HPLC for amoxicillin trihydrate and cephalexin monohydrate

Parameter	Result value		Limited of acceptability
	Amoxicillin trihydrate	Cephalexin monohydrate	
1. System suitability - Tailing factor - Resolution factor	 1.31 -	 1.60 6.40	 ≤2 ≥2
2. Specificity	No other peak interfere	No other peak interfere	No other peak interfere major peak
3. Accuracy - Percentage Recovery (%) - % CV	 99.90-101.79 0.59-1.34	 99.46-101.95 0.57-1.71	 98-102% ≤2
4. Precision (%CV)	0.3.0-0.45	0.11-0.68	≤ 2
5. Linearity -The correlation coefficient (r^2) - % CV	 0.9999 0.11-0.69	 0.9999 0.24-0.49	 >0.999 ≤2

Appendix E

Effect of Buffer

Figure E1 Drug content of amoxicillin trihydrate in citrate buffer pH 6.0, kept at room temperature for 14 days at different buffer concentrations

Times	Buffer Concentration			
	Water	0.05 Molar	0.10 Molar	0.20 Molar
0 day	100.02 (0.52)	100.25 (0.41)	100.17 (0.41)	100.07 (0.54)
1 day	95.50 (0.14)	100.02 (0.14)	99.96 (0.47)	99.87 (1.21)
3 day	87.12 (0.28)	98.97 (0.26)	99.88 (0.15)	99.94 (0.27)
5 day	81.64 (2.25)	98.36 (0.14)	98.74 (0.21)	98.86 (0.14)
7 day	79.36 (3.15)	97.77 (0.22)	98.14 (0.17)	98.24 (0.31)
10 day	67.69 (7.47)	96.87 (0.31)	97.31 (0.09)	98.22 (0.67)
14 day	59.78 (7.98)	95.91 (0.07)	97.12 (0.11)	98.23 (0.14)

Figure E2 Drug content of amoxicillin trihydrate in citrate buffer pH 6.0, kept in refrigerator for 14 days at different buffer concentrations

Times	Buffer Concentration			
	Water	0.05 Molar	0.10 Molar	0.20 Molar
0 day	100.08 (0.25)	100.11 (1.45)	100.36 (1.24)	99.78 (0.84)
1 day	98.18 (0.34)	100.05 (1.25)	99.84 (0.44)	101.01 (0.57)
3 day	95.71 (0.18)	99.87 (1.34)	99.95 (1.62)	100.25 (0.96)
5 day	90.62 (1.00)	99.24 (1.28)	99.63 (0.75)	99.63 (1.24)
7 day	87.36 (0.14)	98.74 (0.94)	100.10 (1.45)	98.97 (0.86)
10 day	87.36 (0.07)	98.74 (0.84)	100.10 (0.47)	98.97 (0.97)
14 day	82.14 (1.02)	99.36 (0.54)	100.07 (1.57)	100.55 (1.03)

Table E3 Drug content of cephalexin monohydrate in citrate buffer pH 6.0, kept at room temperature for 14 days at different buffer concentrations

Times	Buffer Concentration			
	Water	0.05 Molar	0.10 Molar	0.20 Molar
0 day	100.02 (0.03)	99.12 (0.56)	100.26 (0.14)	100.02 (0.12)
1 day	100.14 (0.52)	99.78 (0.67)	100.06 (1.25)	100.14 (1.54)
3 day	99.87 (0.31)	98.96 (0.45)	100.16 (0.84)	99.87 (1.33)
5 day	97.14 (1.29)	100.05 (0.79)	99.84 (0.96)	99.14 (0.88)
7 day	95.76 (0.14)	101.63 (1.02)	99.79 (1.17)	99.76 (0.35)
10 day	92.09 (1.26)	99.96 (2.25)	100.01 (0.36)	100.09 (1.04)
14 day	87.63 (2.47)	100.20 (1.41)	99.93 (1.36)	98.63 (0.98)

Table E4 Drug content of cephalexin monohydrate in citrate buffer pH 6.0, kept in refrigerator for 14 days at different buffer concentrations

Times	Buffer Concentration			
	Water	0.05 Molar	0.10 Molar	0.20 Molar
0 day	100.22 (0.14)	99.63 (0.47)	99.36 (0.11)	100.22 (0.47)
1 day	100.06 (1.06)	99.87 (0.14)	100.54 (0.20)	100.06 (0.22)
3 day	100.11 (0.94)	100.06 (0.16)	100.05 (0.36)	100.11 (0.30)
5 day	99.98 (0.36)	99.47 (0.21)	98.76 (0.38)	99.98 (0.31)
7 day	98.87 (0.07)	98.64 (0.07)	99.87 (0.02)	100.87 (0.51)
10 day	98.78 (0.28)	99.77 (0.70)	99.94 (0.01)	99.78 (0.05)
14 day	95.26 (0.47)	100.15 (0.71)	100.51 (0.17)	100.26 (0.17)

Table E5 Apparent viscosity of suspending agent at various concentrations of citrate buffer at pH 4.5

Buffer (Molar)	Concentration of suspending agent (%w/v)	Apparent viscosity (cps) Average (SD)			
		MGS	MRS	MTS	UT
0.05	0.5	7.05 (0.13)	6.18 (0.60)	11.80 (0.60)	4.55 (0.05)
	1.0	17.13 (0.32)	16.83 (0.70)	29.40 (0.70)	5.34 (0.10)
	1.5	112.37 (0.86)	95.54 (1.52)	73.33 (1.52)	7.98 (0.14)
	2.0	299.73 (3.31)	204.70 (0.51)	132.57 (0.51)	11.98 (3.52)
	2.5	628.13 (5.90)	455.78 (1.47)	180.37 (1.47)	45.03 (0.83)
	3.0	1253.50 (4.70)	1181.93 (2.56)	254.83 (2.56)	84.27 (2.15)
	4.0	- -	- -	- -	486.53 (4.00)
0.10	0.5	5.50 (0.10)	5.42 (0.13)	7.68 (0.50)	4.43 (0.08)
	1.0	17.33 (0.76)	14.57 (0.60)	11.37 (0.81)	4.54 (0.06)
	1.5	65.93 (1.44)	45.40 (0.62)	32.20 (1.30)	7.42 (0.07)
	2.0	103.50 (1.32)	78.43 (0.97)	54.60 (1.10)	14.70 (0.46)
	2.5	225.37 (1.31)	187.00 (2.75)	78.07 (0.40)	43.47 (0.85)
	3.0	392.50 (1.50)	338.13 (2.26)	110.52 (1.38)	71.17 (0.76)
	4.0	- -	- -	- -	485.88 (0.12)
0.20	0.5	5.24 (0.19)	4.65 (0.22)	7.68 (0.50)	4.43 (0.08)
	1.0	9.12 (0.10)	5.10 (0.10)	11.37 (0.81)	4.54 (0.06)
	1.5	24.33 (2.02)	8.62 (0.28)	32.20 (1.30)	7.42 (0.07)
	2.0	49.73 (2.61)	11.06 (0.16)	54.60 (1.10)	14.70 (0.46)
	2.5	106.57 (0.97)	22.60 (0.95)	78.07 (0.40)	43.47 (0.85)
	3.0	222.40 (1.93)	51.93 (1.46)	110.52 (1.38)	71.17 (0.76)
	4.0	- -	- -	- -	451.12 (0.11)

Table E6 Apparent viscosity of suspending agent at various concentrations of citrate buffer at pH 6.0

Buffer (Molar)	Concentration of suspending agent (%w/v)	Apparent viscosity (cps) Average (SD)			
		MGS	MRS	MTS	UT
0.05	0.5	5.20 (0.14)	6.00 (0.10)	9.67 (0.76)	4.42 (0.09)
	1.0	13.03 (0.55)	10.32 (0.36)	21.33 (0.76)	5.05 (0.05)
	1.5	91.60 (1.05)	51.63 (0.77)	33.23 (0.870	7.27 (0.14)
	2.0	201.90 (6.770	125.67 (1.60)	71.53 (1.760	14.00 (1.00)
	2.5	488.00 (2.64)	295.83 (1.04)	122.67 (1.85)	42.23 (1.96)
	3.0	1093.00 (11.35)	562.03 (6.66)	217.83 (1.04)	76.40 (1.63)
	4.0	- -	- -	- -	501.02 (3.19)
0.10	0.5	5.18 (0.13)	4.12 (0.08)	4.45 (0.18)	4.44 (0.12)
	1.0	9.15 (0.12)	5.61 (0.10)	13.33 (0.76)	4.54 (0.05)
	1.5	42.93 (0.59)	11.10 (0.46)	27.60 (0.95)	7.07 (0.11)
	2.0	77.47 (1.50)	22.93 (2.01)	68.43 (0.85)	11.07 (0.60)
	2.5	178.30 (1.93)	78.00 (1.40)	87.10 (1.67)	41.42 (0.43)
	3.0	360.63 (3.07)	153.33 (3.51)	106.30 (1.08)	69.73 (1.11)
	4.0	- -	- -	- -	475.32 (0.17)
0.20	0.5	4.34 (0.15)	4.35 (0.15	4.42 (0.07)	4.04 (0.07)
	1.0	7.10 (0.10)	4.59 (0.10	6.40 (0.18)	4.22 (0.08)
	1.5	12.20 (0.61)	7.44 (0.42	12.93 (0.59)	6.21 (0.30)
	2.0	18.00 (0.50)	10.89 (0.37	19.00 (0.50)	9.98 (0.48)
	2.5	19.37 (0.25)	16.20 (0.44	25.50 (1.32)	40.93 (0.67)
	3.0	21.47 (1.27)	29.40 (0.89)	39.50 (1.15)	65.80 (1.30)
	4.0	- -	- -	- -	411.04 (1.12)

