

表 17 Diclo-puren 與 Weren EMC 生體可用率比較之
受試者資料

編號	年齡(yr)	身高(cm)	體重(Kg)	給藥次序	
1	24.00	173.00	62.10	Y	B
2	22.00	177.00	79.80	B	Y
3	24.00	174.00	63.60	Y	B
4	30.00	178.00	73.90	B	Y
5	25.00	170.50	65.10	B	Y
6	24.00	173.00	72.30	Y	B
7	24.00	168.00	61.00	Y	B
8	21.00	181.50	65.90	B	Y
9	25.00	167.00	57.90	Y	B
10	21.00	170.00	74.60	B	Y
11	24.00	171.50	59.10	B	Y
12	25.00	181.50	77.60	Y	B
Mean	24.08	173.75	67.74		
S.D.	2.35	4.85	7.54		

Y : Weren EMC

B : Diclo-puren 50

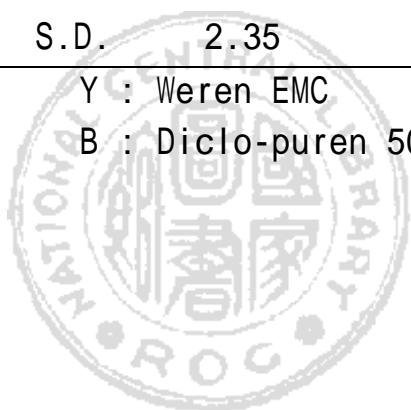


表 18 Diclo-puren 與 Weren EMC 於 pH1.2 溶離度試驗(%)

表18-1 Weren EMC之溶離度

Time(min)	1	2	3	4	5	6	7	8	9	mean	S.D.	C.V. (%)
5.0	0.50	0.40	0.40	0.80	0.80	0.70	0.40	0.40	1.10	0.61	0.25	41.27
10.0	0.50	0.40	0.40	0.50	0.80	0.50	0.70	0.50	1.20	0.61	0.26	42.07
15.0	0.50	0.50	0.40	1.00	0.70	0.50	0.40	0.50	1.60	0.68	0.39	57.98
20.0	0.50	0.50	0.40	0.80	0.80	1.20	0.70	0.70	2.10	0.86	0.52	61.05
25.0	0.70	0.70	0.40	0.80	1.00	1.10	0.70	0.70	1.60	0.86	0.34	40.11
30.0	0.70	0.80	0.70	1.00	0.80	1.10	0.80	1.00	2.50	1.04	0.56	53.97
45.0	2.10	2.20	0.80	1.90	2.10	1.90	1.80	1.80	2.30	1.88	0.44	23.48
60.0	2.70	2.70	2.10	2.70	2.70	2.60	2.20	2.70	2.70	2.57	0.24	9.34
70.0	2.90	3.00	3.00	3.40	3.30	2.70	2.50	3.00	2.90	2.97	0.27	9.23

表18-2 Diclo-puren之溶離度

Time(min)	1	2	3	4	5	6	7	8	9	mean	S.D.	C.V. (%)
5.0	1.10	1.10	0.80	1.20	1.40	1.40	1.20	1.10	1.40	1.19	0.20	16.53
10.0	1.40	1.50	1.40	1.80	1.60	1.50	1.40	1.40	1.50	1.50	0.13	8.82
15.0	1.20	1.40	1.50	1.80	1.60	1.60	1.00	1.60	1.60	1.48	0.24	16.50
20.0	1.50	1.50	1.50	1.90	1.60	1.60	1.60	1.40	1.60	1.58	0.14	8.84
25.0	1.50	1.50	1.60	1.80	1.80	1.80	1.80	1.60	1.80	1.69	0.14	8.08
30.0	1.60	1.60	1.50	1.80	1.90	1.90	1.60	1.60	1.60	1.68	0.15	8.83
45.0	1.60	1.60	1.50	1.80	1.80	1.60	1.50	1.60	1.90	1.66	0.14	8.60
60.0	1.80	1.80	1.60	1.90	1.90	1.80	1.80	1.80	1.60	1.78	0.11	6.15
70.0	1.80	2.20	1.80	2.10	2.10	2.10	1.80	1.60	1.80	1.92	0.20	10.65

表19 Diclo-puren與Weren EMC於pH4.5之溶離試驗(%)

