

表 1 受試者資料

編號	年齡(yr)	身高(cm)	體重(kg)	給藥次序		性別
A	24	176.6	71.4	Y	L	Man
B	23	164.1	67.6	L	Y	Man
C	23	159.2	54.3	Y	L	Man
D	30	179.9	74.6	L	Y	Man
E	21	186.0	81.0	L	Y	Man
F	23	178.6	70.3	Y	L	Man
G	25	171.3	78.3	Y	L	Man
H	29	165.9	54.3	L	Y	Man
I	23	172.8	68.2	Y	L	Man
J	24	177.7	82.1	L	Y	Man
K	24	175.0	73.1	L	Y	Man
L	22	172.0	66.0	Y	L	Man
Mean	24.25	173.26	70.1			
S.D.	2.67	7.45	8.98			

*Y: Cephannmycin[?] (Lot.M001)

L: Keflex[?] (Lot.A0053A)

表 2 血漿中 cephalexin 分析之標準曲線

表 2-1 Cephalexin 分析方法之標準曲線

Spike conc. ($\mu\text{g/ml}$)	Peak area of Cephalexin	Peak area of Internal standard	Measure conc. ($\mu\text{g/ml}$)	Error (%)
16.0	104119	47977	15.980	-0.125
8.0	53717	48783	8.029	0.361
4.0	27815	49235	4.041	1.022
2.0	14322	51135	1.922	-3.891
1.0	8104	48266	1.088	8.783
0.5	3870	47379	0.447	-10.691
0.05	1298	47185	0.044	-12.741

表 2-2 個別受試者之標準曲線

Calibration curve of subject A

Spike conc. ($\mu\text{g/ml}$)	Peak area of Cephalexin	Peak area of Internal standard	Measure conc. ($\mu\text{g/ml}$)	Error (%)
16.0	128817	61174	15.988	0.077
8.0	66748	62860	7.975	0.310
4.0	33247	59403	4.121	-3.021
2.0	17475	62780	1.961	1.926
1.0	9413	62099	0.988	1.157
0.5	5124	61465	0.465	7.033
0.05	1797	60884	0.052	-3.028

Calibration curve of subject B

Spike conc. ($\mu\text{g/ml}$)	Peak area of Cephalexin	Peak area of Internal standard	Measure conc. ($\mu\text{g/ml}$)	Error (%)
16.0	166728	76824	15.973	0.168
8.0	85515	77560	8.018	-0.227
4.0	43103	75156	4.076	-1.908
2.0	20663	70436	1.989	0.551
1.0	11602	70774	1.025	-2.464
0.5	6146	73512	0.426	14.766
0.05	2369	73766	0.043	14.941

Calibration curve of subject C

Spike conc. ($\mu\text{g/ml}$)	Peak area of Cephalexin	Peak area of Internal standard	Measure conc. ($\mu\text{g/ml}$)	Error (%)
16.0	131961	61789	16.003	-0.020
8.0	65417	60844	7.977	0.287
4.0	33918	60930	4.053	-1.324
2.0	16433	59360	1.935	3.246
1.0	9679	60428	1.052	-5.215
0.5	5127	61308	0.473	5.436
0.05	1726	60246	0.057	-13.470

Calibration curve of subject D

Spike conc. ($\mu\text{g/ml}$)	Peak area of Cephalexin	Peak area of Internal standard	Measure conc. ($\mu\text{g/ml}$)	Error (%)
16.0	126282	58771	15.926	0.460
8.0	65701	59112	8.137	-1.709
4.0	34447	60950	4.034	-0.852
2.0	17317	59525	1.975	1.274
1.0	9943	61469	1.005	-0.451
0.5	5089	60126	0.425	14.928
0.05	1998	58007	0.048	3.195

Calibration curve of subject E

Spike conc. ($\mu\text{g/ml}$)	Peak area of Cephalexin	Peak area of Internal standard	Measure conc. ($\mu\text{g/ml}$)	Error (%)
16.0	128615	61769	15.958	0.262
8.0	64773	61098	8.028	-0.348
4.0	34195	61091	4.145	-3.626
2.0	16799	61224	1.931	3.455
1.0	9324	60283	1.002	-0.201
0.5	5155	62367	0.443	11.354
0.05	1891	60897	0.043	14.353

