

A P P E N D I X

Table-28a : Excretion of desacetylated rifampicin as percentage of total rifampicin excretion - Rifampicin single dose study

No.	NP	Hours after drug administration			LP	Hours after drug administration		
		12	24	48		72	12	24
1.	21.9	21.7	43.2	47.3		25.8	24.4	49.6
2.	18.8	27.1	43.4	48.6		20.5	26.5	49.1
3.	20.3	18.1	33.5	33.5		14.4	19.2	44.9
4.	19.2	15.8	38.5	57.3		17.4	24.5	46.2
5.	23.5	19.3	28.2	22.3		29.3	16.9	29.9
6.	14.6	23.7	47.7	46.0		25.9	19.8	38.0
7.	15.9	27.1	17.1	20.2		19.3	23.0	58.2
8.	20.8	40.1	47.5	49.9		18.3	23.9	40.1
9.	23.5	19.9	21.9	24.6		12.6	30.8	41.4
10.	23.4	20.9	33.5	34.7		27.5	34.9	43.4
Mean $\pm$	20.2	23.3	35.4	36.4		21.1	26.4	43.9
SEM	$\pm$ 0.9	$\pm$ 2.1	$\pm$ 3.2	$\pm$ 3.4		$\pm$ 1.7	$\pm$ 1.6	$\pm$ 2.3
								$\pm$ 3.3

Table-28b : Excretion of desacetylated rifampicin as percentage of total rifampicin excretion - Rifampicin chronic study

No.	NP	Hours after drug administration	LP			Hours after drug administration		
			12	24	48	72	12	24
1.	10.4	13.0	17.3	20.7			14.7	14.4
2.	11.9	12.3	15.0	31.9			12.4	18.2
3.	11.5	11.5	23.4	28.4			8.9	15.4
4.	8.8	10.7	27.8	33.8			18.1	22.8
5.	9.7	24.9	21.7	34.4			17.7	21.6
6.	11.3	14.3	27.9	33.6			22.8	23.2
7.	11.8	15.8	20.9	38.3			12.1	17.8
8.	6.7	12.9	19.6	36.6			17.8	15.7
9.	10.6	12.8	27.3	39.2			20.3	24.1
10.	10.6	14.4	24.4	48.7			23.5	27.5
Mean $\pm$ SEM	10.3 $\pm$ 0.5	14.3 $\pm$ 1.2	22.6 $\pm$ 1.3	34.6 $\pm$ 2.2			16.8 $\pm$ 1.4	20.0 $\pm$ 1.3
								37.8 $\pm$ 3.4
								33.1 $\pm$ 3.1

APPENDIX TO TABLE-30a

Group	Cytochrome P-450 umoles/mg microsomal protein			
	Untreated		Treated	
Normally nourished, NP group	1.	1.95	1.	1.84
	2.	1.04	2.	1.44
	3.	1.65	3.	1.97
	4.	1.48	4.	1.73
	5.	-	5.	1.59
	6.	-	6.	1.59
Mean		1.53		1.69
		± 0.16		± 0.10
Undernourished, LP group	1.	0.85	1.	0.60
	2.	0.84	2.	0.74
	3.	0.65	3.	1.12
	4.	0.37	4.	0.39
	5.	0.40	5.	1.00
	6.	0.39	6.	1.88
Mean		0.57		0.95
		± 0.1		± 0.2

APPENDIX TO TABLE-30b

Group	Cytochrome b <sub>5</sub> umoles/mg microsomal protein	
	Untreated	Treated
Normally nourished, NP group	1. 0.98 2. 0.82 3. 1.66 4. 1.26	1. 1.12 2. 1.16 3. 1.29 4.
Mean	1.18 <u>±0.15</u>	1.19 <u>±0.04</u>
Undernourished, LP group	1. 0.39 2. 0.39 3. 0.44 4. 0.41	1. 0.45 2. 0.42 3. 0.61 4. 0.51
Mean	0.41 <u>±0.01</u>	0.49 <u>±0.04</u>

APPENDIX TO TABLE-32b

### Pharmacokinetic parameters (group A)

Sr. No.	Rifam- picin admini- stered (mg)	Co	aVd (l)	Cmax (ug)	Tmax	t <sup>1/2</sup> (hrs)	Excretion rate (mg/ml/ 24 hrs)
1.	350	15.1	23.18	8.5	2.0	1.2	0.577
2.	320	16.2	19.75	6.5	4.0	1.8	0.385
3.	340	16.0	18.75	9.9	4.0	4.0	0.173
4.	320	15.6	20.57	13.7	3.7	1.6	0.433
5.	408	24.8	16.45	20.6	5.1	5.1	0.136
6.	220	20.6	9.70	8.9	2.5	2.0	0.346
7.	245	25.9	7.72	12.0	3.0	2.0	0.346
8.	300	18.0	13.88	7.9	3.8	1.8	0.385
9.	310	13.7	21.83	13.8	2.25	8.0	0.099
10.	300	25.0	12.00	12.9	2.0	2.2	0.315
11.	320	16.7	19.11	11.1	1.8	1.8	0.385
12.	420	24.0	17.50	12.30	2.1	1.6	0.433
13.	280	18.2	15.38	10.30	1.5	1.4	0.495
14.	320	9.8	32.65	8.18	2.0	2.4	0.289
15.	300	13.00	23.15	9.76	2.5	1.6	0.433
Mean		316.87	18.17	18.11	10.42	2.74	2.57
$\pm$ 15.82		$\pm$ 1.21	$\pm$ 1.54	$\pm$ 0.99	$\pm$ 0.22	$\pm$ 0.47	$\pm$ 0.032