表19-1 Weren EMC之溶離度

Time(min)	1	2	3	4	5	6	7	8	9	mean	S.D.	C.V.(%)
5.0	3.30	1.20	1.50	7.20	6.40	7.00	6.00	6.60	6.20	5.04	2.38	47.21
10.0	55.90	47.60	40.70	43.20	42.60	42.60	38.70	41.00	39.40	43.52	5.32	12.22
15.0	86.50	90.40	92.00	78.20	77.90	86.40	88.00	79.00	85.50	84.88	5.29	6.24
20.0	95.70	96.70	95.70	92.50	93.00	93.00	95.10	93.40	92.40	94.17	1.63	1.73
25.0	97.00	102.30	96.40	94.30	94.80	94.20	95.10	95.60	93.00	95.86	2.70	2.81
30.0	97.60	102.30	96.80	96.20	94.70	94.30	95.30	96.50	94.30	96.44	2.48	2.58
45.0	97.20	98.30	96.10	96.20	94.70	94.30	95.20	96.50	94.60	95.90	1.33	1.39
60.0	97.40	99.50	95.70	96.20	94.80	94.30	95.20	96.50	94.60	96.02	1.64	1.71
70.0	97.00	101.20	94.70	96.20	94.80	94.30	95.20	96.50	94.70	96.07	2.14	2.23

表19-2 Diclo-puren之溶離度

Time(min)	1	2	3	4	5	6	7	8	9	mean	S.D.	C.V.(%)
5.0	14.60	14.40	14.30	14.60	14.40	14.30	12.10	14.80	14.60	14.23	0.82	5.74
10.0	70.70	60.70	62.30	70.70	60.70	62.30	48.70	60.60	60.40	61.90	6.48	10.47
15.0	87.20	89.90	86.80	87.20	89.90	86.80	76.50	89.70	96.50	87.83	5.23	5.95
20.0	90.30	93.60	89.40	90.30	93.60	89.40	76.50	93.70	96.50	90.37	5.74	6.35
25.0	91.20	93.70	90.40	91.20	93.70	90.40	77.60	92.60	96.50	90.81	5.33	5.87
30.0	91.40	94.10	90.90	91.40	94.10	90.90	79.40	92.60	96.40	91.24	4.81	5.27
45.0	91.30	94.10	90.90	91.30	94.10	90.90	79.40	92.60	96.40	91.22	4.81	5.28
60.0	91.40	94.00	90.90	91.40	94.00	90.90	79.70	92.60	96.40	91.26	4.71	5.16
70.0	91.40	94.00	90.90	91.40	94.00	90.90	78.90	92.60	96.40	91.17	4.95	5.43

表20 Diclo-puren與Weren EMC於pH6.8之溶離試驗(%)

表20-1 Weren EMC之溶離度

Time(min)	1	2	3	4	5	6	7	8	9	mean	S.D.	C.V.(%)
5.0	45.40	46.90	52.20	48.20	44.90	48.60	46.10	48.20	48.30	47.64	2.19	4.59
10.0	97.20	93.20	92.00	93.00	94.60	91.70	92.40	95.60	91.10	93.42	2.00	2.14
15.0	98.10	96.50	98.50	96.80	97.80	97.20	93.40	97.20	92.80	96.48	2.02	2.09
20.0	98.00	95.60	98.30	97.00	97.80	98.40	95.90	98.30	94.00	97.03	1.55	1.59
25.0	98.10	96.60	99.30	97.40	98.30	98.40	96.90	98.30	96.50	97.76	0.95	0.98
30.0	98.30	97.50	99.80	97.60	98.60	99.00	97.40	98.90	96.90	98.22	0.94	0.95
45.0	98.50	97.00	99.90	97.60	99.10	99.30	98.20	99.40	97.60	98.51	0.98	1.00
60.0	98.40	97.00	99.90	98.10	99.40	99.30	98.20	100.00	98.50	98.76	0.97	0.99
70.0	98.30	97.50	100.00	98.60	99.60	99.80	98.20	100.00	98.40	98.93	0.93	0.94