Calibration curve of subject F

Spike conc. ($\mu\text{g/ml}$)	Peak area of Cephalexin	Peak area of Internal standard	Measure conc. ($\mu\text{g/ml}$)	Error (%)
16.0	131302	61768	16.007	-0.042
8.0	64973	60442	8.002	-0.029
4.0	31954	58902	3.946	1.347
2.0	17381	59939	2.023	-1.127
1.0	9895	60730	1.055	-5.476
0.5	5097	59556	0.466	6.895
0.05	1849	59057	0.052	-4.159

Calibration curve of subject G

Spike conc. ($\mu\text{g/ml}$)	Peak area of Cephalexin	Peak area of Internal standard	Measure conc. ($\mu\text{g/ml}$)	Error (%)
16.0	130989	61430	15.996	0.025
8.0	67610	62731	7.967	0.408
4.0	34945	61729	4.072	-1.795
2.0	18183	61081	2.028	-1.412
1.0	9876	60895	0.997	0.341
0.5	5493	60885	0.449	10.255
0.05	2194	59797	0.041	17.619

Calibration curve of subject H

Spike conc. ($\mu\text{g/ml}$)	Peak area of Cephalexin	Peak area of Internal standard	Measure conc. ($\mu\text{g/ml}$)	Error (%)
16.0	129963	62352	15.970	0.188
8.0	66397	63044	7.976	0.304
4.0	33319	58969	4.191	-4.779
2.0	16560	59296	1.976	1.209
1.0	9004	61808	0.940	5.994
0.5	4867	59168	0.448	10.323
0.05	1855	60354	0.049	2.097

Calibration curve of subject I

Spike conc. ($\mu\text{g/ml}$)	Peak area of Cephalexin	Peak area of Internal standard	Measure conc. ($\mu\text{g/ml}$)	Error (%)
16.0	138844	64873	16.002	-0.010
8.0	68791	63891	8.011	-0.134
4.0	33254	61384	3.991	0.216
2.0	17087	63581	1.940	2.987
1.0	9011	61281	1.026	-2.587
0.5	5013	62756	0.521	-4.248
0.05	1154	62896	0.059	-17.829

Calibration curve of subject J

Spike conc. ($\mu\text{g/ml}$)	Peak area of Cephalexin	Peak area of Internal standard	Measure conc. ($\mu\text{g/ml}$)	Error (%)
16.0	126661	60099	15.978	0.139
8.0	66065	61414	8.058	-0.727
4.0	32387	59471	3.981	0.466
2.0	17557	62787	1.948	2.615
1.0	9963	60053	1.075	-7.481
0.5	5022	58550	0.460	8.046
0.05	1899	58545	0.050	-0.773

Calibration curve of subject K

Spike conc. ($\mu\text{g/ml}$)	Peak area of Cephalexin	Peak area of Internal standard	Measure conc. ($\mu\text{g/ml}$)	Error (%)
16.0	133118	60771	15.947	0.333
8.0	68873	61585	8.060	-0.747
4.0	35000	59650	4.149	-3.733
2.0	17766	63794	1.882	5.918
1.0	9716	62568	0.975	2.468
0.5	5414	60765	0.488	2.317
0.05	1794	61168	0.049	2.516

Calibration curve of subject L

Spike conc. ($\mu\text{g/ml}$)	Peak area of Cephalexin	Peak area of Internal standard	Measure conc. ($\mu\text{g/ml}$)	Error (%)
16.0	132198	59689	16.028	-0.176
8.0	67039	60307	7.957	0.540
4.0	34545	60769	3.983	0.432
2.0	17832	61949	1.930	3.520
1.0	10117	58978	1.079	-7.859
0.5	5702	59587	0.524	-4.732
0.05	1849	59617	0.050	-0.882

表 3 尿液中個別受試者檢品定量之標準曲線

	SLOPE INTERCEPT	Rsqr
檢量線 A	$Y = 21.38575X - 3.12527$	0.998194
檢量線 B	$Y = 19.30211X - 0.38000$	0.999631
檢量線 C	$Y = 19.03623X - 0.90281$	0.998761
檢量線 D	$Y = 19.2894X - 1.93348$	0.999560
檢量線 E	$Y = 18.68734X - 0.96708$	0.998690
檢量線 F	$Y = 18.00425X - 0.10201$	0.999379
檢量線 G	$Y = 19.41299X - 0.96335$	0.999545
檢量線 H	$Y = 18.67297X - 1.04371$	0.999665
檢量線 I	$Y = 18.94671X - 0.87631$	0.999651
檢量線 J	$Y = 20.44694X - 2.43649$	0.999681
檢量線 K	$Y = 19.84651X - 0.61203$	0.999604
檢量線 L	$Y = 20.05948X - 0.75072$	0.999576