APPENDIX TO TABLE-32b  
Pharmacokinetic parameters (group B)

Sr. No.	Rifam- picin admi- nistra- red (mg)	Co	aVd	Cmax	Tmax	t <sup>1/2</sup>	Excretion rate (mg/ ml/24 hrs)
1.	535	19.81	27.00	18.8	1.5	2.6	0.260
2.	440	12.50	32.00	8.16	1.9	3.0	0.231
3.	255	5.90	33.89	4.0	2.5	6.0	0.120
4.	430	13.60	29.62	13.4	1.5	7.3	0.094
5.	245	6.10	32.78	4.2	2.5	9.0	0.077
6.	450	14.41	27.75	11.0	2.0	6.3	0.110
7.	390	14.00	25.00	9.2	3.0	2.0	0.350
8.	450	21.80	20.64	22.5	2.0	6.0	0.120
9.	345	15.80	18.75	15.5	2.16	3.6	0.190
10.	530	24.70	20.25	22.5	2.0	3.1	0.220
Mean	407.00	14.86	26.68	12.93	2.09	4.89	0.177
	±34.96	±1.88	±1.46	±2.06	±0.15	±0.07	±0.028

APPENDIX TO TABLE-32c

Urinary excretion of rifampicin (group A)

Sr. No.	Rifampicin administered (mg)	Urine volume (ml)	mg/day	Excretion rate (mg/ ml/24 hrs)
1.	350	470	162.5	0.346
2.	320	325	130.0	0.400
3.	340	300	138.0	0.460
4.	320	490	145.5	0.296
5.	408	490	149.8	0.305
6.	220	380	142.8	0.375
7.	245	510	158.0	0.308
8.	300	520	165.4	0.318
9.	310	490	170.5	0.347
10.	300	380	145.0	0.381
11.	320	500	160.0	0.320
12.	420	440	157.5	0.357
13.	280	535	162.9	0.304
14.	320	560	158.5	0.283
15.	300	360	175.5	0.487
Mean	316.87	450.0	154.8	0.352
	$\pm 13.3$	$\pm 20.8$	$\pm 3.2$	$\pm 0.015$

APPENDIX TO TABLE-32c  
Urinary excretion of rifampicin (group B)

Sr. No.	Rifampicin administered (mg)	Urine volume (ml)	mg/day	Excretion rate (mg/ml/24 hrs)
1.	535	320	110.0	0.344
2.	440	310	130.5	0.421
3.	255	418	143.8	0.344
4.	430	315	115.5	0.366
5.	245	340	132.8	0.390
6.	450	330	116.2	0.352
7.	390	305	112.2	0.368
8.	450	262	108.4	0.414
9.	345	310	130.0	0.419
10.	530	410	115.6	0.282
Mean	407.0 <u>±31.7</u>	332.0 <u>±15.1</u>	121.5 <u>± 3.76</u>	0.370 <u>±0.01</u>

APPENDIX TO TABLE 33 a

Table 33 a : Anthropometric data of patients of pulmonary tuberculosis (n = 10).

Sr. No.	Subject	Nutri- tional Score	Age (yea- rs)	Height (cms)	Weight (kg)	Total Protein (gm/dl)	Albumin (gm/dl)
1.	R.D.	0.162	50	161	42	5.6	3.1
2.	P.C.	0.120	55	158	30	5.5	3.3
3.	L.K.	0.125	40	160	32	5.9	3.1
4.	B.P.	0.133	35	150	30	6.2	3.5
5.	K.G.	0.168	32	158	44	5.8	3.1
6.	R.M.	0.140	55	169	40	6.2	3.2
7.	G.S.	0.140	55	169	40	6.2	3.2
8.	D.P.	0.176	45	158	44	5.6	3.2
9.	R.M.	0.118	25	162	31	5.1	3.3
10.	S.D.	0.179	48	160	46	6.4	3.4
Mean		0.146	44	150.5	37.9	5.85	3.24
		$\pm 0.72$	$\pm 3.19$	$\pm 10.42$	$\pm 2.03$	$\pm 0.13$	$\pm 0.04$

APPENDIX TO TABLE 33

Table 33 : Effect of concurrently administered drugs of rifampicin pharmacokinetic

- Serum rifampicin level (ug/ml) at different time points

Study No.	Rifampicin administered (mg)	Serum rifampicin concentration (ug/ml)					
		1/2 (hr)	2 1/2 (hrs)	4 (hrs)	6 (hrs)	8 (hrs)	24 (hrs)
1.	420	5.14	9.76	6.97	4.64	1.92	0.64
2.	300	6.16	9.18	6.40	4.80	1.90	0.43
3.	320	5.44	6.72	-	4.60	2.08	0.48
4.	300	5.40	8.16	7.00	5.63	2.53	0.40
5.	440	6.31	10.13	13.78	6.47	0.99	0.16
6.	400	10.27	21.91	13.61	-	7.30	5.80
7.	400	5.31	10.13	8.96	5.15	1.49	0.16
8.	440	-	12.99	11.60	10.08	4.08	1.12
9.	310	4.82	9.60	15.10	11.20	4.52	1.72
10.	460	6.20	10.60	13.17	12.00	8.62	2.24
Mean	379.0	6.12	10.92	10.72	7.17	3.54	1.32
	±19.32	±0.55	±1.32	±1.12	±1.01	±0.82	±0.54