Appendix F

Ultrasperse®2000 (UT)

Ultrasperse®2000 (UT) is a high performance, cold water swelling modified food starch derived from waxy maize. It is particularly well suited for instant food preparations where high viscosity and creamy mouthfeel are desired. It exhibits excellent dispersibility and imparts superior sheen and smoothness when compared to traditional pregelatinized starches

Physical Properties:

Color	White to off-white
Form	Free-flowing coarse powder
Moisture	Approximately 8%
PH	Approximately 6

Features and Benefits

Ultrasperse®2000 (UT) disperses easily in hot or cold water without lumping and yields a heavy bodied, short texture with excellent sheen. The product is well suited for mild to moderate processing conditions, yielding rapid, high viscosity development. The product imparts a rich, creamy mouthfeel to prepared foods. It also offers excellent cold temperature storage stability to refrigerated or frozen foods.

Applications

Ultrasperse®2000 (UT) is recommended for many instant food applications where excellent dispersibility, high viscosity and rich mouthfeel are required. Ultrasperse®2000 (UT) is ideally suited for instant cream style soups, cheese sauces, and savory gravies that are to be microwave reconstituted or kept on a steam table for long periods of time.

Since Ultrasperse®2000 (UT) is particularly resistant to heating, it is also recommended for use in turnover fillings, etc. ,to retard boil out during cooking.

Ultrasperse®2000 (UT) is strongly recommended when an instant thickener with excellent dispersibility is required. Additionally, it delivers rapid high viscosity and premium cook up textural characteristics.

Label Declaration:

Food Starch - Modified

Citric Acid Monohydrate

Nonproprietary Names

BP:Citric acid monohydrate

PhEur:Acidum citricum monohydricum

USP: Citric acid

Synonyms

2-Hydroxypropane-1, 2, 3-tricarboxylic acid monohydrate

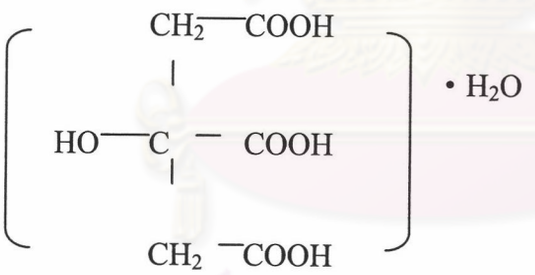
Chemical Name and CAS Registry Number

2-Hydroxy-1, 2, 3-propanetricarboxylic acid monohydrate [5949-29-1]

Empirical Formula **Molecular Weight**

$C_6H_8O_7H_2O$ 210.14

Structural Formula



Functional Category

Acidifying agent; buffering agent; chelating agent; flavor enhancer.

Applications in Pharmaceutical Formulation or Technology

Citric acid, as either the monohydrate or anhydrous material, is widely used in Pharmaceutical formulations and food products primarily to adjust the pH of solutions. Citric acid monohydrate is used in the preparation of effervescent granules whilst anhydrous citric acid is widely used in the preparation of effervescent tablets

In food products citric acid is used as a flavor enhancer, for its tart, acid taste. Citric acid monohydrate is also used as a sequestering agent and antioxidant synergist.

Use	Concentration (%)
Flavor improver in liquid formulations	0.3-2.0
Sequestering agent	0.3-2.0

Description

Citric acid monohydrate occurs as colorless or translucent. Crystals or as a white crystalline efflorescent powder, it is odorless and has a strong acidic taste. Crystal structure is Orthorhombic.

Typical Properties

Acidity/ alkalinity: pH = 2.2{1% w/v aqueous solution}

Density: 1.542 g / cm^3

Heat of combustions:

- 1972 kJ/mol (-471.4 kcel/mol)

Heat of solution:

- 16.3 kJ/mol (-3.9 kcel/mol) at 25°C

Hygroscopic: at relative humidity less than about 65% citric acid monohydrate effloresces at 25 °C, the anhydrous acid being formed at relative humidity less than about 40% alterative humidity between about 65-755, Citric acid monohydrate absorbed insignificant amounts of moisture but under more humidity conditions substantial amounts of water are a absorbed

Melting point: ≈100℃ (softens at 75℃)

Solubility: soluble 1 in 1.5 parts of ethanol (95%) and 1 in less than 1 part of water, sparingly soluble in ether.

Viscosity (dynamic):6.5mPas(6.5cP)for a50%w/

Acesulfame Potassium

1. Nonproprietary Names

BAN: Acesulfame potassium

I NN: Acesulfame potassium

2. Synonyms

Acesulfame K;E950; 6-methyl-3,4-dihydro-1,2,3-oxathiazin-4(*3H*)-one 2,2-dioxide potassium salt; *Sunett.*

3. Chemical Name and CAS R registry Number

6-Methyl-1,2,3-oxathiazin-4(*3H*)-one 2,2-dioxide potassium salt [55589-62-3]

4. Empirical Formula Molecular Weight

$C_4 H_4 KNO_4 S$ 201.24

6. Functional Category

Sweetening agent

7. Applications in Pharmaceutical Formulation or Technology

Acesulfame Potassium is used as an intense sweetening agent in cosmetics, foods, beverage products, table-top sweeteners, vitamin and pharmaceutical excipients including powder mixes, tablets and liquid products. The approximate sweetening powder is 180-200 times that of sucrose. It enhances flavor systems and can be used to mask some unpleasant taste characteristics.

8. Description

Acesulfame potassium occurs as a colorless to white-colored, odorless, crystalline powder with an intensely sweet taste.

10. Typical Properties

Density (bulk): 1.1-1.3 g/cm^3

Melting point;250 C. decomposition can be observed at 225° C If slowly heated.

Solubility;

Solvent	Solubility at 20° °C Unless otherwise stated
Ethanol	I in 1000
Ethanol (50%)	I in 100
Water	I in 7.1 at 0 °C
	I in 3.7
	I in 0.77 at 100°C

12. Stability and Storage Conditions

Acesulfame potassium possesses good stability. In the bulk from it shows no sign of decomposition, at ambient temperature. Over many years, in aqueous solutions (pH 3-3.5 at 20 °C) no reduction in sweetness was observed over a period of approximately 2 years. Stability at elevated temperatures is good. Although, some decomposition was noted following storage at 40° °C for several months. Sterilization and pasteurization do not affect the taste of acesulfame potassium. The bulk material should be stored in a well-closed container in a cool, dry place.

13. Method of Manufacture

Acesulfame potassium is synthesized from acetoacetic acid *tert-butyl* ester and fluorosulfonyl isocyanate. The resulting compound is transfmed to fluorosulfonyl acetoacetic acid amide which is then cyclized, in the presence of potassium hydroxide, to from the oxathiazinone dioxide ring system. Because of the strong acidity of thid compound the potassium salt is produced directly.

14. Safety

Pharmacokinetic studies have shown that acesulfame potassium is not metabolized and is rapidly excreted unchanged in the urine. Long-term feeding studies in rats and dogs showed no evidence to suggest acesulfame potassium is mutagenic or carcinogenic. The WHO has set an acceptable daily intake for acesulfame potassium of up to 15 mg/kg body-weight.

LD_{50}(rat,IP):2.2 g/kg

LD_{50}(rat,oral):6.9-8.0 g/kg

15. Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection. Gloves and a dust mask are recommended.

16. Comments

The perceived intensity of sweeteners relative to sucrose depends upon their concentration. Temperature of tasting, pH and on the flavor and texture of the product concerned. Intense sweetening agents will not replace the latter ingredient is removed from a formulation. Synergistic effects for combinations of sweeteners have been reported. e.g. acesulfame potassium with aspartame or sodium cyclamate.

Note that free acesulfame acid is not suitable for use as a sweetener. Although there are no pharmacopoeia specifications for acesulfame potassium, the FAO, in 1983, set the following limits for acesulfame potassium purity.