表 4 血漿中 cephalexin 以 HPLC 定量法定量分析之確效性試驗

表 4-1 定量分析之偵測極限及定量極限

Cephalexin conc. (µg/ml)	Peak High(mm)		
	Sample A	Sample B	Sample C
0.02	10.2	9.9	9.8
0.03	11.8	11.1	11.1
0.04	15	16.2	14

總回歸方程式 : $Y = 255X + 4.4722$

取 A、B、C calibration curve 截距之標準偏差 =1.322

總回歸方程式之斜率 $S=255$

依 ICH

$$LOD = 3.3 \times / S = 0.0171 \mu g/ml$$

$$LOQ = 10 \times / S = 0.0518 \mu g/ml \quad 0.05 \mu g/ml$$

實驗上以 0.05 µg/ml 為檢量線之 LOQ，即可測得 Plasma Sample 最低濃度。

表 4-2 定量分析之同日 (Intraday) 精密度及準確度試驗

Cephalexin Conc. (µg/ml)	Runs			Mean	S.D.	C.V. (%)	Error (%)
	1	2	3				
16.0	15.890	15.972	16.015	15.973	0.044	0.274	0.168
	15.973	15.997	15.992				
8.0	8.240	8.070	7.945	8.049	0.104	1.286	-0.615
	8.050	7.999	7.991				
4.0	3.954	3.984	4.059	4.018	0.044	1.099	-0.450
	4.018	4.022	4.071				
2.0	1.991	1.965	1.974	1.973	0.016	0.793	1.367
	1.982	1.978	1.946				
1.0	1.002	1.026	1.022	1.021	0.011	1.121	-2.133
	1.015	1.029	1.034				
0.5	0.426	0.477	0.486	0.466	0.021	4.472	6.767
	0.466	0.472	0.470				
0.05	0.047	0.056	0.050	0.050	0.004	8.295	0
	0.047	0.054	0.046				

表 4-3 定量分析之異日 (Interday) 精密度及準確度試驗

Cephalexin Conc. ($\mu\text{g/ml}$)	Days			Mean	S.D.	C.V. (%)	Error (%)
	1	2	3				
16.0	15.839	16.022	15.919	15.938	0.093	0.584	0.389
	16.010	16.019	15.818				
8.0	8.323	7.908	8.156	8.110	0.200	2.467	-1.373
	7.925	7.987	8.360				
4.0	3.997	4.110	4.026	4.032	0.058	1.436	-0.808
	4.085	3.951	4.025				
2.0	1.974	1.953	1.969	1.973	0.041	2.100	1.375
	2.052	1.953	1.934				
1.0	0.949	1.024	0.996	0.992	0.053	5.358	0.833
	1.007	1.061	0.913				
0.5	0.425	0.473	0.442	0.458	0.040	8.619	8.333
	0.429	0.531	0.450				
0.05	0.043	0.052	0.042	0.046	0.004	9.532	7.667
	0.042	0.048	0.050				

表 4-4 定量分析中之相對回收率試驗 (n=3)

Cephalexin conc. ($\mu\text{g/ml}$)	Plasma sample peak area ratio	Solvent sample peak area ratio	Recovery (%)
16.00	2.1270	2.1859	97.30
8.00	1.0930	1.1083	98.62
4.00	0.5622	0.5793	97.05
2.00	0.2762	0.2926	94.38
1.00	0.1627	0.1673	97.25
0.50	0.0823	0.0864	95.25
0.05	0.0242	0.0267	90.51
Mean			95.77
S.D.			2.71
C.V. (%)			2.83