表20-2 Diclo-puren之溶離度

Time(min)	1	2	3	4	5	6	7	8	9	mean	S.D.	C.V.(%)
5.0	19.40	15.30	18.40	28.80	25.00	22.60	20.50	21.90	20.70	21.40	3.89	18.17
10.0	61.90	65.00	69.20	62.70	62.60	62.20	61.90	62.80	62.60	63.43	2.35	3.71
15.0	81.50	93.00	94.00	94.80	92.20	90.30	86.50	85.10	82.90	88.92	5.02	5.64
20.0	94.60	99.80	102.50	101.40	95.80	92.10	96.90	95.40	86.10	96.07	5.03	5.23
25.0	96.20	100.70	103.00	101.50	98.20	94.90	99.40	96.10	90.80	97.87	3.79	3.87
30.0	100.20	101.00	103.40	103.50	99.10	97.30	101.2	97.20	91.60	99.39	3.70	3.72
45.0	92.50	100.90	102.30	103.70	99.10	98.10	100.8	97.20	92.60	98.58	3.96	4.02
60.0	100.90	101.70	102.20	104.00	100.9	99.00	100.8	90.10	93.40	99.22	4.52	4.55
70.0	102.70	101.70	104.00	104.00	101.7	101.2	101.5	102.50	94.20	101.5	2.92	2.88

表21 Diclo-puren與Weren EMC於H2O之溶離試驗(%)

表21-1 Weren EMC之溶離度

Time(min)	1	2	3	4	5	6	7	8	9	mean	S.D.	C.V. (%)
5.0	17.80	16.80	25.30	23.10	24.30	24.30	30.80	27.70	28.80	24.32	4.68	19.23
10.0	84.60	84.90	85.60	60.10	67.40	68.70	86.70	90.80	83.90	79.19	10.78	13.61
15.0	95.40	96.20	95.90	93.20	99.70	97.60	94.40	100.60	94.00	96.33	2.53	2.63
20.0	95.90	97.50	97.00	98.10	100.00	99.30	95.60	95.70	94.40	97.06	1.85	1.90
25.0	97.00	97.50	97.30	97.20	99.80	99.70	94.50	91.20	99.60	97.09	2.79	2.87
30.0	97.00	97.60	97.80	97.60	99.80	99.60	98.50	92.80	96.90	97.51	2.05	2.10
45.0	97.30	97.80	97.40	97.70	99.60	98.80	92.50	97.40	93.50	96.89	2.34	2.42
60.0	97.60	97.80	97.80	97.70	99.60	99.70	92.00	97.00	99.70	97.66	2.36	2.42
70.0	97.60	97.80	98.00	97.80	99.40	99.80	97.20	99.30	99.00	98.43	0.94	0.96

表21-2 Diclo-puren之溶離度

Time(min)	1	2	3	4	5	6	7	8	9	mean	S.D.	C.V. (%)
5.0	22.70	16.20	16.20	16.40	16.80	17.20	22.30	14.40	13.10	17.26	3.23	18.74
10.0	74.10	66.10	66.40	62.90	57.10	57.40	70.70	65.30	53.10	63.68	6.79	10.67
15.0	89.50	95.30	95.20	80.80	87.60	81.30	80.60	88.60	91.20	87.79	5.80	6.61
20.0	94.80	100.50	100.70	93.30	93.60	97.20	88.70	99.40	97.60	96.20	3.96	4.11
25.0	95.40	101.00	101.20	95.70	95.60	96.80	89.20	99.60	99.60	97.12	3.78	3.89
30.0	95.70	100.00	101.40	95.70	85.30	96.90	89.20	99.90	99.60	95.97	5.42	5.65
45.0	95.60	99.60	101.40	96.10	93.50	96.50	89.20	99.80	99.40	96.79	3.80	3.92
60.0	96.10	101.70	101.40	95.80	91.20	96.40	89.40	99.80	99.60	96.82	4.33	4.47
70.0	95.90	101.00	101.30	95.90	81.90	96.50	89.40	99.80	99.60	95.70	6.35	6.63

表22 口服Diclo-puren 50膠囊後血漿中Diclofenac sod.之濃度(μg/ml)