Appendix G

Stability

Table G1 Viscosity of selected amoxicillin trihydrate reconstitution suspension using difference suspending agents, kept at room temperature and 45 °C, 75 % RH for 4 months

	Suspending agents	Viscosity (cps) Average (SD)							
		Initial		1 month		2 months		3 months		4 months	
CR	MGS	538.42	(5.47)	535.76	(5.06)	528.82	(1.42)	525.34	(1.89)	521.20	(2.11)
	MRS	623.83	(10.65)	608.48	(2.61)	591.12	(4.62)	588.78	(1.34)	579.46	(1.75)
	UT	450.47	(11.44)	448.08	(4.49)	438.83	(1.41)	433.13	(2.33)	424.73	(3.16)
CS	MGS	538.42	(5.47)	529.35	(6.44)	526.31	(3.63)	521.39	(1.00)	515.51	(1.69)
	MRS	623.83	(10.65)	597.12	(6.22)	584.70	(4.96)	572.14	(4.36)	565.58	(4.79)
	UT	450.47	(11.44)	440.89	(7.76)	422.54	(4.14)	417.61	(3.92)	405.26	(2.80)

Table G2 Viscosity of selected cephalexin monohydrate reconstitution suspension using difference suspending agents, kept at room temperature and 45 °C, 75 % RH for 4 months

	Suspending agents	Viscosity (cps) Average (SD)							
		Initial		1 month		2 months		3 months		4 months	
CR	MGS	563.92	(9.00)	551.19	(2.68)	541.53	(3.16)	535.93	(5.21)	529.06	(7.89)
	MRS	415.05	(10.48)	403.12	(3.61)	394.90	(2.54)	389.94	(5.29)	384.68	(1.26)
	UT	408.11	(2.42)	406.17	(3.20)	402.70	(1.69)	393.82	(3.17)	386.76	(2.72)
CS	MGS	563.92	(9.00)	551.49	(3.69)	541.19	(4.25)	530.19	(5.23)	521.17	(9.29)
	MRS	415.05	(10.48)	389.84	(5.53)	380.51	(3.69)	371.20	(4.09)	368.59	(2.05)
	UT	408.11	(2.42)	399.66	(3.92)	382.96	(3.87)	371.57	(7.07)	365.91	(3.06)

Table G3 Average number of inversion selected amoxicillin trihydrate reconstitution suspension using difference suspending agents, kept at room temperature and 45 °C, 75 % RH for 4 months

	Suspending agents	Average number of inversion (times) Average (SD)				
		Initial	1 month	2 months	3 months	4 months
CR	MGS	3.33 (0.58)	3.00 (0.00)	3.67 (0.58)	3.67 (0.58)	3.00 (0.00)
	MRS	3.00 (0.00)	3.33 (0.58)	3.33 (0.58)	3.33 (0.58)	3.67 (0.58)
	UT	2.67 (0.58)	3.00 (0.00)	3.33 (0.58)	3.67 (0.58)	3.67 (0.58)
CS	MGS	4.33 (0.58)	4.67 (0.58)	5.33 (0.58)	5.67 (0.58)	5.33 (0.58)
	MRS	4.33 (0.58)	5.00 (0.00)	4.67 (0.58)	4.67 (0.58)	5.33 (0.58)
	UT	4.00 (0.00)	5.00 (0.00)	4.67 (0.58)	5.67 (0.58)	5.00 (1.00)

Table G4 Average number of inversion of selected cephalexin monohydrate reconstitution suspension using difference suspending agents, kept at room temperature and 45 °C, 75 % RH for 4 months

	Suspending agents	Average number of inversion (times) Average (SD)				
		Initial	1 month	2 months	3 months	4 months
CR	MGS	4.33 (0.58)	4.33 (1.15)	4.67 (0.58)	5.00 (0.00)	5.33 (0.58)
	MRS	4.33 (0.58)	4.00 (0.00)	4.67 (0.58)	4.67 (0.58)	4.67 (0.58)
	UT	4.00 (0.00)	4.33 (0.58)	4.33 (0.58)	4.67 (0.58)	5.00 (0.00)
CS	MGS	4.33 (0.58)	4.67 (0.58)	5.33 (0.58)	5.67 (0.58)	5.33 (0.58)
	MRS	4.33 (0.58)	5.00 (0.00)	4.67 (0.58)	4.67 (0.58)	5.33 (0.58)
	UT	4.00 (0.00)	5.00 (0.00)	4.67 (0.58)	5.67 (0.58)	5.00 (1.00)

Table G5 Percentage drugs remaining of amoxicillin monohydrate reconstituted suspensions using different suspending agent, when kept at room temperature for 14 days. Based on dry syrup (powder) stored room temperature for 4 months

Suspending agent	days	Drug content (%) Average (SD)									
		Initial		1 months		2 months		3 months		4 months	
MGS	0	104.83	(1.90)	103.09	(1.44)	102.99	(2.44)	101.58	(2.40)	100.92	(0.87)
	1	103.90	(1.40)	101.13	(1.14)	101.84	(1.91)	100.35	(1.84)	100.22	(3.22)
	3	100.58	(0.63)	101.76	(2.91)	99.64	(1.95)	99.02	(0.97)	97.59	(1.98)
	5	101.76	(2.84)	97.34	(2.01)	99.77	(4.55)	100.20	(1.50)	94.76	(3.88)
	7	97.63	(0.66)	92.56	(2.54)	94.47	(3.92)	90.85	(2.25)	93.06	(1.77)
	10	95.26	(2.45)	90.92	(1.35)	93.01	(3.37)	91.19	(1.36)	92.96	(1.81)
	14	95.16	(0.27)	90.47	(0.89)	90.41	(0.60)	91.31	(2.85)	91.23	(0.52)
MRS	0	104.56	(1.59)	104.62	(0.61)	104.27	(1.05)	102.81	(0.50)	101.12	(0.84)
	1	102.22	(1.58)	103.65	(1.36)	103.29	(0.86)	100.19	(0.78)	98.35	(0.91)
	3	100.69	(0.78)	101.00	(2.84)	100.66	(2.25)	101.25	(2.82)	97.76	(2.18)
	5	101.76	(2.84)	99.90	(2.62)	102.08	(0.56)	93.97	(2.35)	96.58	(1.02)
	7	97.88	(0.70)	97.54	(1.24)	96.96	(1.65)	92.24	(0.90)	93.06	(1.77)
	10	95.26	(2.45)	93.30	(0.69)	94.31	(1.33)	92.19	(1.80)	93.61	(0.71)
	14	95.60	(0.69)	94.68	(0.73)	95.58	(0.52)	90.75	(0.46)	89.46	(1.33)
UT	0	101.31	(1.97)	99.34	(2.01)	98.84	(2.00)	94.89	(1.92)	94.41	(1.91)
	1	99.25	(2.32)	97.06	(1.96)	96.58	(1.95)	92.72	(1.87)	92.25	(1.86)
	3	99.79	(0.58)	99.42	(2.26)	98.93	(2.25)	94.97	(2.16)	94.49	(2.15)
	5	100.35	(2.13)	98.51	(2.39)	94.57	(2.29)	90.79	(2.20)	91.45	(1.32)
	7	100.15	(2.21)	98.22	(2.11)	94.29	(2.02)	90.52	(1.94)	90.86	(0.94)
	10	99.27	(2.15)	98.82	(3.65)	94.86	(3.51)	91.07	(3.37)	91.56	(2.03)
	14	97.83	(2.65)	95.94	(3.17)	92.10	(3.04)	88.42	(2.92)	89.81	(1.13)

Table G6 Percentage drugs remaining of amoxicillin monohydrate reconstituted suspensions using different suspending agent, when kept at refrigerator (8 ±1 °C) for 14 days. Based on dry syrup (powder) stored at room temperature for 4 months