表 4-5 Cephalexin 標準血漿檢品於 25°C 之安定性試驗

Time (hr)	Cephalexin Conc. ($\mu\text{g/ml}$)		
	0.050	2.000	16.000
0.00	0.055	2.058	16.210
3.00	0.052	2.033	16.156
6.00	0.052	2.028	16.093
9.00	0.050	2.014	15.988
12.00	0.046	1.995	15.969
18.00	0.043	1.981	15.857
24.00	0.041	1.965	15.796
Mean	0.048	2.011	16.010
S.D.	0.005	0.032	0.153
C.V.	10.720	1.607	0.953
Error	-3.143	0.529	0.062

表 4-6 Cephalexin 標準血漿檢品於 -30°C 之安定性試驗

Time (Day)	Cephalexin Conc. ($\mu\text{g/ml}$)		
	0.050	2.000	16.000
0	0.053	2.084	16.131
10	0.052	2.076	16.118
15	0.049	1.997	16.022
30	0.043	1.986	15.982
45	0.047	1.875	15.974
60	0.045	1.863	15.876
90	0.043	1.852	15.778
Mean	0.047	1.962	15.983
S.D.	0.004	0.099	0.126
C.V.	8.595	5.061	0.788
Error	-0.051	-1.907	-0.106

表 4-7 Cephalexin 標準溶液之母液於室溫之安定性試驗

Cephalexin($\mu\text{g}/\text{ml}$)	Runs		
	1	2	3
0	16.218	16.235	16.187
1	16.169	16.301	16.256
2	16.256	16.217	16.263
4	16.173	16.150	16.132
6	16.175	16.264	16.105
168	16.198	16.189	16.204

表 4-8 Cephalexin 血漿標準品連續解凍之安定性試驗

Cephalexin Conc.($\mu\text{g}/\text{ml}$)	Runs			Mean	S.D.	C.V.(%)	Error(%)
	1	2	3				
第一次解凍							
16.00	16.159	16.296	16.512	16.322	0.178	1.090	2.015
2.00	2.161	2.240	2.137	2.179	0.054	2.473	8.967
0.05	0.056	0.054	0.054	0.055	0.001	2.112	9.333
第二次解凍							
16.00	16.567	16.312	16.214	16.364	0.182	1.114	2.277
2.00	2.151	2.154	2.122	2.142	0.018	0.825	7.117
0.05	0.048	0.051	0.051	0.050	0.001	2.966	0.200
第三次解凍							
16.00	16.401	16.772	15.956	16.376	0.409	2.495	2.352
2.00	2.187	2.151	2.165	2.168	0.018	0.837	8.383
0.05	0.047	0.049	0.051	0.049	0.002	3.699	2.467

表 4-9 Cephalixin 血漿檢品之品質管制試驗

Subject	16.00 (高)		2.00 (中)		0.05 (低)	
	($\mu\text{g/ml}$)	Error (%)	($\mu\text{g/ml}$)	Error (%)	($\mu\text{g/ml}$)	Error (%)
A1	16.284	-1.77	2.268	-13.40	0.0498	0.40
A2	16.819	-5.12	2.113	-5.65	0.0501	-0.20
B1	15.583	2.61	2.106	-5.30	0.0448	10.40
B2	15.052	5.93	2.062	-3.10	0.0450	10.00
C1	16.029	-0.18	1.972	1.40	0.0470	6.00
C2	15.446	3.46	1.983	0.85	0.0464	7.20
D1	15.177	5.14	2.117	-5.85	0.0583	-16.60
D2	15.268	4.58	1.991	0.45	0.0435	13.00
E1	16.238	-1.49	2.120	-6.00	0.0456	8.80
E2	15.805	1.22	2.264	-13.20	0.0486	2.80
F1	15.931	0.43	2.008	-0.40	0.0583	-16.60
F2	14.887	6.96	1.967	1.65	0.0452	9.60
G1	15.810	1.19	1.939	3.05	0.0584	-16.80
G2	16.520	-3.25	2.179	-8.95	0.0506	-1.20
H1	15.816	1.15	2.283	-14.15	0.0496	0.80
H2	15.563	2.73	1.843	7.85	0.0414	17.20
I1	16.242	-1.51	2.231	-11.55	0.0554	-10.80
I2	15.620	2.38	2.177	-8.85	0.0557	-11.40
J1	16.515	-3.22	2.031	-1.55	0.0415	17.00
J2	15.270	4.56	2.112	-5.60	0.0477	4.60
K1	15.993	0.04	2.002	-0.10	0.0427	14.60
K2	15.425	3.59	2.216	-10.80	0.0469	6.20
L1	14.921	6.74	2.003	-0.15	0.0564	-12.80
L2	16.112	-0.70	2.219	-10.95	0.0479	4.20