受試者 編號	Time (hr)										
	0.50	1.00	1.50	2.00	2.50	3.00	3.50	4.00	5.00	6.00	8.00
1	0.113	0.650	0.893	0.765	0.437	0.358	0.212	0.171	0.091	0.054	0.033
2	0.071	0.686	1.024	0.739	0.517	0.328	0.228	0.158	0.084	0.053	0.028
3	0.101	0.727	1.056	0.755	0.584	0.359	0.232	0.167	0.098	0.055	0.028
4	0.074	0.687	1.163	0.756	0.534	0.419	0.278	0.140	0.092	0.061	0.033
5	0.142	0.706	1.171	0.820	0.412	0.361	0.235	0.181	0.083	0.053	0.033
6	0.115	0.568	0.915	0.768	0.418	0.287	0.225	0.152	0.095	0.052	0.028
7	0.124	0.705	1.556	1.080	0.595	0.433	0.270	0.163	0.087	0.050	0.038
8	0.107	0.645	0.992	0.801	0.571	0.362	0.212	0.176	0.081	0.057	0.038
9	0.119	0.703	1.382	0.927	0.551	0.367	0.247	0.167	0.108	0.048	0.035
10	0.129	0.618	1.172	0.748	0.424	0.311	0.243	0.188	0.097	0.061	0.037
11	0.120	0.750	1.041	1.041	0.452	0.281	0.210	0.136	0.070	0.054	0.034
12	0.103	0.730	1.162	0.909	0.483	0.381	0.263	0.174	0.083	0.053	0.035
mean	0.110	0.681	1.127	0.842	0.498	0.354	0.238	0.164	0.089	0.054	0.033
S.D.	0.021	0.052	0.190	0.119	0.069	0.047	0.023	0.016	0.010	0.004	0.004
C.V. (%)	18.923	7.668	16.843	14.134	13.793	13.160	9.656	9.555	11.128	7.166	11.029

表23 口服Weren EMC 50膠囊後血漿中Diclofenac sod.之濃度($\mu\text{g}/\text{ml}$)

受試者 編號	Time (hr)										
	0.50	1.00	1.50	2.00	2.50	3.00	3.50	4.00	5.00	6.00	8.00
1	0.104	0.656	0.962	0.760	0.427	0.356	0.266	0.169	0.098	0.062	0.026
2	0.092	0.690	1.013	0.742	0.548	0.333	0.242	0.147	0.098	0.053	0.027
3	0.143	0.707	1.028	0.741	0.541	0.349	0.262	0.167	0.091	0.057	0.026
4	0.113	0.693	1.090	0.781	0.498	0.343	0.257	0.168	0.084	0.056	0.038
5	0.101	0.587	1.190	0.844	0.413	0.301	0.265	0.171	0.085	0.050	0.032
6	0.108	0.643	0.946	0.789	0.438	0.313	0.192	0.160	0.087	0.049	0.027
7	0.190	0.702	1.517	0.975	0.533	0.325	0.232	0.173	0.085	0.061	0.033
8	0.138	0.676	1.032	0.815	0.497	0.364	0.271	0.198	0.093	0.063	0.033
9	0.094	0.744	1.342	0.921	0.618	0.380	0.213	0.169	0.079	0.060	0.040
10	0.123	0.644	1.157	0.735	0.491	0.379	0.307	0.183	0.085	0.059	0.036
11	0.132	0.747	1.514	0.903	0.574	0.339	0.213	0.143	0.088	0.059	0.036
12	0.097	0.729	1.168	0.904	0.495	0.365	0.266	0.196	0.075	0.051	0.038
mean	0.120	0.685	1.163	0.826	0.506	0.346	0.249	0.170	0.087	0.057	0.033
S.D.	0.028	0.047	0.198	0.082	0.061	0.025	0.032	0.017	0.007	0.005	0.005
C.V. (%)	23.522	6.834	17.037	9.931	12.047	7.205	12.762	9.713	7.893	8.557	15.627

表24 Diclo-puren與Weren EMC於個別受試者血漿中
Diclofenac sod.之濃度(μg/ml)

表24-1 Plasma Diclofenac sod. Concentration of Subject No. 1

Time (hr)	Diclo-puren 50	Weren EMC 50
0.50	0.113	0.104
1.00	0.650	0.656
1.50	0.893	0.962
2.00	0.765	0.760
2.50	0.437	0.427
3.00	0.358	0.356
3.50	0.212	0.266
4.00	0.171	0.169
5.00	0.091	0.098
6.00	0.054	0.062
8.00	0.033	0.026

表24-2 Plasma Diclofenac sod. Concentration of Subject No. 2

Time (hr)	Diclo-puren 50	Weren EMC 50
0.50	0.071	0.092
1.00	0.686	0.690
1.50	1.024	1.013
2.00	0.739	0.742
2.50	0.517	0.548
3.00	0.328	0.333
3.50	0.228	0.242
4.00	0.158	0.147
5.00	0.084	0.098
6.00	0.053	0.053
8.00	0.028	0.027