Appendix to Table-33: Rifampicin (10 mg/kg) + INH (300 mg)

Study-ii

No.	Hours after drug administration					
	72	24	4	8	12	24
1.	7.20	10.32	7.0	5.32	2.18	0.82
2.	6.24	9.92	5.92	3.64	1.48	0.40
3.	6.20	12.34	8.92	4.60	3.40	1.82
4.	9.51	11.60	12.32	10.80	5.81	1.12
5.	5.30	8.32	11.82	8.40	3.12	1.40
6.	2.92	12.96	8.64	5.28	2.24	1.60
7.	8.47	12.78	6.80	3.15	1.33	0.49
8.	9.42	19.00	13.20	2.58	4.00	1.82
9.	5.40	10.83	9.42	4.32	3.20	1.00
10.	6.20	9.12	11.30	10.52	6.32	1.60
Mean	6.68 ±0.61	11.72 ±0.89	9.32 ±0.76	5.88 ±0.89	3.31 ±0.50	1.20 ±0.16

Study-iv : Rifampicin (10 mg/kg) + INH (300 mg) + streptomycin (0.75 g)

1.	5.44	8.47	6.20	4.80	3.12	0.86
2.	4.10	9.44	4.81	3.48	1.76	0.64
3.	3.72	10.64	7.30	4.60	1.72	1.32
4.	4.38	11.22	7.01	3.98	1.21	0.52
5.	3.84	8.62	13.06	6.82	2.10	1.10
6.	1.92	12.96	8.64	5.28	2.24	1.66
7.	4.80	9.12	12.63	7.18	1.89	0.36
8.	6.32	14.40	16.32	11.19	3.20	1.12
9.	2.32	11.00	10.22	3.50	2.12	1.20
10.	8.00	9.82	12.60	10.20	6.40	1.80
Mean	4.48 ±0.59	10.57 ±0.57	9.88 ±1.10	6.10 ±0.82	2.58 ±0.44	1.06 ±0.14

APPENDIX TO TABLE-33c

Urinary excretion of rifampicin

Study-i : Rifampicin alone

No.	Urine volume (ml)	mg/day	Excretion rate (mg/ml/24 hrs)
1.	720	142	0.197
2.	650	132	0.203
3.	700	140	0.202
4.	640	122	0.191
5.	720	158.5	0.220
6.	650	140	0.215
7.	690	144.8	0.210
8.	750	160	0.213
9.	620	128	0.206
10.	760	148	0.195
Mean	690.0 ±15.28	141.53 ± 3.84	0.205 ±2.96

APPENDIX TO TABLE-33c

Urinary excretion of rifampicin

Study-ii : Rifampicin + INH

No.	Urine volume (ml)	mg/day	Excretion rate (mg/ml/24 hrs)
1.	750	148	0.197
2.	700	140	0.200
3.	720	142	0.197
4.	650	125	0.192
5.	800	160	0.200
6.	730	148.5	0.212
7.	750	150	0.200
8.	800	162.8	0.203
9.	620	130	0.209
10.	820	156.2	0.190
Mean	731.0	146.25	0.200
	<u>±20.85</u>	<u>± 3.88</u>	<u>±2.15</u>

APPENDIX TO TABLE-33c

Urinary excretion of rifampicin

Study-iii : Rifampicin + INH + ethambutol

No.	Urine volume (ml)	mg/day	Excretion rate (mg/ml/24 hrs)
1.	680	140	0.205
2.	620	130	0.209
3.	750	142.5	0.190
4.	580	125	0.215
5.	790	162	0.205
6.	730	150	0.205
7.	590	154	0.202
8.	800	161.5	0.202
9.	580	132	0.227
10.	740	158	0.214
Mean	686.0 ±27.6	145.5 ± 4.29	0.207 ±3.10

APPENDIX TO TABLE 34

Table 34 : Anthropometric data of patients of pulmonary tuberculosis (n = 8)

Sr. No.	Sub-ject	Age (yrs)	Heig- ht (cms)	Weig- ht (kg)	Nutri- tional score	Total prot- eins (gm/dl)	Serum Albu- min (gm/dl)	Rifam- picin admini- stered (mgs)
1.	P.G.	34	157	34	0.138	6.0	2.8	340
2.	B.M.	28	152	28	0.121	6.5	3.0	280
3.	S.C.	39	160	39	0.152	6.6	3.0	390
4.	D.G.	38	161	39	0.150	6.2	3.8	390
5.	D.B.	38	154	38	0.160	6.5	3.0	380
6.	B.M.	39	156	39	0.160	6.8	3.5	390
7.	S.G.	42	159	42	0.166	6.5	3.3	420
8.	L.P.	38	164	38	0.141	6.0	3.0	380
Mean		37.00	157.87	37.13	0.148	6.39	3.18	371.25
		$\pm 1.86$	$\pm 1.71$	$\pm 1.88$	$\pm 0.005$	$\pm 0.13$	$\pm 0.15$	$\pm 14.23$

Appendix to Table-34 : Serum rifampicin concentration (ug/ml)  
Study-i : Rifampicin alone