Suspending agent	days	Drug content (%) Average (SD)				
		Initial	1 months	2 months	3 months	4 months
MGS	0	105.65 (1.50)	102.13 (2.98)	101.89 (0.65)	102.28 (1.38)	100.25 (0.50)
	1	103.74 (0.53)	102.04 (0.15)	101.47 (0.61)	100.82 (0.98)	99.53 (1.90)
	3	101.15 (0.96)	100.36 (1.17)	99.88 (1.94)	99.77 (0.14)	98.32 (1.46)
	5	100.81 (0.81)	99.84 (1.53)	99.43 (0.89)	100.33 (1.00)	99.73 (2.21)
	7	101.03 (1.34)	99.53 (2.07)	100.75 (1.77)	97.67 (4.09)	96.77 (4.94)
	10	100.92 (1.27)	99.29 (1.21)	99.08 (2.38)	96.51 (3.56)	98.16 (3.44)
	14	101.10 (0.91)	99.48 (1.78)	97.93 (1.67)	98.29 (3.44)	98.21 (4.09)
MRS	0	105.65 (1.50)	103.45 (1.12)	101.70 (2.25)	102.44 (0.91)	102.64 (1.77)
	1	103.74 (0.53)	102.36 (0.76)	101.66 (1.37)	100.66 (0.95)	101.91 (2.04)
	3	101.15 (0.96)	100.36 (1.76)	99.74 (1.72)	102.23 (0.87)	100.28 (0.55)
	5	101.58 (1.16)	101.14 (2.54)	100.10 (2.88)	100.70 (1.50)	102.22 (0.89)
	7	100.51 (0.88)	100.38 (2.68)	101.72 (1.06)	101.66 (2.19)	101.08 (1.98)
	10	101.16 (1.99)	100.37 (2.99)	101.15 (0.45)	102.54 (1.19)	101.61 (0.86)
	14	97.78 (2.23)	98.26 (4.60)	101.27 (0.95)	100.06 (1.19)	100.38 (1.87)
UT	0	101.42 (1.81)	102.83 (2.22)	101.28 (1.71)	101.32 (0.64)	100.29 (0.52)
	1	101.24 (2.03)	100.66 (1.47)	101.82 (0.88)	101.67 (0.67)	101.01 (1.67)
	3	101.37 (1.99)	102.93 (0.83)	100.47 (1.16)	100.82 (1.94)	99.90 (0.96)
	5	101.56 (1.12)	99.93 (2.32)	101.81 (0.86)	101.69 (1.18)	99.54 (1.10)
	7	102.28 (0.18)	99.99 (2.03)	101.43 (1.55)	99.77 (0.28)	99.47 (2.54)
	10	100.61 (1.41)	99.49 (2.02)	102.14 (0.88)	99.74 (0.77)	99.05 (2.37)
	14	99.17 (1.88)	99.56 (2.86)	103.11 (0.32)	100.47 (0.61)	97.94 (1.52)

Table G7 Percentage drugs remaining of amoxicillin monohydrate reconstituted suspensions using different suspending agent, when kept at room temperature for 14 days. Based on dry syrup (powder) stored at temperature 45 ^{0}C, 75% RH for 4 months

Suspending agent	days	Drug content (%) Average (SD)				
		Initial	1 months	2 months	3 months	4 months
MGS	0	104.83 (1.90)	103.09 (1.44)	102.99 (2.44)	101.58 (2.40)	100.92 (0.87)
	1	103.90 (1.40)	101.13 (1.14)	101.84 (1.91)	100.35 (1.84)	100.22 (3.22)
	3	100.58 (0.63)	101.76 (2.91)	99.64 (1.95)	99.02 (0.97)	97.59 (1.98)
	5	101.76 (2.84)	97.34 (2.01)	99.77 (4.55)	100.20 (1.50)	94.76 (3.88)
	7	97.63 (0.66)	92.56 (2.54)	94.47 (3.92)	90.85 (2.25)	93.06 (1.77)
	10	95.26 (2.45)	90.92 (1.35)	93.01 (3.37)	91.19 (1.36)	92.96 (1.81)
	14	95.16 (0.27)	90.47 (0.89)	90.41 (0.60)	91.31 (2.85)	90.60 (1.15)
MRS	0	104.83 (1.90)	104.62 (0.61)	104.27 (1.05)	102.81 (0.50)	101.12 (0.84)
	1	103.90 (1.40)	103.65 (1.36)	103.29 (0.86)	100.08 (0.62)	98.35 (0.91)
	3	100.58 (0.63)	101.00 (2.84)	100.66 (2.25)	101.25 (2.82)	97.76 (2.18)
	5	101.76 (2.84)	99.90 (2.62)	102.08 (0.56)	93.97 (2.35)	96.58 (1.02)
	7	97.63 (0.66)	97.54 (1.24)	96.96 (1.65)	92.24 (0.90)	93.06 (1.77)
	10	95.26 (2.45)	93.30 (0.69)	94.31 (1.33)	92.19 (1.80)	93.61 (0.71)
	14	95.16 (0.27)	94.68 (0.73)	95.58 (0.52)	90.75 (0.46)	89.46 (1.33)
UT	0	105.65 (1.50)	103.54 (1.47)	102.50 (1.45)	101.37 (1.19)	99.91 (0.57)
	1	103.74 (0.53)	101.67 (0.52)	101.42 (0.82)	100.65 (0.95)	98.57 (1.09)
	3	101.15 (0.96)	99.13 (0.94)	98.14 (0.93)	98.27 (1.42)	96.67 (1.83)
	5	98.76 (1.42)	96.79 (1.40)	95.82 (1.38)	96.62 (2.20)	96.15 (2.12)
	7	97.10 (2.21)	96.40 (1.68)	95.44 (1.66)	95.63 (2.91)	94.57 (1.33)
	10	97.07 (1.95)	95.13 (1.92)	94.17 (1.90)	94.90 (0.65)	93.81 (0.41)
	14	94.29 (1.05)	92.41 (1.03)	92.62 (2.39)	92.72 (2.81)	89.95 (0.51)

Table G8 Percentage drugs remaining of amoxicillin monohydrate reconstituted suspensions using different suspending agent, when kept at refrigerator (8 ±1 °C) for 14 days. Based on dry syrup (powder) stored at temperature 45 ^{0}C, 75% RH for 4 months

Suspending agent	days	Drug content (%) Average (SD)				
		Initial	1 months	2 months	3 months	4 months
MGS	0	103.87 (2.48)	103.35 (2.46)	102.32 (2.44)	101.77 (1.93)	99.42 (0.36)
	1	102.28 (1.94)	101.77 (1.93)	101.95 (0.88)	99.87 (0.66)	98.43 (1.09)
	3	100.37 (0.66)	99.87 (0.66)	98.87 (0.65)	100.42 (1.18)	98.50 (2.75)
	5	100.92 (1.19)	100.42 (1.18)	99.41 (1.17)	98.99 (2.75)	98.23 (2.46)
	7	99.49 (2.76)	98.99 (2.75)	98.00 (2.72)	95.86 (3.29)	94.57 (1.33)
	10	100.25 (0.27)	99.75 (0.26)	98.76 (0.26)	96.64 (2.91)	95.52 (2.97)
	14	100.01 (0.56)	99.51 (0.56)	97.60 (2.15)	96.23 (1.56)	95.28 (1.53)
MRS	0	104.33 (2.69)	103.80 (2.68)	102.77 (2.65)	101.05 (1.16)	99.05 (0.56)
	1	101.56 (1.16)	101.05 (1.16)	101.24 (1.00)	99.27 (0.48)	97.83 (0.44)
	3	99.77 (0.48)	99.27 (0.48)	98.28 (0.48)	100.16 (0.98)	98.24 (2.54)
	5	100.66 (0.99)	100.16 (0.98)	99.16 (0.97)	97.53 (0.71)	96.78 (0.36)
	7	98.02 (0.71)	97.53 (0.71)	96.55 (0.70)	93.56 (1.39)	94.74 (1.41)
	10	100.22 (0.32)	99.72 (0.32)	98.72 (0.31)	94.63 (0.90)	93.53 (0.65)
	14	99.79 (0.44)	99.29 (0.44)	97.38 (1.97)	95.99 (1.36)	95.03 (1.33)
UT	0	105.05 (0.98)	104.53 (0.97)	103.48 (0.96)	103.22 (1.12)	99.59 (0.56)
	1	103.74 (1.13)	103.22 (1.12)	102.19 (1.11)	100.32 (0.93)	99.31 (0.92)
	3	100.82 (0.94)	100.32 (0.93)	99.31 (0.92)	101.31 (0.39)	100.29 (0.39)
	5	101.82 (0.39)	101.31 (0.39)	100.29 (0.39)	100.93 (2.42)	99.92 (2.39)
	7	101.44 (2.43)	100.93 (2.42)	99.92 (2.39)	97.47 (3.88)	95.27 (0.50)
	10	100.25 (0.27)	99.75 (0.26)	98.76 (0.26)	98.23 (3.36)	97.25 (3.33)
	14	100.53 (0.35)	100.03 (0.35)	99.03 (0.34)	97.33 (0.37)	96.36 (0.37)

Table G9 Percentage drugs remaining of cephalexin monohydrate reconstituted suspensions using different suspending agent, when kept at room temperature for 14 days. Based on dry syrup (powder) stored room temperature for 4 months