表 5 尿液中 cephalexin 以 HPLC 法定量分析之確效性試驗

表 5-1 尿液定量分析之同日 (Intraday) 精密度及準確度試驗

Cephalexin Conc. ($\mu\text{g/ml}$)	Runs			Mean	S.D.	C.V. (%)	Error (%)
	1 4	2 5	3 6				
100.0	100.125 99.508	100.157 100.263	99.659 99.598	99.885	0.332	0.332	-0.115
50.0	49.457 50.824	49.327 49.187	50.459 50.671	49.988	0.741	1.483	-0.025
25.0	25.170 25.091	25.174 25.004	25.132 25.013	25.097	0.075	0.299	0.389
10.0	11.017 10.804	11.494 11.457	11.060 10.861	11.116	0.295	2.652	11.155
5.0	4.938 4.285	4.213 4.407	4.213 4.370	4.404	0.273	6.205	-11.913
2.5	2.204 2.175	2.161 2.328	2.164 2.177	2.202	0.064	2.898	-11.940
1.0	0.959 0.813	0.973 0.854	0.813 0.810	0.870	0.076	8.733	-12.967

表 5-2 尿液定量分析之異日 (Interday) 精密度及準確度試驗

Cephalexin Conc. ($\mu\text{g/ml}$)	Days			Mean	S.D.	C.V. (%)	Error (%)
	1 4	2 5	3 6				
100.0	99.356 100.711	99.431 99.053	100.549 99.633	99.789	0.680	0.681	-0.211
50.0	51.188 47.408	51.251 52.571	47.533 50.132	50.014	2.117	4.233	0.028
25.0	24.955 26.648	24.618 22.814	27.010 26.242	25.381	1.572	6.193	1.525
10.0	10.766 10.963	10.395 10.773	11.036 10.110	10.674	0.355	3.322	6.738
5.0	4.315 4.320	4.644 5.128	4.357 4.273	4.506	0.333	7.384	-9.877
2.5	2.101 2.400	2.311 2.344	2.167 2.280	2.267	0.113	4.975	-9.320
1.0	0.820 1.051	0.850 0.815	0.849 0.830	0.869	0.090	10.383	-13.083

表 5-3 尿液定量分析中之定量極限

Cephalexin Conc. ($\mu\text{g/ml}$)	Runs			Mean	S.D.	C.V. (%)	Error (%)
	1	2	3				
	4	5	6				
100.0	99.565 99.957	100.091 100.577	100.893 100.559	100.274	0.488	0.487	0.274
50.0	50.753 49.939	49.846 47.667	47.982 48.835	49.170	1.211	2.464	-1.659
25.0	24.817 24.742	24.417 26.683	24.307 24.341	24.885	0.906	3.642	-0.462
10.0	11.267 11.559	11.412 11.071	12.078 11.609	11.499	0.345	3.001	14.993
5.0	4.106 4.027	4.335 4.245	4.674 4.578	4.328	0.257	5.928	-13.450
2.5	2.130 2.361	2.223 2.386	2.432 2.408	2.323	0.120	5.157	-7.067
1.0	0.863 0.915	1.176 0.872	1.135 1.169	1.022	0.153	14.993	2.167

表 5-4 尿液定量分析中之相對回收率試驗(n=3)

Cephalexin conc. ($\mu\text{g/ml}$)	Urea sample peak area ratio	Solvent sample peak area ratio	Recovery (%)
100.0	5.1644	5.3556	96.43
50.0	2.5788	2.6615	96.89
25.0	1.3394	1.3404	99.93
10.0	0.6258	0.6486	96.50
5.0	0.2444	0.2533	96.48
2.5	0.1358	0.1384	98.14
1.0	0.0850	0.0881	96.49
Mean			97.27
S.D.			1.32
C.V. (%)			1.36

表 5-5 Cephalexin 標準尿液檢品於 25°C 之安定性試驗

Time (hr)	Cephalexin Conc. ($\mu\text{g/ml}$)		
	1.000	10.000	100.000
0.00	1.116	11.065	100.712
3.00	1.172	11.019	100.856
6.00	1.063	10.978	100.094
9.00	1.048	10.745	99.992
12.00	1.009	10.395	99.961
18.00	0.993	10.112	99.857
24.00	0.877	10.065	99.510
Mean	1.040	10.626	100.140
S.D.	0.094	0.432	0.478
C.V.	9.085	4.062	0.478
Error	3.971	6.256	0.140