No.	Hours after drug administration			
	24	8	12	24
1.	10.0	6.7	2.8	1.76
2.	23.3	13.3	3.15	0.99
3.	22.5	8.3	2.50	0.80
4.	10.0	8.8	5.00	3.20
5.	34.2	24.2	10.00	5.20
6.	13.3	9.2	2.5	0.90
7.	29.2	13.3	5.0	3.17
8.	12.5	4.9	3.5	2.70
Mean	20.0 ±2.97	11.08 ±2.52	4.30 ±0.64	2.46 ±0.54

Study-ii : Rifampicin + INH

1.	10.8	3.2	1.4	0.60
2.	21.7	11.7	4.32	0.49
3.	21.7	11.2	1.80	0.40
4.	10.3	7.2	3.30	0.20
5.	27.8	21.7	8.30	2.10
6.	11.7	5.0	1.80	1.40
7.	18.3	8.3	2.20	0.71
8.	11.3	6.2	4.30	1.80
Mean	16.7 ±2.33	9.31 ±2.04	3.25 ±0.80	1.98 ±0.76

Study-iii : Rifampicin + INH + ethambutol

1.	11.7	5.0	2.8	0.48
2.	24.2	12.5	6.8	1.35
3.	19.5	6.7	2.0	0.60
4.	13.3	5.0	1.8	0.50
5.	30.0	20.2	7.5	1.80
6.	10.8	3.3	0.9	0.40
7.	24.2	7.5	3.2	1.20
8.	9.2	4.0	2.1	1.00
Mean	17.86 ±2.97	8.02 ±2.00	3.38 ±0.83	0.91 ±0.17

APPENDIX TO TABLE-34c  
Urine excretion of rifampicin

Study-i : Rifampicin alone

No.	Urine volume (ml)	mg/day	Excretion rate (mg/ml/24 hrs)
1.	460	130	0.282
2.	620	158	0.255
3.	520	113	0.217
4.	490	145	0.296
5.	570	172	0.301
6.	600	160	0.267
7.	550	130	0.236
8.	450	112	0.249
Mean	532.5 ± 20.96	140.0 ± 7.40	0.263 ± 0.01

Study-ii : Rifampicin + INH

1.	450	142	0.315
2.	608	168	0.280
3.	440	120	0.273
4.	510	140	0.275
5.	600	178	0.297
6.	340	171	0.503
7.	500	132	0.264
8.	410	120	0.293
Mean	482.25 ± 30.46	146.4 ± 7.66	0.312 ± 0.028

Study-iii : Rifampicin + INH + ethambutol

1.	480	135	0.281
2.	600	150	0.250
3.	500	125	0.250
4.	540	141	0.256
5.	550	182	0.331
6.	500	168	0.336
7.	520	125	0.240
8.	460	120	0.261
Mean	518.75 ± 14.67	143.25 ± 7.35	0.276 ± 0.013

APPENDIX TO TABLE 35

Table 35 : Anthropometric data of patients of pulmonary tuberculosis (n = 8)

Sr. No.	Sub- ject	Age (yrs)	Heig- ht (cms)	Weig- ht (kg)	Nutri- tional score	Total prot- eins (gm/dl)	Serum Albu- min (gm/dl)	Rifampi- cin admi- nistered (mgs)
1.	F.G.	55	157	41	0.166	6.2	3.0	410
2.	L.S.	45	158	34.5	0.138	6.0	2.8	345
3.	D.P.	36	161	36	0.138	6.2	3.2	360
4.	B.D.	24	154	35	0.147	6.2	3.0	350
5.	S.T.	30	151	40	0.175	6.6	3.0	400
6.	C.L.	50	160	38	0.148	6.0	3.0	380
7.	A.D.	37	160	39.5	0.154	6.2	3.1	395
8.	R.S.	58	150	45	0.200	6.0	2.8	450
<hr/>								
Mean		41.88	156.38	39.31	0.158	6.18	2.99	386.25
		$\pm 5.31$	$\pm 1.50$	$\pm 1.36$	$\pm 0.007$	$\pm 0.09$	$\pm 0.06$	$\pm 11.65$

Appendix to Table-35b : Serum rifampicin concentration (ug/ml)

Study-i : Rifampicin alone

No.	Hours after drug administration			
	2/2	8	12	24
1.	22.5	14.0	7.2	4.0
2.	14.3	7.5	5.1	1.0
3.	18.0	11.5	6.2	1.8
4.	10.8	3.2	2.7	1.2
5.	9.0	3.2	2.0	0.4
6.	13.5	4.0	3.5	0.8
7.	12.5	8.4	6.2	2.1
8.	35.0	24.2	18.5	4.8
Mean	16.95 ±2.98	9.5 ±2.52	6.42 ±1.84	2.01 ±0.56

Study-ii : Rifampicin + INH

1.	20.2	10.8	5.0	2.2
2.	11.0	8.0	4.2	1.0
3.	12.8	10.0	5.0	1.0
4.	11.2	5.4	2.0	1.0
5.	10.0	5.0	3.0	0.6
6.	15.0	3.2	3.2	1.0
7.	11.2	7.5	6.4	2.0
8.	34.0	26.0	20.0	4.0
Mean	15.67 ±2.87	9.48 ±2.53	6.05 ±2.05	1.60 ±0.40