Suspending agent	days	Drug content (%) Average (SD)				
		Initial	1 months	2 months	3 months	4 months
MGS	0	103.14 (2.01)	100.99 (1.29)	100.94 (1.99)	101.03 (1.29)	101.46 (1.46)
	1	101.75 (2.38)	101.69 (1.35)	100.31 (0.71)	101.17 (0.39)	101.00 (0.54)
	3	100.89 (1.08)	102.76 (0.81)	101.96 (0.92)	101.16 (0.91)	101.02 (0.79)
	5	101.98 (0.63)	101.29 (0.82)	101.24 (1.51)	100.23 (0.92)	101.18 (1.39)
	7	100.36 (1.87)	101.22 (1.79)	100.38 (1.48)	100.60 (1.42)	99.99 (0.93)
	10	101.42 (0.17)	100.44 (1.18)	101.03 (1.32)	98.71 (5.72)	98.48 (4.12)
	14	101.10 (1.02)	102.17 (1.78)	101.12 (1.38)	98.52 (3.48)	98.81 (1.05)
MRS	0	104.83 (1.90)	104.62 (0.61)	101.70 (1.53)	102.81 (0.50)	101.12 (0.84)
	1	103.90 (1.40)	103.65 (1.36)	100.91 (0.52)	100.08 (0.62)	99.32 (1.65)
	3	100.58 (0.63)	101.01 (0.21)	100.03 (0.16)	100.56 (1.57)	100.82 (2.07)
	5	100.91 (0.52)	100.00 (0.55)	101.81 (0.56)	99.97 (1.17)	98.15 (1.63)
	7	101.14 (1.58)	101.32 (1.30)	100.09 (1.00)	101.70 (1.53)	98.95 (1.72)
	10	101.43 (0.41)	100.56 (1.57)	100.81 (0.81)	100.91 (0.52)	98.69 (1.36)
	14	98.29 (0.62)	99.97 (1.17)	101.03 (1.34)	98.63 (1.55)	99.37 (0.81)
UT	0	104.61 (1.56)	101.94 (0.37)	101.38 (1.74)	101.55 (1.91)	100.97 (1.19)
	1	103.74 (0.53)	101.65 (1.49)	100.54 (0.77)	100.91 (1.20)	100.31 (2.37)
	3	101.15 (0.96)	100.75 (1.56)	101.37 (1.52)	100.49 (0.15)	101.75 (1.93)
	5	100.63 (0.39)	100.09 (1.65)	101.54 (1.29)	102.25 (1.32)	100.68 (0.96)
	7	100.63 (0.92)	100.52 (2.83)	100.53 (0.75)	99.17 (1.82)	99.05 (1.47)
	10	100.09 (1.03)	99.37 (2.24)	101.95 (0.60)	99.46 (0.64)	100.68 (1.62)
	14	99.39 (3.70)	100.21 (0.71)	101.51 (1.44)	100.35 (0.94)	100.89 (1.99)

Table G10 Percentage drugs remaining of cephalexin monohydrate reconstituted suspensions using different suspending agent, when kept at refrigerator (8 ±1 °C) for 14 days. Based on dry syrup (powder) stored at room temperature for 4 months

Suspending agent	days	Drug content (%) Average (SD)				
		Initial	1 months	2 months	3 months	4 months
MGS	0	105.65 (1.50)	104.72 (1.48)	103.67 (1.47)	102.40 (0.93)	101.85 (1.31)
	1	103.74 (0.53)	102.83 (0.52)	102.19 (0.16)	100.62 (1.29)	99.49 (1.16)
	3	101.15 (0.96)	100.26 (0.95)	99.26 (0.94)	99.97 (2.02)	100.94 (2.30)
	5	101.75 (1.27)	100.86 (1.25)	99.85 (1.24)	99.41 (1.90)	100.57 (2.35)
	7	100.32 (0.90)	99.44 (0.89)	98.45 (0.88)	100.38 (2.56)	98.93 (1.62)
	10	101.41 (0.17)	100.51 (0.17)	99.51 (0.17)	100.32 (2.35)	99.44 (2.33)
	14	101.06 (1.03)	100.18 (1.02)	98.08 (2.68)	101.54 (2.10)	99.68 (2.53)
MRS	0	103.73 (2.92)	103.70 (1.36)	102.20 (1.20)	100.71 (1.69)	101.13 (1.90)
	1	102.88 (1.25)	102.74 (0.44)	101.46 (1.18)	100.74 (0.88)	99.65 (0.77)
	3	100.88 (1.09)	100.91 (1.42)	100.91 (0.60)	100.77 (0.54)	101.12 (1.67)
	5	101.95 (0.96)	101.21 (0.73)	100.16 (0.66)	100.72 (1.75)	100.93 (1.84)
	7	100.97 (0.32)	101.04 (1.91)	100.29 (1.66)	101.00 (1.95)	99.72 (0.93)
	10	101.35 (0.20)	100.05 (0.81)	99.42 (1.16)	101.18 (1.95)	100.39 (1.96)
	14	101.58 (1.14)	100.67 (1.12)	100.03 (0.58)	102.13 (1.09)	99.78 (2.67)
UT	0	102.66 (2.59)	103.30 (1.20)	101.87 (0.66)	100.92 (2.05)	102.07 (1.33)
	1	102.53 (0.88)	101.60 (1.72)	102.04 (0.81)	100.13 (0.74)	99.95 (1.25)
	3	101.51 (1.08)	102.14 (0.89)	102.24 (1.18)	101.35 (1.48)	102.13 (1.94)
	5	101.18 (0.65)	101.52 (1.25)	100.51 (0.86)	101.04 (2.13)	101.60 (1.22)
	7	101.84 (1.21)	101.33 (1.66)	102.15 (1.10)	101.17 (1.85)	100.14 (1.21)
	10	100.65 (1.32)	100.73 (1.61)	99.24 (1.15)	101.51 (2.08)	101.21 (2.61)
	14	102.23 (1.96)	101.08 (1.59)	101.64 (2.20)	102.68 (0.23)	100.86 (1.28)

Table G11 Percentage drugs remaining of cephalexin monohydrate reconstituted suspensions using different suspending agent, when kept at room temperature for 14 days. Based on dry syrup (powder) stored at temperature 45 ^{0}C, 75% RH for 4 months

Suspending agent	days	Drug content (%) Average (SD)				
		Initial	1 months	2 months	3 months	4 months
MGS	0	102.36 (2.11)	101.33 (2.09)	100.32 (2.07)	102.05 (0.91)	100.54 (0.73)
	1	102.57 (0.92)	101.54 (0.91)	100.91 (1.43)	100.96 (1.04)	99.94 (1.02)
	3	101.46 (1.04)	100.45 (1.03)	99.44 (1.02)	100.53 (0.43)	99.43 (0.28)
	5	101.04 (0.43)	100.03 (0.42)	99.03 (0.42)	101.28 (1.25)	99.30 (2.64)
	7	101.79 (1.26)	100.77 (1.25)	99.77 (1.24)	100.58 (1.86)	99.67 (0.86)
	10	100.31 (1.07)	100.41 (0.96)	99.41 (0.95)	98.84 (3.93)	98.96 (1.60)
	14	101.15 (0.95)	100.10 (0.99)	97.88 (2.57)	98.80 (1.00)	98.17 (0.50)
MRS	0	104.83 (1.90)	103.79 (1.88)	102.75 (1.86)	101.72 (1.84)	100.70 (1.82)
	1	103.90 (1.40)	102.86 (1.39)	101.83 (1.37)	100.81 (1.36)	99.80 (1.35)
	3	100.58 (0.63)	99.57 (0.62)	98.58 (0.61)	97.59 (0.61)	98.26 (1.31)
	5	100.91 (0.52)	99.90 (0.51)	98.91 (0.51)	97.92 (0.50)	97.69 (0.82)
	7	101.14 (1.58)	100.13 (1.57)	99.13 (1.55)	98.14 (1.54)	98.60 (1.48)
	10	101.43 (0.41)	100.42 (0.41)	99.41 (0.40)	98.42 (0.40)	97.44 (0.39)
	14	98.29 (0.62)	97.30 (0.62)	96.33 (0.61)	98.42 (1.96)	98.01 (1.35)
UT	0	104.08 (1.64)	101.66 (1.65)	101.26 (1.70)	100.37 (1.07)	99.05 (0.63)
	1	103.78 (0.46)	101.50 (0.37)	100.39 (0.42)	99.60 (0.38)	98.61 (0.37)
	3	101.23 (1.07)	99.75 (1.33)	99.31 (2.07)	98.46 (2.26)	98.49 (1.23)
	5	101.95 (2.31)	100.35 (1.87)	100.12 (1.85)	98.98 (1.76)	97.99 (1.74)
	7	101.36 (1.84)	100.33 (0.99)	99.32 (0.98)	98.33 (0.97)	97.34 (0.96)
	10	100.09 (1.03)	99.42 (1.75)	98.49 (1.82)	97.50 (1.81)	96.53 (1.79)
	14	101.03 (1.08)	100.07 (1.30)	99.11 (1.35)	98.12 (1.33)	96.38 (2.55)

Table G12 Percentage drugs remaining of cephalexin monohydrate reconstituted suspensions using different suspending agent, when kept at refrigerator (8 ±1 °C) for 14 days. Based on dry syrup (powder) stored at temperature 45 ^{0}C, 75% RH for 4 months