表24-3 Plasma Diclofenac sod. Concentration of Subject No. 3

Time (hr)	Diclo-puren 50	Weren EMC 50
0.50	0.101	0.143
1.00	0.727	0.707
1.50	1.056	1.028
2.00	0.755	0.741
2.50	0.584	0.541
3.00	0.359	0.349
3.50	0.232	0.262
4.00	0.167	0.167
5.00	0.098	0.091
6.00	0.055	0.057
8.00	0.028	0.026

表24-4 Plasma Diclofenac sod. Concentration of Subject No. 4

Time (hr)	Diclo-puren 50	Weren EMC 50
0.50	0.074	0.113
1.00	0.687	0.693
1.50	1.163	1.090
2.00	0.756	0.781
2.50	0.534	0.498
3.00	0.419	0.343
3.50	0.278	0.257
4.00	0.140	0.168
5.00	0.092	0.084
6.00	0.061	0.056
8.00	0.033	0.038

表24-5 Plasma Diclofenac sod. Concentration of Subject No. 5

Time (hr)	Diclo-puren 50	Weren EMC 50
0.50	0.142	0.101
1.00	0.706	0.587
1.50	1.171	1.190
2.00	0.820	0.844
2.50	0.412	0.413
3.00	0.361	0.301
3.50	0.235	0.265
4.00	0.181	0.171
5.00	0.083	0.085
6.00	0.053	0.050
8.00	0.033	0.032

表24-6 Plasma Diclofenac sod. Concentration of Subject No. 6

Time (hr)	Diclo-puren 50	Weren EMC 50
0.50	0.115	0.108
1.00	0.568	0.643
1.50	0.915	0.946
2.00	0.768	0.789
2.50	0.418	0.438
3.00	0.287	0.313
3.50	0.225	0.192
4.00	0.152	0.160
5.00	0.095	0.087
6.00	0.052	0.049
8.00	0.028	0.027

表24-7 Plasma Diclofenac sod. Concentration of Subject No. 7

Time (hr)	Diclo-puren 50	Weren EMC 50
0.50	0.124	0.190
1.00	0.705	0.702
1.50	1.556	1.517
2.00	1.080	0.975
2.50	0.595	0.533
3.00	0.433	0.325
3.50	0.270	0.232
4.00	0.163	0.173
5.00	0.087	0.085
6.00	0.050	0.061
8.00	0.038	0.033

表24-8 Plasma Diclofenac sod. Concentration of Subject No. 8

Time (hr)	Diclo-puren 50	Weren EMC 50
0.50	0.107	0.138
1.00	0.645	0.676
1.50	0.992	1.032
2.00	0.801	0.815
2.50	0.571	0.497
3.00	0.362	0.364
3.50	0.212	0.271
4.00	0.176	0.198
5.00	0.081	0.093
6.00	0.057	0.063
8.00	0.038	0.033

表24-9 Plasma Diclofenac sod. Concentration of Subject No. 9

Time (hr)	Diclo-puren 50	Weren EMC 50
0.50	0.119	0.094
1.00	0.703	0.744
1.50	1.382	1.342
2.00	0.927	0.921
2.50	0.551	0.618
3.00	0.367	0.380
3.50	0.247	0.213
4.00	0.167	0.169
5.00	0.108	0.079
6.00	0.048	0.060
8.00	0.035	0.040

表24-10 Plasma Diclofenac sod. Concentration of Subject No. 10

Time (hr)	Diclo-puren 50	Weren EMC 50
0.50	0.129	0.123
1.00	0.618	0.644
1.50	1.172	1.157
2.00	0.748	0.735
2.50	0.424	0.491
3.00	0.311	0.379
3.50	0.243	0.307
4.00	0.188	0.183
5.00	0.097	0.085
6.00	0.061	0.059
8.00	0.037	0.036

表24-11 Plasma Diclofenac sod. Concentration of Subject No.11

Time (hr)	Diclo-puren 50	Weren EMC 50
0.50	0.120	0.132
1.00	0.750	0.747
1.50	1.600	1.514
2.00	1.041	0.903
2.50	0.452	0.574
3.00	0.281	0.339
3.50	0.210	0.213
4.00	0.136	0.143
5.00	0.070	0.088
6.00	0.054	0.059
8.00	0.034	0.036