Study-v : Rifampicin + INH + pyrazinamide

1.	24.0	10.0	5.2	1.0
2.	15.0	7.0	4.0	0.8
3.	20.2	11.0	3.2	0.2
4.	15.0	4.2	1.8	0.4
5.	9.0	5.8	1.0	0.1
6.	14.5	3.0	1.0	1.0
7.	12.0	8.0	2.2	0.2
8.	30.0	18.0	13.2	1.0
Mean	17.46 ±2.43	8.37 ±1.68	3.95 ±1.42	0.59 ±0.14

APPENDIX TO TABLE-35c

Urine excretion of rifampicin

Study-i : Rifampicin alone

No.	Urine volume (ml)	mg/day	Excretion rate (mg/ml/24 hrs)
1.	370	123	0.332
2.	520	172	0.273
3.	340	120	0.361
4.	620	140	0.223
5.	640	150.8	0.262
6.	400	108	0.283
7.	530	132	0.260
8.	710	144	0.206
Mean	516.25 ±59.72	136.22 ± 6.66	0.275 ±0.02

Study-ii : Rifampicin + INH

1.	350	100	0.285
2.	550	150	0.311
3.	320	115.5	0.231
4.	600	134	0.226
5.	550	144.2	0.236
6.	360	102	0.270
7.	500	130	0.249
8.	680	140	0.203
Mean	488.75 ±57.63	126.9 ± 6.32	0.259 ±0.01

Study-iii : Rifampicin + INH + ethambutol

1.	340	125	0.368
2.	500	162	0.476
3.	325	116	0.357
4.	630	136	0.219
5.	610	148	0.243
6.	410	108	0.263
7.	520	134	0.257
8.	690	145	0.210
Mean	503.13 ±45.16	134.25 ± 5.86	0.299 ±0.03

APPENDIX TO TABLE-36

Anthropometric data of healthy volunteers (n = 6) (Rifampicin alone, 10 mg/kg)

Sr. No.	Subjects	Rifam- picin admini- stered (mg)	Age (yrs)	Height (cms)	Weight (kg)	Nutritional score	Total proteins (g/dl)	Albumin (g/dl)
1.	M.P.	600	34	168	60	0.212	7.0	3.6
2.	S.G.	490	26	153	49	0.209	7.2	4.0
3.	S.T.	800	28	172	80	0.270	7.5	3.4
4.	C.T.	465	26	156	46.5	0.191	7.8	4.2
5.	R.P.	480	26	155	48	0.200	6.9	3.8
6.	S.K.	600	38	162	60	0.228	7.6	3.6
Mean		572.5	29.66	161.0	57.25	0.218	7.33	3.77
		$\pm 40.99$	$\pm 2.09$	$\pm 3.1$	$\pm 4.72$	$\pm 0.011$	$\pm 0.14$	$\pm 0.12$

Appendix to Table-36b : Serum rifampicin concentration (ug/ml)

Study-i : Rifampicin alone

No.	Hours after drug administration						
	72	1	2	4	8	12	24
1.	9.2	10.8	17.8	9.5	4.3	4.2	2.0
2.	8.2	9.8	11.5	7.2	5.2	3.8	2.2
3.	-	-	-	-	-	-	-
4.	11.5	15.2	19.8	14.0	10.8	5.8	3.3
5.	11.6	12.8	15.2	11.2	9.5	5.0	3.0
6.	8.6	10.8	14.2	10.2	7.3	4.0	1.8
7.	7.8	9.5	18.2	12.8	7.8	5.2	3.4
Mean	9.48 ±0.68	11.48 ±0.88	16.12 ±1.25	10.82 ±1.00	7.48 ±1.01	4.67 ±0.32	2.62 ±0.29

Study-ii : Rifampicin + INH

1.	8.5	11.0	14.8	10.5	4.9	3.2	1.8
2.	8.0	10.8	13.2	8.8	3.4	2.8	1.0
3.	10.8	14.4	19.2	12.8	7.6	4.0	3.0
4.	10.4	12.8	16.3	11.0	5.2	3.0	1.2
5.	7.8	9.2	13.0	11.8	8.0	4.1	3.2
6.	9.5	11.6	12.0	8.1	4.5	3.2	2.0
Mean	9.16 ±0.52	11.63 ±0.73	14.75 ±1.08	10.50 ±0.73	5.60 ±0.74	3.38 ±0.22	2.03 ±0.37

Study-iii : Rifampicin + INH + Ethambutol

1.	9.8	11.5	15.0	11.0	5.2	3.8	2.0
2.	10.0	12.8	14.2	9.8	5.0	2.8	1.2
3.	12.0	14.2	17.8	11.5	6.8	3.8	2.6
4.	14.3	10.8	13.5	10.0	4.3	3.1	2.0
5.	6.8	9.2	14.8	11.0	5.2	3.2	1.8
6.	10.0	11.2	14.5	10.5	4.8	3.4	2.4
Mean	10.48 ±1.02	11.62 ±0.71	14.97 ±0.61	10.63 ±0.27	5.22 ±0.34	3.35 ±0.16	2.00 ±0.2

APPENDIX TO TABLE-36c

Urinary excretion of rifampicin

Study-i : Rifampicin alone

No.	Urine volume (ml)	mg/day	Excretion rate (mg/ml/24 hrs)
1.	780	170	0.217
2.	630	130	0.206
3.	1060	220	0.207
4.	750	145	0.193
5.	870	140	0.160
6.	690	190	0.275
Mean	796.66 ±62.26	165.83 ±14.05	0.199 ±0.020