Suspending agent	days	Drug content (%) Average (SD)				
		Initial	1 months	2 months	3 months	4 months
MGS	0	105.65 (1.50)	102.97 (0.84)	100.42 (0.87)	102.03 (0.66)	101.46 (1.40)
	1	102.51 (2.00)	101.91 (0.31)	102.14 (1.02)	100.92 (0.61)	100.91 (1.80)
	3	101.42 (0.63)	100.09 (0.88)	101.26 (1.68)	101.42 (1.59)	100.47 (0.65)
	5	100.05 (1.33)	100.17 (1.88)	100.37 (1.01)	100.30 (1.02)	101.12 (1.33)
	7	99.08 (2.45)	99.25 (1.72)	99.38 (2.54)	100.14 (1.31)	99.85 (3.58)
	10	99.66 (1.54)	99.44 (2.02)	100.46 (1.58)	99.61 (4.65)	99.47 (2.54)
	14	98.16 (2.56)	99.33 (1.70)	99.26 (0.98)	99.89 (1.37)	99.05 (1.24)
MRS	0	106.29 (0.89)	102.88 (0.98)	99.88 (1.37)	101.42 (1.16)	100.23 (0.87)
	1	100.89 (2.01)	101.60 (0.51)	102.46 (0.52)	100.56 (1.06)	99.43 (0.88)
	3	101.06 (1.06)	100.27 (0.57)	101.47 (1.73)	100.26 (0.50)	99.84 (1.14)
	5	100.05 (1.33)	101.08 (0.87)	99.84 (0.71)	100.49 (0.68)	99.90 (1.28)
	7	99.29 (2.55)	99.44 (1.46)	97.82 (0.63)	99.23 (1.83)	97.28 (3.46)
	10	100.02 (1.53)	99.94 (1.25)	99.09 (1.12)	96.34 (4.27)	97.85 (3.08)
	14	99.31 (0.57)	98.75 (2.21)	98.57 (1.49)	99.22 (1.91)	99.55 (0.69)
UT	0	106.29 (0.89)	102.88 (0.98)	99.88 (1.37)	101.42 (1.16)	100.23 (0.87)
	1	101.32 (1.10)	99.96 (0.94)	100.94 (0.63)	100.18 (1.95)	98.67 (1.93)
	3	102.09 (1.04)	101.29 (0.56)	101.14 (1.17)	101.13 (0.67)	99.00 (1.20)
	5	101.43 (0.80)	99.29 (1.22)	101.56 (1.80)	99.92 (0.58)	98.93 (1.88)
	7	99.39 (0.82)	101.61 (1.28)	100.26 (1.00)	101.63 (0.73)	100.26 (1.01)
	10	98.21 (2.63)	101.61 (0.72)	98.70 (1.26)	100.67 (0.72)	100.23 (1.01)
	14	98.76 (2.97)	100.93 (0.58)	99.33 (0.94)	100.09 (1.11)	100.35 (1.01)

Appendix H

Table H1 Analysis of variance of pH of amoxicillin trihydrate suspension containing MGS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	4.827E-03	4	1.207E-03	1.046	0.431
Within Groups	1.153E-02	10	1.153E-03		
Total	1.636E-02	14			

Table H2 Dependent comparison (Duncan's New Multiple Range Test) for pH of amoxicillin trihydrate suspension containing MGS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H3 Analysis of variance of pH of amoxicillin trihydrate suspension containing MRS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	9.693E-03	4	2.423E-03	1.289	0.338
Within Groups	1.880E-02	10	1.880E-03		
Total	2.849E-02	14			

Table H4 Dependent comparison (Duncan's New Multiple Range Test) for pH of amoxicillin trihydrate suspension containing MRS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H5 Analysis of variance of pH of amoxicillin trihydrate suspension containing UT as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	4.893E-03	4	1.223E-03	0.350	0.839
Within Groups	3.500E-02	10	3.500E-03		
Total	3.989E-02	14			

Table H6 Dependent comparison (Duncan's New Multiple Range Test) for pH of amoxicillin trihydrate suspension containing UT as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H7 Analysis of variance of pH of amoxicillin trihydrate suspension containing MGS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	1.667E-02	4	4.167E-03	2.376	0.122
Within Groups	1.753E-02	10	1.753E-03		
Total	3.420E-02	14			

Table H8 Dependent comparison (Duncan's New Multiple Range Test) for pH of amoxicillin trihydrate suspension containing MGS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H9 Analysis of variance of pH of amoxicillin trihydrate suspension containing MRS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	2.723E-02	4	6.807E-03	4.498	0.025
Within Groups	1.513E-02	10	1.513E-03		
Total	4.236E-02	14			

Table H10 Dependent comparison (Duncan's New Multiple Range Test) for pH of amoxicillin trihydrate suspension containing MRS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	S
Month 1		-	S	NS	NS
Month 2			-	S	S
Month 3				-	NS
Month 4					-

Table H11 Analysis of variance of pH of amoxicillin trihydrate suspension containing UT as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	9.293E-03	4	2.323E-03	0.999	0.452
Within Groups	2.327E-02	10	2.327E-03		
Total	3.256E-02	14			

Table H12 Dependent comparison (Duncan's New Multiple Range Test) for pH of amoxicillin trihydrate suspension containing UT as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H13 Analysis of variance of pH of cephalexin suspension containing MGS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	9.027E-03	4	2.257E-03	0.967	0.467
Within Groups	2.333E-02	10	2.333E-03		
Total	3.236E-02	14			

Table H14 Dependent comparison (Duncan's New Multiple Range Test) for pH of cephalexin suspension containing MGS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H15 Analysis of variance of pH of cephalexin suspension containing MRS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	7.107E-03	4	1.777E-03	2.050	0.163
Within Groups	8.667E-03	10	8.667E-04		
Total	1.577E-02	14			

Table H16 Dependent comparison (Duncan's New Multiple Range Test) for pH of cephalexin suspension containing MRS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H17 Analysis of variance of pH of cephalexin suspension containing UT as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	3.467E-03	4	8.667E-04	0.670	0.627
Within Groups	1.293E-02	10	1.293E-03		
Total	1.640E-02	14			

Table H18 Dependent comparison (Duncan's New Multiple Range Test) for pH of cephalexin suspension containing UT as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H19 Analysis of variance of pH of cephalexin suspension containing MGS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	6.960E-03	4	1.740E-03	0.715	0.600
Within Groups	2.433E-02	10	2.433E-03		
Total	3.129E-02	14			

Table H20 Dependent comparison (Duncan's New Multiple Range Test) for pH of cephalexin suspension containing MGS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H21 Analysis of variance of pH of cephalexin suspension containing MRS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	5.640E-03	4	1.410E-03	2.820	0.084
Within Groups	5.000E-03	10	5.000E-04		
Total	1.064E-02	14			

Table H22 Dependent comparison (Duncan's New Multiple Range Test) for pH of cephalexin suspension containing MRS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H23 Analysis of variance of pH of cephalexin suspension containing UT as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	3.907E-03	4	9.767E-04	0.805	0.549
Within Groups	1.213E-02	10	1.213E-03		
Total	1.604E-02	14			

Table H24 Dependent comparison (Duncan's New Multiple Range Test) for pH of cephalexin suspension containing UT as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H25 Analysis of variance of content uniformity of amoxicillin trihydrate suspension containing MGS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	36.060	4	9.015	4.256	0.029
Within Groups	21.180	10	2.118		
Total	57.240	14			

Table H26 Dependent comparison (Duncan's New Multiple Range Test) for content uniformity of amoxicillin trihydrate suspension containing MGS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	S	S
Month 1		-	NS	NS	S
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H27 Analysis of variance of content uniformity of amoxicillin trihydrate suspension containing MRS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	154.717	4	38.679	7.944	0.004
Within Groups	48.690	10	4.869		
Total	203.407	14			

Table H28 Dependent comparison (Duncan's New Multiple Range Test) for content uniformity of amoxicillin trihydrate suspension containing MRS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	S	S	S
Month 1		-	NS	S	S
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H29 Analysis of variance of content uniformity of amoxicillin trihydrate suspension containing UT as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	115.765	4	28.941	9.080	0.002
Within Groups	31.874	10	3.187		
Total	147.639	14			

Table H30 Dependent comparison (Duncan's New Multiple Range Test) for content uniformity of amoxicillin trihydrate suspension containing UT as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	S	S	S
Month 1		-	NS	S	S
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H31 Analysis of variance of content uniformity of amoxicillin trihydrate suspension containing MGS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	88.800	4	22.200	9.136	0.002
Within Groups	24.298	10	2.430		
Total	113.099	14			

Table H32 Dependent comparison (Duncan's New Multiple Range Test) for content uniformity of amoxicillin trihydrate suspension containing MGS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	S	S	S
Month 1		-	NS	S	S
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H33 Analysis of variance of content uniformity of amoxicillin trihydrate suspension containing MRS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	213.779	4	53.445	33.510	0.000
Within Groups	15.949	10	1.595		
Total	229.728	14			