表 5-6 Cephalexin 標準尿液檢品於 -30°C 之安定性試驗

Time (Day)	Cephalexin Conc. ($\mu\text{g/ml}$)		
	1.000	10.000	100.000
0	1.125	11.084	100.131
10	1.056	11.067	100.118
15	1.089	10.985	100.022
30	1.063	10.941	99.982
45	1.017	10.206	99.973
60	1.005	10.560	99.855
90	0.898	10.052	99.470
Mean	1.036	10.699	99.936
S.D.	0.073	0.429	0.226
C.V.	7.073	4.011	0.226
Error	3.614	6.993	-0.064

表 6 Keflex[®]與 Cepharmycin[®]之溶離試驗

表 6-1 Keflex (Eli Lilly, 台灣) 與 Cepharmycin(永信)膠囊劑於
0.1N HCl 溶離液之溶離試驗

Keflex (Eli Lilly, 台灣) 膠囊劑之溶離度

時間 (min)	S1	S2	S3	S4	S5	S6	mean	S.D.	C.V. (%)
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
5	10.04	6.01	19.20	11.16	9.20	8.59	10.70	4.51	42.13
10	60.46	53.59	89.01	74.50	76.11	72.17	70.97	12.48	17.58
15	93.21	93.99	97.38	94.20	95.38	100.16	95.72	2.61	2.73
30	96.33	101.40	100.19	98.89	100.48	102.31	99.93	2.11	2.11
45	97.28	102.85	99.86	99.70	102.09	102.64	100.74	2.18	2.16
60	97.85	102.71	99.48	99.74	102.51	102.15	100.74	2.00	1.98
120	98.07	102.43	99.37	99.33	101.85	101.95	100.50	1.80	1.79

Cepharmycin(永信)膠囊劑之溶離度

時間 (min)	S1	S2	S3	S4	S5	S6	mean	S.D.	C.V. (%)
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
5	57.34	94.15	64.80	98.15	83.49	84.33	80.38	16.15	20.09
10	102.30	102.75	103.69	102.64	103.18	102.08	102.77	0.59	0.57
15	102.22	102.91	103.81	102.72	103.23	102.56	102.91	0.56	0.54
30	102.56	103.44	104.14	102.85	103.42	102.70	103.19	0.60	0.58
45	102.66	103.35	104.06	102.85	103.43	102.82	103.20	0.52	0.51
60	102.85	103.69	104.27	103.17	103.75	103.12	103.48	0.52	0.50
120	102.85	103.88	104.30	103.27	103.88	103.28	103.58	0.53	0.51

表 6-2 Keflex (Eli Lilly, 台灣) 與 Cepharmycin(永信)膠囊劑於 pH=4.5 溶離液之溶離試驗

Keflex (Eli Lilly, 台灣)膠囊劑之溶離度

時間 (min)	S1	S2	S3	S4	S5	S6	mean	S.D.	C.V. (%)
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
5	9.22	5.56	12.12	11.85	7.63	7.90	9.06	2.54	28.00
10	39.71	66.97	56.35	36.70	33.72	29.45	43.82	14.62	33.37
15	77.88	88.93	73.81	71.34	86.12	80.62	79.78	6.86	8.59
30	92.82	96.02	84.39	84.95	95.90	96.77	91.81	5.70	6.20
45	97.23	97.28	90.35	90.27	98.32	100.25	95.62	4.25	4.45
60	99.32	97.85	94.94	93.25	99.23	101.40	97.67	3.04	3.11
120	103.88	99.05	99.96	99.54	101.10	103.73	101.21	2.12	2.10

Cepharmycin(永信)膠囊劑之溶離度

時間 (min)	S1	S2	S3	S4	S5	S6	mean	S.D.	C.V. (%)
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
5	18.73	42.00	44.57	37.08	45.17	49.19	39.46	10.91	27.65
10	88.85	89.88	85.21	85.05	87.17	86.99	87.19	1.93	2.21
15	100.50	100.75	95.99	98.19	97.66	96.58	98.28	1.98	2.01
30	103.28	103.41	102.43	102.34	101.71	102.14	102.55	0.66	0.65
45	104.45	103.81	103.06	102.62	101.91	102.41	103.04	0.94	0.91
60	103.61	103.73	103.06	102.56	101.86	102.30	102.85	0.74	0.72
120	104.29	103.83	102.82	102.67	101.84	102.85	103.05	0.88	0.85