表24-12 Plasma Diclofenac sod. Concentration of Subject No.12

Time (hr)	Diclo-puren 50	Weren EMC 50
0.50	0.103	0.097
1.00	0.730	0.729
1.50	1.162	1.168
2.00	0.909	0.904
2.50	0.483	0.495
3.00	0.381	0.365
3.50	0.263	0.266
4.00	0.174	0.196
5.00	0.083	0.075
6.00	0.053	0.051
8.00	0.035	0.038

表25 Diclo-puren與Weren EMC於血漿中Diclofenac sod. 平均濃度(μg/ml)

Time (hr)	Diclo-puren 50 (Mean ± S.D.)	Weren EMC 50 (Mean ± S.D.)
0.50	0.110 ± 0.021	0.120 ± 0.028
1.00	0.681 ± 0.052	0.685 ± 0.047
1.50	1.127 ± 0.190	1.163 ± 0.198
2.00	0.842 ± 0.119	0.826 ± 0.082
2.50	0.498 ± 0.069	0.506 ± 0.061
3.00	0.354 ± 0.047	0.346 ± 0.025
3.50	0.238 ± 0.023	0.249 ± 0.032
4.00	0.164 ± 0.016	0.170 ± 0.017
5.00	0.089 ± 0.010	0.087 ± 0.007
6.00	0.054 ± 0.004	0.057 ± 0.005
8.00	0.033 ± 0.004	0.033 ± 0.005

表 26 Weren EMC 及 Diclo-puren 個別及平均之全部藥物動力學參數

No.	AUC _{partial} ($\mu\text{g}\cdot\text{hr}/\text{ml}$)		AUC _{total} ($\mu\text{g}\cdot\text{hr}/\text{ml}$)		LAMBDA-Z (hr^{-1})		T _{1/2} (hr)		MRT (hr)		C _{max} ($\mu\text{g}/\text{ml}$)		T _{max} (hr)		CI/F (L/hr)		VD _{ss} /F (L)	
	Y	B	Y	B	Y	B	Y	B	Y	B	Y	B	Y	B	Y	B	Y	B
1	2.09	2.03	2.14	2.11	0.46	0.40	1.50	1.72	2.64	2.73	0.96	0.89	1.50	1.50	23.32	23.69	61.53	64.74
2	2.12	2.08	2.18	2.15	0.43	0.42	1.61	1.64	2.60	2.62	1.01	1.02	1.50	1.50	23.25	22.94	60.99	59.69
3	2.19	2.22	2.25	2.28	0.46	0.45	1.52	1.56	2.56	2.59	1.03	1.06	1.50	1.50	22.21	21.94	56.92	56.80
4	2.20	2.25	2.31	2.34	0.35	0.36	1.96	1.93	2.77	2.73	1.09	1.16	1.50	1.50	21.36	21.69	59.32	60.16
5	2.15	2.24	2.23	2.32	0.41	0.41	1.71	1.71	2.64	2.61	1.19	1.17	1.50	1.50	21.56	22.46	56.30	59.35
6	2.00	1.94	2.07	2.01	0.44	0.25	1.58	1.63	2.59	2.67	0.95	0.92	1.50	1.50	24.21	24.91	62.76	66.37
7	2.57	2.71	2.65	2.82	0.40	0.35	1.76	1.96	2.52	2.58	1.51	1.56	1.50	1.50	18.86	17.75	47.57	45.72
8	2.25	2.17	2.33	2.27	0.43	0.36	1.62	1.93	2.69	2.81	1.03	0.99	1.50	1.50	22.00	21.49	61.75	57.77
9	2.48	2.46	2.60	2.54	0.34	0.40	2.07	1.73	2.73	2.58	1.34	1.38	1.50	1.50	19.27	19.67	52.62	50.78
10	2.24	2.17	2.33	2.27	0.40	0.39	1.74	1.76	2.71	2.75	1.16	1.17	1.50	1.50	22.07	21.47	60.63	58.12
11	2.51	2.50	2.62	2.60	0.34	0.33	2.05	2.13	2.62	2.55	1.51	1.60	1.50	1.50	19.21	19.09	49.01	49.94
12	2.33	2.32	2.43	2.41	0.38	0.38	1.83	1.81	2.69	2.66	1.17	1.16	1.50	1.50	20.60	20.74	55.51	55.11
Mean	2.26	2.26	2.34	2.34	0.40	0.37	1.74	1.79	2.65	2.66	1.16	1.17	1.50	1.50	21.49	21.49	57.08	57.05
S.D.	0.18	0.21	0.19	0.22	0.04	0.05	0.20	0.16	0.07	0.08	0.20	0.23	0.00	0.00	1.73	1.99	5.09	5.97
C.V. (%)	7.84	9.50	8.23	9.59	10.91	13.70	11.30	9.16	2.77	3.07	16.91	19.67	0.00	0.00	8.04	9.25	8.92	10.46