Table H34 Dependent comparison (Duncan's New Multiple Range Test) for content uniformity of amoxicillin trihydrate suspension containing MRS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	S	S	S	S
Month 1		-	S	S	S
Month 2			-	S	S
Month 3				-	S
Month 4					-

Table H35 Analysis of variance of content uniformity of amoxicillin trihydrate suspension containing UT as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	212.606	4	53.151	12.476	0.001
Within Groups	42.602	10	4.260		
Total	255.207	14			

Table H36 Dependent comparison (Duncan's New Multiple Range Test) for content uniformity of amoxicillin trihydrate suspension containing UT as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	S	S	S	S
Month 1		-	NS	S	S
Month 2			-	S	S
Month 3				-	NS
Month 4					-

Table H37 Analysis of variance of content uniformity of cephalexin suspension containing MGS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	75.763	4	18.941	7.039	0.006
Within Groups	26.906	10	2.691		
Total	102.669	14			

Table H38 Dependent comparison (Duncan's New Multiple Range Test) for content uniformity of cephalexin suspension containing MGS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	S	S	S
Month 1		-	NS	S	S
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H39 Analysis of variance of content uniformity of cephalexin suspension containing MRS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	60.104	4	15.026	8.323	0.003
Within Groups	18.053	10	1.805		
Total	78.156	14			

Table H40 Dependent comparison (Duncan's New Multiple Range Test) for content uniformity of cephalexin suspension containing MRS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	S	S
Month 1		-	NS	NS	S
Month 2			-	NS	S
Month 3				-	S
Month 4					-

Table H41 Analysis of variance of content uniformity of cephalexin suspension containing UT as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	60.609	4	15.152	10.001	0.002
Within Groups	15.151	10	1.515		
Total	75.761	14			

Table H42 Dependent comparison (Duncan's New Multiple Range Test) for content uniformity of cephalexin suspension containing UT as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	S	S
Month 1		-	NS	S	S
Month 2			-	NS	S
Month 3				-	NS
Month 4					-

Table H43 Analysis of variance of content uniformity of cephalexin suspension containing MGS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	129.935	4	32.484	6.354	0.008
Within Groups	51.124	10	5.112		
Total	181.059	14			

Table H44 Dependent comparison (Duncan's New Multiple Range Test) for content uniformity of cephalexin suspension containing MGS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	S	S	S
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H45 Analysis of variance of content uniformity of cephalexin suspension containing MRS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	65.666	4	16.416	4.061	0.033
Within Groups	40.428	10	4.043		
Total	106.093	14			

Table H46 Dependent comparison (Duncan's New Multiple Range Test) for content uniformity of cephalexin suspension containing MRS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	S
Month 1		-	NS	NS	S
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H47 Analysis of variance of content uniformity of cephalexin suspension containing UT as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	67.432	4	16.858	4.339	0.027
Within Groups	38.850	10	3.885		
Total	106.282	14			

Table H48 Dependent comparison (Duncan's New Multiple Range Test) for content uniformity of cephalexin suspension containing UT as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	S	S	S
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H49 Analysis of variance of inversion of amoxicillin trihydrate suspension containing MGS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	1.067	4	0.267	1.000	0.452
Within Groups	2.667	10	0.267		
Total	3.733	14			

Table H50 Dependent comparison (Duncan's New Multiple Range Test) for inversion of amoxicillin trihydrate suspension containing MGS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H51 Analysis of variance of inversion of amoxicillin trihydrate suspension containing MRS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	0.667	4	0.167	0.526	0.719
Within Groups	3.167	10	0.317		
Total	3.833	14			

Table H52 Dependent comparison (Duncan's New Multiple Range Test) for inversion of amoxicillin trihydrate suspension containing MRS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H53 Analysis of variance of inversion of amoxicillin trihydrate suspension containing UT as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	2.600	4	0.650	2.294	0.131
Within Groups	2.833	10	0.283		
Total	5.433	14			

Table H54 Dependent comparison (Duncan's New Multiple Range Test) for inversion of amoxicillin trihydrate suspension containing UT as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H55 Analysis of variance of inversion of amoxicillin trihydrate suspension containing MGS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	0.933	4	0.233	0.933	0.483
Within Groups	2.500	10	0.250		
Total	3.433	14			

Table H56 Dependent comparison (Duncan's New Multiple Range Test) for inversion of amoxicillin trihydrate suspension containing MGS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H57 Analysis of variance of inversion of amoxicillin trihydrate suspension containing MRS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	2.067	4	0.517	1.824	0.201
Within Groups	2.833	10	0.283		
Total	4.900	14			

Table H58 Dependent comparison (Duncan's New Multiple Range Test) for inversion of amoxicillin trihydrate suspension containing MRS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H59 Analysis of variance of inversion of amoxicillin trihydrate suspension containing UT as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	6.667	4	1.667	3.571	0.047
Within Groups	4.667	10	0.467		
Total	11.333	14			

Table H60 Dependent comparison (Duncan's New Multiple Range Test) for inversion of amoxicillin trihydrate suspension containing UT as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	S	S
Month 1		-	NS	NS	S
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H61 Analysis of variance of inversion of cephalexin suspension containing MGS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	2.000	4	0.500	0.938	0.481
Within Groups	5.333	10	0.533		
Total	7.333	14			

Table H62 Dependent comparison (Duncan's New Multiple Range Test) for inversion of cephalexin suspension containing MGS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H63 Analysis of variance of inversion of cephalexin suspension containing MRS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	1.067	4	0.267	0.571	0.690
Within Groups	4.667	10	0.467		
Total	5.733	14			

Table H64 Dependent comparison (Duncan's New Multiple Range Test) for inversion of cephalexin suspension containing MRS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H65 Analysis of variance of inversion of cephalexin suspension containing UT as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	4.400	4	1.100	3.300	0.057
Within Groups	3.333	10	0.333		
Total	7.733	14			

Table H66 Dependent comparison (Duncan's New Multiple Range Test) for inversion of cephalexin suspension containing UT as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H67 Analysis of variance of inversion of cephalexin suspension containing MGS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	3.600	4	0.900	2.700	0.092
Within Groups	3.333	10	0.333		
Total	6.933	14			

Table H68 Dependent comparison (Duncan's New Multiple Range Test) for inversion of cephalexin suspension containing MGS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H69 Analysis of variance of inversion of cephalexin suspension containing MRS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	1.733	4	0.433	0.929	0.485
Within Groups	4.667	10	0.467		
Total	6.400	14			

Table H70 Dependent comparison (Duncan's New Multiple Range Test) for inversion of cephalexin suspension containing MRS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H71 Analysis of variance of inversion of cephalexin suspension containing UT as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	4.933	4	1.233	1.542	0.263
Within Groups	8.000	10	0.800		
Total	12.933	14			

Table H72 Dependent comparison (Duncan's New Multiple Range Test) for inversion of cephalexin suspension containing UT as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H73 Analysis of variance of viscosity of amoxicillin trihydrate suspension containing MGS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	2227.375	4	556.844	14.851	0.000
Within Groups	374.965	10	37.496		
Total	2602.340	14			

Table H74 Dependent comparison (Duncan's New Multiple Range Test) for viscosity of amoxicillin trihydrate suspension containing MGS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	S	S	S	S
Month 1		-	NS	S	S
Month 2			-	NS	S
Month 3				-	NS
Month 4					-

Table H75 Analysis of variance of viscosity of amoxicillin trihydrate suspension containing MRS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	1703.444	4	425.861	13.392	0.001
Within Groups	318.003	10	31.800		
Total	2021.448	14			

Table H76 Dependent comparison (Duncan's New Multiple Range Test) for viscosity of amoxicillin trihydrate suspension containing MRS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	S	S	S	S
Month 1		-	NS	S	S
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H77 Analysis of variance of viscosity of amoxicillin trihydrate suspension containing UT as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	972.089	4	243.022	32.925	0.000
Within Groups	73.810	10	7.381		
Total	1045.900	14			

Table H78 Dependent comparison (Duncan's New Multiple Range Test) for viscosity of amoxicillin trihydrate suspension containing UT as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	S	S	S
Month 1		-	NS	S	S
Month 2			-	S	S
Month 3				-	S
Month 4					-

Table H79 Analysis of variance of viscosity of amoxicillin trihydrate suspension containing MGS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	3431.054	4	857.764	18.956	0.000
Within Groups	452.508	10	45.251		
Total	3883.562	14			

Table H80 Dependent comparison (Duncan's New Multiple Range Test) for viscosity of amoxicillin trihydrate suspension containing MGS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	S	S	S	S
Month 1		-	NS	S	S
Month 2			-	NS	S
Month 3				-	NS
Month 4					-