表 6-3 Keflex (Eli Lilly, 台灣) 與 Cephanmycin(永信)膠囊劑於 pH=6.8 溶離液之溶離試驗

Keflex (Eli Lilly, 台灣)膠囊劑之溶離度

時間 (min)	S1	S2	S3	S4	S5	S6	mean	S.D.	C.V. (%)
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
5	6.22	6.77	6.42	5.82	5.15	8.30	6.45	1.06	16.51
10	20.64	23.81	19.94	21.79	15.21	21.67	20.51	2.91	14.18
15	52.88	67.70	65.42	67.06	53.82	48.03	59.15	8.56	14.47
30	75.11	91.46	90.85	85.23	78.54	79.39	83.43	6.82	8.17
45	82.21	97.26	96.74	92.71	87.74	94.01	91.78	5.80	6.32
60	87.31	100.37	100.11	96.91	92.62	99.46	96.13	5.21	5.42
120	95.67	106.68	105.63	102.61	100.30	107.11	103.00	4.44	4.31

Cephanmycin(永信)膠囊劑之溶離度

時間 (min)	S1	S2	S3	S4	S5	S6	mean	S.D.	C.V. (%)
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
5	50.53	38.68	29.12	27.65	60.98	46.25	42.20	12.91	30.60
10	99.14	97.87	97.66	90.24	96.46	91.81	95.53	3.63	3.80
15	101.93	101.53	102.03	98.86	101.76	98.48	100.77	1.64	1.62
30	102.42	102.01	102.29	100.90	101.80	102.64	102.01	0.62	0.61
45	102.58	102.26	102.56	101.04	101.97	102.94	102.23	0.67	0.65
60	103.43	101.01	102.79	101.18	102.09	103.07	102.26	1.01	0.98
120	103.00	102.32	102.62	101.43	102.19	103.49	102.51	0.71	0.69

表 7 十二位受試者個別之血漿中 cephalexin 濃度

Subject A		
Time(hr)	Keflex($\mu\text{g/ml}$)	Cephanmycin($\mu\text{g/ml}$)
0.0	0	0
0.33	2.327	1.608
0.66	5.450	5.954
1.0	9.677	9.779
1.5	7.918	6.786
2.0	4.732	5.441
2.5	3.063	3.733
3.0	2.381	3.296
4.0	1.679	1.601
5.0	1.214	1.026
6.0	0.658	0.512
8.0	0.164	0.109
10.0	0.094	0.067

Subject B		
Time(hr)	Keflex($\mu\text{g/ml}$)	Cephanmycin($\mu\text{g/ml}$)
0.0	0	0
0.33	2.631	3.440
0.66	10.494	11.559
1.0	6.728	7.691
1.5	4.714	5.513
2.0	3.146	3.369
2.5	1.947	2.321
3.0	1.516	1.916
4.0	0.780	1.294
5.0	0.357	0.718
6.0	0.102	0.481
8.0	n.d.	0.194
10.0	n.d.	n.d.

Subject C

Time(hr)	Keflex($\mu\text{g/ml}$)	Cephanmycin($\mu\text{g/ml}$)
0.0	0	0
0.33	0.221	2.445
0.66	9.396	9.178
1.0	12.084	11.617
1.5	9.804	7.439
2.0	7.903	6.596
2.5	4.307	4.974
3.0	3.193	4.627
4.0	1.889	2.812
5.0	1.182	1.535
6.0	0.459	0.964
8.0	0.198	0.111
10.0	n.d.	0.090

Subject D

Time(hr)	Keflex($\mu\text{g/ml}$)	Cephanmycin($\mu\text{g/ml}$)
0.0	0	0
0.33	7.460	11.553
0.66	13.977	14.618
1.0	7.522	8.544
1.5	6.115	4.737
2.0	4.158	2.675
2.5	2.714	2.175
3.0	2.110	1.414
4.0	1.635	0.889
5.0	0.474	0.525
6.0	0.332	0.298
8.0	0.283	0.148
10.0	0.094	n.d.