Y : Weren EMC

B : Diclo-puren 50

表27 Weren EMC及Diclo-puren之個別受試者的藥品動力學參數

表27-1 Diclofenac sod. Parameters of subject No. 1

Parameters	Weren EMC	Diclo-puren 50
AUC _{partial} (µg.hr/ml)	2.088	2.028
AUC _{total} (µg.hr/ml)	2.144	2.110
-Z (hr ⁻¹)	0.463	0.402
T _{1/2} (hr)	1.496	1.724
MRT (hr)	2.639	2.733
C _{max} (µg/ml)	0.962	0.893
T _{max} (hr)	1.50	1.50
Cl/F(L/hr)	23.32	23.69
VD _{ss} /F (L)	61.53	64.74

表27-2 Diclofenac sod. Parameters of subject No. 2

Parameters	Weren EMC	Diclo-puren 50
AUC _{partial} (µg.hr/ml)	2.117	2.084
AUC _{total} (µg.hr/ml)	2.179	2.150
-Z (hr ⁻¹)	0.430	0.422
T _{1/2} (hr)	1.611	1.642
MRT (hr)	2.602	2.623
C _{max} (µg/ml)	1.013	1.024
T _{max} (hr)	1.50	1.50
Cl/F(L/hr)	23.25	22.94
VD _{ss} /F (L)	60.99	59.69

表27-3 Diclofenac sod. Parameters of subject No. 3

Parameters	Weren EMC	Diclo-puren 50
AUC _{partial} (µg.hr/ml)	2.194	2.216
AUC _{total} (µg.hr/ml)	2.251	2.279
-Z (hr ⁻¹)	0.457	0.445
T _{1/2} (hr)	1.517	1.556
MRT (hr)	2.562	2.589
C _{max} (µg/ml)	1.028	1.056
T _{max} (hr)	1.50	1.50
Cl/F(L/hr)	22.21	21.94
VD _{ss} /F (L)	56.92	56.80

表27-4 Diclofenac sod. Parameters of subject No. 4

Parameters	Weren EMC	Diclo-puren 50
AUC _{partial} (µg.hr/ml)	2.198	2.249
AUC _{total} (µg.hr/ml)	2.305	2.341
-Z (hr ⁻¹)	0.354	0.359
T _{1/2} (hr)	1.957	1.928
MRT (hr)	2.773	2.730
C _{max} (µg/ml)	1.090	1.163
T _{max} (hr)	1.50	1.50
Cl/F(L/hr)	21.36	21.69
VD _{ss} /F (L)	58.32	60.16

表27-5 Diclofenac sod. Parameters of subject No. 5

Parameters	Weren EMC	Diclo-puren 50
AUC _{partial} (µg.hr/ml)	2.147	2.238
AUC _{total} (µg.hr/ml)	2.226	2.319
-Z (hr ⁻¹)	0.406	0.406
T _{1/2} (hr)	1.706	1.707
MRT (hr)	2.643	2.611
C _{max} (µg/ml)	1.190	1.171
T _{max} (hr)	1.50	1.50
Cl/F(L/hr)	21.56	22.46
VD _{ss} /F (L)	56.30	59.35

表27-6 Diclofenac sod. Parameters of subject No. 6

Parameters	Weren EMC	Diclo-puren 50
AUC _{partial} (µg.hr/ml)	2.004	1.942
AUC _{total} (µg.hr/ml)	2.065	2.008
-Z (hr ⁻¹)	0.439	0.249
T _{1/2} (hr)	1.578	1.629
MRT (hr)	2.592	2.665
C _{max} (µg/ml)	0.946	0.915
T _{max} (hr)	1.50	1.50
Cl/F(L/hr)	24.21	24.91
VD _{ss} /F (L)	62.76	66.37