Table H81 Analysis of variance of viscosity of amoxicillin trihydrate suspension containing MRS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	4041.190	4	1010.298	27.525	0.000
Within Groups	367.052	10	36.705		
Total	4408.242	14			

Table H82 Dependent comparison (Duncan's New Multiple Range Test) for viscosity of amoxicillin trihydrate suspension containing MRS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	S	S	S	S
Month 1		-	NS	S	S
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H83 Analysis of variance of viscosity of amoxicillin trihydrate suspension containing UT as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	3887.646	4	971.911	50.849	0.000
Within Groups	191.136	10	19.114		
Total	4078.782	14			

Table H84 Dependent comparison (Duncan's New Multiple Range Test) for viscosity of amoxicillin trihydrate suspension containing UT as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	S	S	S	S
Month 1		-	S	S	S
Month 2			-	S	S
Month 3				-	NS
Month 4					-

Table H85 Analysis of variance of viscosity of cephalexin suspension containing MGS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	613.791	4	153.448	11.691	0.001
Within Groups	131.249	10	13.125		
Total	745.039	14			

Table H86 Dependent comparison (Duncan's New Multiple Range Test) for viscosity of cephalexin suspension containing MGS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	S	S	S
Month 1		-	S	S	S
Month 2			-	NS	S
Month 3				-	NS
Month 4					-

Table H87 Analysis of variance of viscosity of cephalexin suspension containing MRS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	3758.507	4	939.627	31.186	0.000
Within Groups	301.299	10	30.130		
Total	4059.807	14			

Table H88 Dependent comparison (Duncan's New Multiple Range Test) for viscosity of cephalexin suspension containing MRS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	S	S	S	S
Month 1		-	S	S	S
Month 2			-	NS	S
Month 3				-	NS
Month 4					-

Table H89 Analysis of variance of viscosity of cephalexin suspension containing UT as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	1356.933	4	339.233	8.249	0.003
Within Groups	411.256	10	41.126		
Total	1768.189	14			

Table H90 Dependent comparison (Duncan's New Multiple Range Test) for viscosity of cephalexin suspension containing UT as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	S	S
Month 1		-	NS	S	S
Month 2			-	NS	S
Month 3				-	NS
Month 4					-

Table H91 Analysis of variance of viscosity of cephalexin suspension containing MGS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	691.374	4	172.843	4.366	0.027
Within Groups	395.851	10	39.585		
Total	1087.224	14			

Table H92 Dependent comparison (Duncan's New Multiple Range Test) for viscosity of cephalexin suspension containing MGS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	S	S
Month 1		-	NS	NS	S
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H93 Analysis of variance of viscosity of cephalexin suspension containing MRS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	6389.165	4	1597.291	36.527	0.000
Within Groups	437.295	10	43.730		
Total	6826.460	14			

Table H94 Dependent comparison (Duncan's New Multiple Range Test) for viscosity of cephalexin suspension containing MRS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	S	S	S	S
Month 1		-	S	S	S
Month 2			-	S	S
Month 3				-	NS
Month 4					-

Table H95 Analysis of variance of viscosity of cephalexin suspension containing UT as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	3991.180	4	997.795	21.649	0.000
Within Groups	460.895	10	46.090		
Total	4452.075	14			

Table H96 Dependent comparison (Duncan's New Multiple Range Test) for viscosity of cephalexin suspension containing UT as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	S	S	S
Month 1		-	S	S	S
Month 2			-	NS	S
Month 3				-	S
Month 4					-

Table H97 Analysis of variance of reconstitution time of amoxicillin trihydrate suspension containing MGS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	0.433	4	0.108	2.167	0.147
Within Groups	0.500	10	5.000E-02		
Total	0.933	14			

Table H98 Dependent comparison (Duncan's New Multiple Range Test) for reconstitution time of amoxicillin trihydrate suspension containing MGS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H99 Analysis of variance of reconstitution time of amoxicillin trihydrate suspension containing MRS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	3.167	4	0.792	2.500	0.109
Within Groups	3.167	10	0.317		
Total	6.333	14			

Table H100 Dependent comparison (Duncan's New Multiple Range Test) for reconstitution time of amoxicillin trihydrate suspension containing MRS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H101 Analysis of variance of reconstitution time of amoxicillin trihydrate suspension containing UT as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	1.567	4	0.392	0.940	0.480
Within Groups	4.167	10	0.417		
Total	5.733	14			

Table H102 Dependent comparison (Duncan's New Multiple Range Test) for reconstitution time of amoxicillin trihydrate suspension containing UT as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H103 Analysis of variance of reconstitution time of amoxicillin trihydrate suspension containing MGS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	9.000	4	2.250	67.500	0.000
Within Groups	0.333	10	3.333E-02		
Total	9.333	14			

Table H104 Dependent comparison (Duncan's New Multiple Range Test) for reconstitution time of amoxicillin trihydrate suspension containing MGS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	S	S	S	S
Month 1		-	NS	NS	NS
Month 2			-	S	S
Month 3				-	NS
Month 4					-

Table H105 Analysis of variance of reconstitution time of amoxicillin trihydrate suspension containing MRS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	1.433	4	0.358	7.167	0.005
Within Groups	0.500	10	5.000E-02		
Total	1.933	14			

Table H106 Dependent comparison (Duncan's New Multiple Range Test) for reconstitution time of amoxicillin trihydrate suspension containing MRS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	S	S	S	S
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H107 Analysis of variance of reconstitution time of amoxicillin trihydrate suspension containing UT as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	2.400	4	0.600	2.571	0.103
Within Groups	2.333	10	0.233		
Total	4.733	14			

Table H108 Dependent comparison (Duncan's New Multiple Range Test) for reconstitution time of amoxicillin trihydrate suspension containing UT as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	NS	NS	NS
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H109 Analysis of variance of reconstitution time of cephalexin suspension containing MGS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	6.100	4	1.525	7.625	0.004
Within Groups	2.000	10	0.200		
Total	8.100	14			

Table H110 Dependent comparison (Duncan's New Multiple Range Test) for reconstitution time of cephalexin suspension containing MGS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	S	NS	S
Month 1		-	S	NS	S
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H111 Analysis of variance of reconstitution time of cephalexin suspension containing MRS as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	10.833	4	2.708	10.833	0.001
Within Groups	2.500	10	0.250		
Total	13.333	14			

Table H112 Dependent comparison (Duncan's New Multiple Range Test) for reconstitution time of cephalexin suspension containing MRS as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	S	S	S
Month 1		-	S	S	S
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H113 Analysis of variance of reconstitution time of cephalexin suspension containing UT as suspending agent (room condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	11.600	4	2.900	21.750	0.000
Within Groups	1.333	10	0.133		
Total	12.933	14			

Table H114 Dependent comparison (Duncan's New Multiple Range Test) for reconstitution time of cephalexin suspension containing UT as suspending agent (room condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	S	S	S
Month 1		-	S	S	S
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H115 Analysis of variance of reconstitution time of cephalexin suspension containing MGS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	2.767	4	0.692	3.773	0.040
Within Groups	1.833	10	0.183		
Total	4.600	14			

Table H116 Dependent comparison (Duncan's New Multiple Range Test) for reconstitution time of cephalexin suspension containing MGS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	NS	S	S	S
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H117 Analysis of variance of reconstitution time of cephalexin suspension containing MRS as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	8.500	4	2.125	14.167	0.000
Within Groups	1.500	10	.150		
Total	10.000	14			

Table H118 Dependent comparison (Duncan's New Multiple Range Test) for reconstitution time of cephalexin suspension containing MRS as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	S	S	S	S
Month 1		-	NS	NS	NS
Month 2			-	NS	NS
Month 3				-	NS
Month 4					-

Table H119 Analysis of variance of reconstitution time of cephalexin suspension containing UT as suspending agent (stress condition)

Source of Variation	SS	df	MS	F	Sig.
Between Groups	10.433	4	2.608	17.389	0.000
Within Groups	1.500	10	0.150		
Total	11.933	14			

Table H120 Dependent comparison (Duncan's New Multiple Range Test) for reconstitution time of cephalexin suspension containing UT as suspending agent (stress condition)

	Month 0	Month 1	Month 2	Month 3	Month 4
Month 0	-	S	S	S	S
Month 1		-	NS	S	NS
Month 2			-	S	NS
Month 3				-	NS
Month 4					-

Vita

Miss Chitradee Luprasong was born on 18thApril 1977 in Chiangmai province, Thailand. She got her bachelor degree in Pharmaceutical Sciences from Faculty of Pharmacy, Khon Kaen University in 1999. In June of 2000, she was accepted to the Graduate School in Pharmaceutical Sciences of Chulalongkorn University. Miss Luprasong was a recipient of the University Development Council (UDC) scholarship in the area of Manufacturing Pharmacy as required by Faculty of Pharmacy, Ubonratchatanee University.