Study-ii : Rifampicin + INH

1.	800	149	0.186
2.	560	120	0.214
3.	950	195	0.205
4.	900	140	0.155
5.	820	125	0.152
6.	780	170	0.217
Mean	801.17 ±55.03	149.83 ±11.62	0.188 ±0.012

Study-iii : Rifampicin + INH + ethambutol

1.	680	160	0.235
2.	700	130	0.185
3.	1260	230	0.182
4.	1090	158	0.144
5.	1150	135	0.117
6.	900	185	0.205
Mean	963.33 ±90.12	166.33 ±15.12	0.178 ±0.02

APPENDIX TO TABLE-27

Anthropometric data of well but undernourished subjects (n = 5)

Sr. No.	Subjects	Age (yrs)	Rifam- picin admini- stered (mg)	Height (cms)	Weight (kg)	Nutritional score	Total proteins (g/dl)	Albumin (g/dl)
1.	R.G.	30	360	152.0	36.0	0.152	7.8	3.6
2.	S.S.	35	400	154.0	40.0	0.168	6.9	4.0
3.	S.N.	21	400	150.0	40.0	0.177	7.9	4.6
4.	M.R.	21	400	154.0	40.0	0.168	7.7	4.4
5.	S.P.	45	390	156.0	39.0	0.160	7.6	4.2

Appendix to Table-37b : Serum rifampicin concentration

No.	Hours after drug administration						
	1/2	1	2	4	8	12	24
1.	2.6	3.4	8.1	5.2	2.8	1.3	0.02
2.	5.8	7.2	9.0	9.5	6.6	4.4	3.2
3.	6.5	8.1	12.8	10.2	7.5	3.6	2.1
4.	8.2	10.5	12.6	9.4	5.3	3.4	2.6
5.	5.0	9.8	13.5	10.4	6.5	2.2	1.8
Mean	5.62	7.80	11.20	8.94	5.75	2.98	1.94
	±0.92	±1.25	±1.10	±0.96	±0.82	±0.55	±0.54

### Study-II : Rifampicin + INH

1.	3.1	5.6	7.5	6.2	4.5	2.2	1.6
2.	4.2	6.4	8.1	10.4	7.6	4.2	2.2
3.	6.0	9.2	10.5	7.2	5.2	3.4	2.0
4.	7.2	10.0	14.8	9.8	5.1	2.4	1.5
5.	6.5	8.2	12.4	9.5	6.8	3.2	1.8
Mean	5.4	8.48	10.66	8.62	5.84	3.08	1.82
	$\pm 0.76$	$\pm 1.07$	$\pm 1.36$	$\pm 0.82$	$\pm 0.58$	$\pm 0.36$	$\pm 0.13$

### Study-III : Rifampicin + INH + ethambutol

1.	2.5	4.4	8.0	6.5	3.8	2.3	1.0
2.	5.1	6.5	9.2	9.4	5.8	3.4	2.8
3.	6.2	8.4	12.0	9.8	7.2	3.2	1.9
4.	6.5	9.8	13.2	8.9	4.8	3.5	2.2
5.	6.4	8.4	11.4	9.2	5.8	2.9	1.5
Mean	5.35	7.50	10.76	8.76	5.48	3.06	1.88
	$\pm 0.76$	$\pm 0.94$	$\pm 0.95$	$\pm 0.59$	$\pm 0.57$	$\pm 0.23$	$\pm 0.31$

APPENDIX TO TABLE-37c

Urinary excretion of rifampicin

Study-i : Rifampicin alone

No.	Urine volume (ml)	mg/day	Excretion rate (mg/ml/24 hrs)
1.	560	98	0.175
2.	440	132	0.300
3.	720	104	0.144
4.	550	118	0.214
5.	400	102	0.255
Mean	534.0 ±48.12	110.8 ± 5.63	0.218 ±0.028

Study-ii : Rifampicin + INH

1.	630	104	0.165
2.	410	125	0.305
3.	590	100	0.169
4.	600	112	0.186
5.	450	108	0.270
Mean	536.00 ±39.66	109.8 ± 3.85	0.219 ±0.029

Study-iii : Rifampicin + INH + ethambutol

1.	700	102	0.146
2.	510	138	0.270
3.	630	130	0.237
4.	590	140	0.237
5.	440	110	0.250
Mean	574.0 ±40.76	124.00 ± 6.85	0.228 ±0.021

Table-38 : AUC of volunteers

Study No.	Undernourished (n = 5)		Well nourished (n = 6)	
i) Rifampicin alone	1.	20.5	1.	46.6
	2.	29.8	2.	33.8
	3.	37.0	3.	57.9
	4.	38.1	4.	46.5
	5.	39.2	5.	41.7
			6.	53.4
Mean		32.92		46.65
		$\pm 3.54$		$\pm 3.54$
ii) Rifampicin + INH	1.	22.37	1.	42.57
	2.	28.40	2.	38.7
	3.	31.35	3.	55.1
	4.	41.30	4.	47.6
	5.	35.80	5.	40.15
Mean		31.84		43.55
		$\pm 3.26$		$\pm 2.80$
iii) Rifampicin + Ethambu- tol	1.	22.4	1.	43.5
	2.	29.35	2.	43.2
	3.	35.65	3.	51.8
	4.	37.67	4.	41.65
	5.	34.20	5.	41.8
			6.	43.1
Mean		31.85		44.17
		$\pm 2.77$		$\pm 1.59$