表27-7 Diclofenac sod. Parameters of subject No. 7

Parameters	Weren EMC	Diclo-puren 50
AUC _{partial} (µg.hr/ml)	2.567	2.710
AUC _{total} (µg.hr/ml)	2.651	2.817
-Z (hr ⁻¹)	0.395	0.354
T _{1/2} (hr)	1.755	1.955
MRT (hr)	2.522	2.576
C _{max} (µg/ml)	1.517	1.556
T _{max} (hr)	1.50	1.50
Cl/F(L/hr)	18.86	17.75
VD _{ss} /F (L)	47.57	45.72

表27-8 Diclofenac sod. Parameters of subject No. 8

Parameters	Weren EMC	Diclo-puren 50
AUC _{partial} (µg.hr/ml)	2.250	2.167
AUC _{total} (µg.hr/ml)	2.327	2.272
-Z (hr ⁻¹)	0.429	0.360
T _{1/2} (hr)	1.617	1.926
MRT (hr)	2.688	2.806
C _{max} (µg/ml)	1.032	0.992
T _{max} (hr)	1.50	1.50
Cl/F(L/hr)	22.00	21.49
VD _{ss} /F (L)	61.75	57.77

表27-9 Diclofenac sod. Parameters of subject No. 9

Parameters	Weren EMC	Diclo-puren 50
AUC _{partial} (µg.hr/ml)	2.475	2.455
AUC _{total} (µg.hr/ml)	2.595	2.542
-Z (hr ⁻¹)	0.335	0.400
T _{1/2} (hr)	2.069	1.732
MRT (hr)	2.730	2.581
C _{max} (µg/ml)	1.342	1.382
T _{max} (hr)	1.50	1.50
Cl/F(L/hr)	19.27	19.67
VD _{ss} /F (L)	52.62	50.78

表27-10 Diclofenac sod. Parameters of subject No. 10

Parameters	Weren EMC	Diclo-puren 50
AUC _{partial} (µg.hr/ml)	2.244	2.172
AUC _{total} (µg.hr/ml)	2.329	2.266
-Z (hr ⁻¹)	0.399	0.393
T _{1/2} (hr)	1.737	1.761
MRT (hr)	2.708	2.747
C _{max} (µg/ml)	1.157	1.172
T _{max} (hr)	1.50	1.50
Cl/F(L/hr)	22.07	21.47
VD _{ss} /F (L)	60.63	58.12

表27-11 Diclofenac sod. Parameters of subject No. 11

Parameters	Weren EMC	Diclo-puren 50
AUC _{partial} (µg.hr/ml)	2.512	2.499
AUC _{total} (µg.hr/ml)	2.619	2.603
-Z (hr ⁻¹)	0.338	0.326
T _{1/2} (hr)	2.048	2.126
MRT (hr)	2.616	2.551
C _{max} (µg/ml)	1.514	1.600
T _{max} (hr)	1.50	1.50
Cl/F(L/hr)	19.21	19.09
VD _{ss} /F (L)	49.01	49.94

表27-12 Diclofenac sod. Parameters of subject No. 12

Parameters	Weren EMC	Diclo-puren 50
AUC _{partial} (µg.hr/ml)	2.326	2.319
AUC _{total} (µg.hr/ml)	2.427	2.411
-Z (hr ⁻¹)	0.378	0.383
T _{1/2} (hr)	1.833	1.810
MRT (hr)	2.694	2.657
C _{max} (µg/ml)	1.168	1.162
T _{max} (hr)	1.50	1.50
Cl/F(L/hr)	20.60	20.74
VD _{ss} /F (L)	55.51	55.11

表28 Weren EMC及Diclo-puren之平均藥物動力學參數

Parameters	Weren EMC	Diclo-puren 50	Statistics
AUC _{partial} (μg.hr/ml)	2.26 ± 0.18	2.26 ± 0.21	P>0.05
AUC _{total} (μg.hr/ml)	2.34 ± 0.19	2.34 ± 0.22	P>0.05
-Z (hr ⁻¹)	0.40 ± 0.04	0.37 ± 0.05	P>0.05
T _{1/2} (hr)	1.74 ± 0.20	1.79 ± 0.16	P>0.05
MRT (hr)	2.65 ± 0.07	2.66 ± 0.08	P>0.05
C _{max} (μg/ml)	1.16 ± 0.20	1.17 ± 0.23	P>0.05
T _{max} (hr)	1.50 ± 0.00	1.50 ± 0.00	P>0.05
Cl/F(L/hr)	21.49 ± 1.73	21.49 ± 1.99	P>0.05
VD _{ss} /F (L)	57.08 ± 5.09	57.05 ± 5.97	P>0.05