Subject E

Time(hr)	Keflex($\mu\text{g/ml}$)	Cephanmycin($\mu\text{g/ml}$)
0.0	0	0
0.33	n.d.	0.054
0.66	n.d.	0.389
1.0	2.101	3.733
1.5	7.843	8.819
2.0	6.012	6.328
2.5	4.200	5.971
3.0	2.830	3.927
4.0	1.353	2.039
5.0	0.814	1.072
6.0	0.547	0.662
8.0	0.163	0.228
10.0	n.d.	n.d.

Subject F

Time(hr)	Keflex($\mu\text{g/ml}$)	Cephanmycin($\mu\text{g/ml}$)
0.0	0	0
0.33	n.d.	4.041
0.66	11.177	12.054
1.0	6.216	9.324
1.5	5.785	6.545
2.0	5.641	4.331
2.5	4.337	2.954
3.0	3.465	2.154
4.0	1.766	1.250
5.0	0.866	0.717
6.0	0.728	0.262
8.0	n.d.	0.139
10.0	n.d.	0.095

Subject G

Time(hr)	Keflex($\mu\text{g/ml}$)	Cephanmycin($\mu\text{g/ml}$)
0.0	0	0
0.33	0.117	1.148
0.66	8.336	6.105
1.0	11.425	10.245
1.5	9.235	6.952
2.0	5.190	4.304
2.5	3.638	3.021
3.0	2.812	2.060
4.0	1.622	1.276
5.0	1.078	0.817
6.0	0.761	0.367
8.0	0.345	0.133
10.0	n.d.	n.d.

Subject H

Time(hr)	Keflex($\mu\text{g/ml}$)	Cephanmycin($\mu\text{g/ml}$)
0.0	0	0
0.33	1.589	2.524
0.66	12.086	11.323
1.0	9.764	6.434
1.5	5.660	5.428
2.0	3.912	4.432
2.5	2.712	2.916
3.0	2.022	1.843
4.0	1.290	0.818
5.0	0.732	0.515
6.0	0.317	0.144
8.0	0.116	n.d.
10.0	n.d.	n.d.

Subject I

Time(hr)	Keflex($\mu\text{g/ml}$)	Cephanmycin($\mu\text{g/ml}$)
0.0	0	0
0.33	0.188	0.502
0.66	7.486	2.740
1.0	10.150	10.647
1.5	5.933	6.627
2.0	3.518	4.988
2.5	2.525	3.288
3.0	1.716	2.143
4.0	1.040	1.330
5.0	0.379	0.684
6.0	0.216	0.482
8.0	0.092	0.052
10.0	n.d.	n.d.

Subject J

Time(hr)	Keflex($\mu\text{g/ml}$)	Cephanmycin($\mu\text{g/ml}$)
0.0	0	0
0.33	n.d.	3.164
0.66	5.255	8.819
1.0	8.226	7.587
1.5	6.628	5.161
2.0	3.887	3.588
2.5	2.704	2.554
3.0	1.790	1.999
4.0	1.108	1.147
5.0	0.722	0.499
6.0	0.236	0.221
8.0	n.d.	0.092
10.0	n.d.	0.051

Subject K

Time(hr)	Keflex($\mu\text{g/ml}$)	Cephanmycin($\mu\text{g/ml}$)
0.0	0	0
0.33	n.d.	2.398
0.66	9.125	9.736
1.0	7.802	8.072
1.5	7.454	5.081
2.0	4.471	2.804
2.5	2.805	1.898
3.0	1.639	1.400
4.0	0.768	0.543
5.0	0.422	0.350
6.0	0.113	0.086
8.0	n.d.	n.d.
10.0	n.d.	n.d.

Subject L

Time(hr)	Keflex($\mu\text{g/ml}$)	Cephanmycin($\mu\text{g/ml}$)
0.0	0	0
0.33	1.663	1.642
0.66	14.081	14.056
1.0	9.764	9.574
1.5	6.992	5.151
2.0	3.980	3.171
2.5	3.164	2.371
3.0	2.462	1.231
4.0	1.759	0.961
5.0	1.408	0.407
6.0	0.734	0.094
8.0	n.d.	0.087
10.0	n.d.	n.d.