APPENDIX TO TABLE-39

Studies on patients of pulmonary tuberculosis

Poor nourished group (n = 26)

Serum rifampicin concentration (ug/ml)					
2 (hrs)	2½ (hrs)	4 (hrs)	6 (hrs)	8 (hrs)	
9.2	-	13.4	10.8	9.2	
6.3	-	13.3	11.7	5.8	
8.2	-	3.2	1.4	0.6	
3.8	-	6.4	3.2	6.4	
3.4	-	9.6	7.4	2.8	
6.2	-	6.2	5.8	4.2	
11.2	-	15.8	13.2	10.0	
3.9	-	4.5	2.1	0.8	
4.8	-	14.8	4.0	1.2	
4.1	-	7.2	3.2	0.4	
12.2	-	11.0	9.2	8.8	
12.9	-	6.2	3.0	1.9	
11.0	-	8.5	3.5	1.0	
7.2	-	12.0	3.8	1.0	
3.1	-	2.2	1.8	0.4	
8.2	-	4.9	4.0	1.2	
			4.0		
5.2	9.18	4.9	4.0	2.0	
		6.4	5.0	4.8	
-	6.7	5.2	5.1	4.6	
-	8.2	7.0	6.2	5.6	
-	10.1	9.0	6.3	5.2	
-	9.6	15.1	13.1	11.2	
-	10.0	-	-	6.7	
-	23.3	-	-	13.3	
-	14.3	-	-	7.5	
-	18.0	-	-	11.5	
-	-	-	-	-	
7.11 ±0.79	12.15 ±1.80	8.29 ±0.85	5.73 ±0.74	4.93 ±0.78	
17	9	23	23	26	

Table-39 : Studies on patients of pulmonary tuberculosis  
Comparatively better nourished group (n = 37)  
(N.S.      0.14    and      0.18,    n = 37 )

	Serum rifampicin concentration (ug/ml)				
2 (hrs)	2½ (hrs)	4 (hrs)	6 (hrs)	8 (hrs)	
25.0	-	23.1	15.0		10.8
18.8	-	15.0	9.2		6.8
20.8	-	10.8	8.3		5.8
11.7	-	9.2	5.4		3.3
15.0	-	14.2	8.3		1.7
10.3	-	11.7	6.7		3.3
9.2	-	7.5	4.2		1.7
8.1	-	9.2	5.8		2.7
12.5	-	14.2	12.9		6.7
7.5	-	13.3	12.5		6.8
20.2	-	8.5	4.4		3.2
8.2	-	6.3	4.8		2.5
3.2	-	3.9	3.4		2.8
13.4	-	10.1	9.8		4.9
3.4	-	3.2	3.0		2.1
9.2	-	5.8	2.1		0.8
11.5	-	12.8	10.4		7.5
22.5	-	17.4	13.2		10.6
14.8	-	9.8	7.2		7.0
22.4	-	17.2	8.8		8.2
9.0	9.8	6.8	4.6		2.8
9.9	10.1	13.8	10.4		6.5

APPENDIX TO TABLE-16  
Growth chart (weekly weight gain in gms)

Weeks of dietary treatment							
III		VI		IX		XII	
NP	LP	NP	LP	NP	LP	NP	
87.0	62.0	127.0	108.0	162.0	120.0	195.0	
85.0	65.0	121.0	108.0	173.0	117.0	209.0	
89.0	66.8	122.0	110.0	174.05	119.0	198.0	
91.0	63.1	121.5	99.0	173.0	117.0	199.0	
85.0	58.2	110.0	89.0	163.0	110.0	199.5	
108.0	64.0	160.0	109.0	198.0	118.0	231.0	
92.0	61.0	134.0	100.8	182.0	117.5	221.0	
108.0	72.5	142.0	108.5	183.0	120.0	245.0	
111.0	48.8	161.0	99.0	200.0	113.0	249.0	
85.0	74.0	118.0	108.0	157.0	149.0	220.5	
68.0	63.5	113.0	100.0	159.0	110.0	227.0	
101.0	72.0	142.0	103.0	192.0	111.0	253.0	
88.0	60.0	116.0	97.0	155.0	107.0	218.0	
81.0	64.0	113.0	99.0	158.0	113.0	233.0	
105.0	70.0	144.0	110.0	184.0	118.0	231.0	
69.2	65.0	108.5	108.0	163.0	116.0	218.0	
89.0	58.0	128.0	94.0	179.0	102.0	243.0	
87.0	67.0	139.0	100.0	183.0	109.0	252.8	
71.0	60.0	112.2	92.0	170.2	105.0	237.0	
89.5	61.5	145.0	98.0	183.8	119.0	250.0	
88.0	70.0	133.0	99.0	130.0	115.0	193.0	
78.0	62.4	107.0	73.0	118.0	98.0	176.0	
79.8	61.0	114.0	86.0	120.0	100.0	199.0	
73.0	60.0	113.0	84.5	130.0	105.0	186.0	
77.0	58.2	113.0	66.0	142.0	86.0	181.0	

Appendix to Table-16 (Contd.)

Sr. No.	Weeks of dietary treatment							
	I		III		VI		IX	
	NP	LP	NP	LP	NP	LP	NP	LP
26.	39.4	47.5	74.8	64.8	117.0	97.0	130.0	112.0
27.	35.2	47.0	62.5	63.0	96.0	97.0	123.0	112.0
28.	39.0	45.0	59.5	68.2	98.0	92.0	127.0	107.0
29.	42.0	39.0	75.0	54.0	117.0	76.0	128.0	92.0
30.	46.0	40.0	78.5	60.0	109.0	85.0	133.0	108.0
31.	40.0	43.0	61.2	61.0	99.0	89.0	132.0	109.0
32.	42.0	37.5	74.0	53.5	104.0	66.0	130.0	86.0
33.	47.8	50.0	81.5	69.0	121.0	99.0	141.0	115.0
34.	45.0	39.8	75.2	67.0	118.0	92.0	139.0	110.0
35.	39.0	39.0	79.5	59.2	110.0	80.0	131.0	98.0
36.	41.8	40.0	72.5	58.0	104.0	82.0	142.0	97.0
37.	44.0	42.0	78.0	61.0	100.0	98.0	121.0	114.0
38.	47.0	49.5	75.0	60.0	104.0	99.0	125.0	117.0
39.	50.0	38.8	89.5	52.0	117.0	78.0	151.0	100.0
40.	42.0	43.0	74.0	59.4	114.0	94.0	130.0	112.0
Mean	43.98	42.46	82.20	62.44	119.7	95.07	152.88	110.11
	$\pm 0.66$	$\pm 0.15$	$\pm 1.93$	$\pm 1.25$	$\pm 2.51$	$\pm 2.10$	$\pm 3.87$	$\pm 1.69$

Treatment: Rifampicin alone\*

W e e k s					
IX		XII		XV	
NP	LP	NP	LP	NP	LP
172.0	108.0	222.0	141.0	263.0	190.0
163.0	126.0	218.0	172.0	270.0	208.0
173.0	131.0	224.0	162.0	259.0	210.0
200.0	119.0	237.0	153.0	272.0	182.5
201.0	114.0	238.0	140.0	262.0	155.0
187.0	109.0	229.0	140.0	272.5	170.0
181.0	119.0	220.0	150.0	258.0	192.0
184.0	121.0	229.0	160.0	280.0	167.0
165.0	100.0	207.0	129.0	254.0	160.0
160.5	126.0	208.0	158.0	264.0	198.0
164.0	97.0	211.0	122.0	263.0	152.5
193.0	141.0	219.0	175.0	240.0	308.0
143.0	110.0	211.0	141.0	234.0	170.0
161.0	125.0	231.0	160.0	292.0	195.0
191.0	118.0	238.0	163.0	270.0	166.2
200.0	122.0	229.0	159.0	290.0	193.5
203.0	118.0	223.0	140.0	244.0	170.0
177.0	115.0	242.0	144.0	270.0	190.5
189.0	131.0	228.0	169.0	279.5	200.0
168.0	114.0	228.0	148.0	260.0	178.0
<hr/>					
178.77	118.2	224.6	151.3	264.85	187.81
± 3.6	± 2.28	± 2.20	± 3.07	± 3.23	± 3.83

\* Drug treatment started from 8th week.

In vivo

Table-40a : Percentage binding of rifampicin to albumin and alpha<sub>2</sub> protein fraction

Sr. No.	Albumin (gm/dl)	Alpha <sub>2</sub> (gm/dl)	concentration in gm/dl of -			24 hours affecting concen- tration of rifampicin ug/dl bound to	Albumin	Alpha <sub>2</sub>
			Rifam- picin ug/dl bound to	Albu- min %	Alpha <sub>2</sub> %			
1.	4.8	0.62	280	18.91	1200	81.0	-	-
2.	5.2	0.68	390	17.64	1820	82.3	-	-
3.	4.5	0.40	320	16.00	1680	84.0	-	-
4.	5.0	0.49	352	14.53	2070	85.46	-	-
5.	4.0	0.45	600	30.76	1350	69.23	-	-
6.	5.1	0.50	344	15.35	1900	84.67	-	-
7.	4.4	0.56	508	21.91	1810	78.08	-	-
8.	4.9	0.43	590	23.32	1940	76.68	-	-
9.	4.2	0.52	430	22.05	1520	77.95	-	-
Mean	4.7	0.5	423.8	20.0	1698.9	79.9	-	-
	$\pm 0.1$	$\pm 0.0$	$\pm 36.8$	$\pm 1.6$	$\pm 90.7$	$\pm 1.6$		

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In vitro

Table-40b

Sr. No.	Albumin (gm/dl)	Alpha <sub>2</sub> (gm/dl)	4 hours after drug admini- stration concentration of rifampicin ug/dl bound to	24 hours affecting concentration of rifampicin ug/dl bound to	Albumin	Alpha <sub>2</sub>	Albumin %	Alpha <sub>2</sub> %
1.	4.2	0.52	52000	-	22000	20.0	88000	80.0
2.	5.2	0.68	66280	-	19200	21.0	72000	78.94
3.	4.5	0.40	51460	-	18150	31.05	40310	68.95
4.	5.0	0.49	40600	-	11960	17.96	54600	82.03
5.	4.0	0.45	62500	-	16714	17.25	80200	82.75
6.	4.4	0.56	83415	-	32520	30.97	72470	69.02
Mean	4.55	0.52	59375.8	-	48890.6	23.04	67930	76.95
	<u>±0.19</u>	<u>±0.04</u>			<u>±2.36</u>		<u>±2.36</u>	

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