

Figure 1

Tests on 80 mg tablets (Formulation 1)	specifications	T0	1 month	2 months	3 months	6 months	9 months	12 months	24 months	36 months
Tablet Appearance	White round tablet	OK	OK	OK	OK	OK	OK	OK	OK	OK
Mean mass (mg)	220.0 mg (± 5.0%)	220.3	222.5	222.2	222.7	220.8	222.7	222.0	223.3	223.0
Mass uniformity	Complies	OK	OK	OK	OK	OK	OK	OK	OK	OK
Disintegration time (min)	≤ 15 min	3	3	2	2	2	3	2	6	2
Dissolution rate (%)	At 15 min	93			95	97	95	94	91	94

Figure 2

Tests on 120 mg tablets (Formulation 2)	specifications	T0	3 months	6 months	12 months	18 months	24 months	36 months
Tablet Appearance	White round tablet	OK	OK	OK	OK	OK	OK	OK
Mean mass (mg)	328.0 mg (± 5.0%)	332.2	330.7	328.7	329.3	329.0	329.6	331.5
Mass uniformity	Complies	OK	OK	OK	OK	OK	OK	OK
Disintegration time (min)	≤ 15 min	4	3	4	4	3	4	5
Dissolution rate (%)	At 15 min	86	91	90	90	89	89	87

Figure 3

Tests on 80mg tablets (Formulation 4)	Specifications	T0	3 months	6 months	9 months	12 months	18 months
Tablet Appearance	White round tablet	OK	OK	OK	OK	OK	OK
Mean mass (mg)	209.3 (± 7.50%)	209.8	210.0	210.1	209.7	209.5	209.6
Mass uniformity	Complies	OK	OK	OK	OK	OK	OK
Active ingredient content (HPLC)	80.0mg (±5%)	78.8	78.6	79.1	78.5	78.1	78.3
Disintegration time (min)	≤ 15 min	4	3	4	3	4	3
Dissolution rate (%)	At 30 mn	96	94	96		93	
			24 months	30 months	36 months	48 months	60 months
Tablet Appearance	White round tablet		OK	OK	OK	OK	OK
Mean mass (mg)	209.3mg (± 7.50%)		209.5	208.6	210.7	209.4	209.9
Mass uniformity	Complies		OK	OK	OK	OK	OK
Active ingredient content (HPLC)	80.0mg (±5%)		78.7	79.7	78.4	78.1	78.6
Disintegration time (min)	≤ 15 min		3	3	3	4	3
Dissolution rate (%)	At 30 min		95	93	91	94	95

Figure 4

Tests on 120mg tablets (Formulation 3)	Specifications	T0	3 months	6 months	9 months	12 months
Tablet Appearance	White round tablet	OK	OK	OK	OK	OK
Mean mass (mg)	314.0 mg (± 5.0%)	316.0	315.6	316.2	315.9	317.0
Mass uniformity	Complies	OK	OK	OK	OK	OK
Active ingredient content (HPLC)	120.0mg (±5%)	119.5	119.4	119.7	118.9	120.7
Disintegration time (min)	≤ 15 min	5	5	4	4	5
Dissolution rate (%)	At 30 mn			95		96
Tablet Appearance	White round tablet		18 months	24 months	36 months	48 months
Mean mass (mg)	314.0 mg (± 5.0%)		315.9	315.4	316.7	317.3
Mass uniformity	Complies		OK	OK	OK	OK
Active ingredient content (HPLC)	120.0mg (±5%)		118.9	117.8	120.0	120.0
Disintegration time (min)	≤ 15 min		4	3	5	5
Dissolution rate (%)	At 30 min			95	94	95

Figure 5

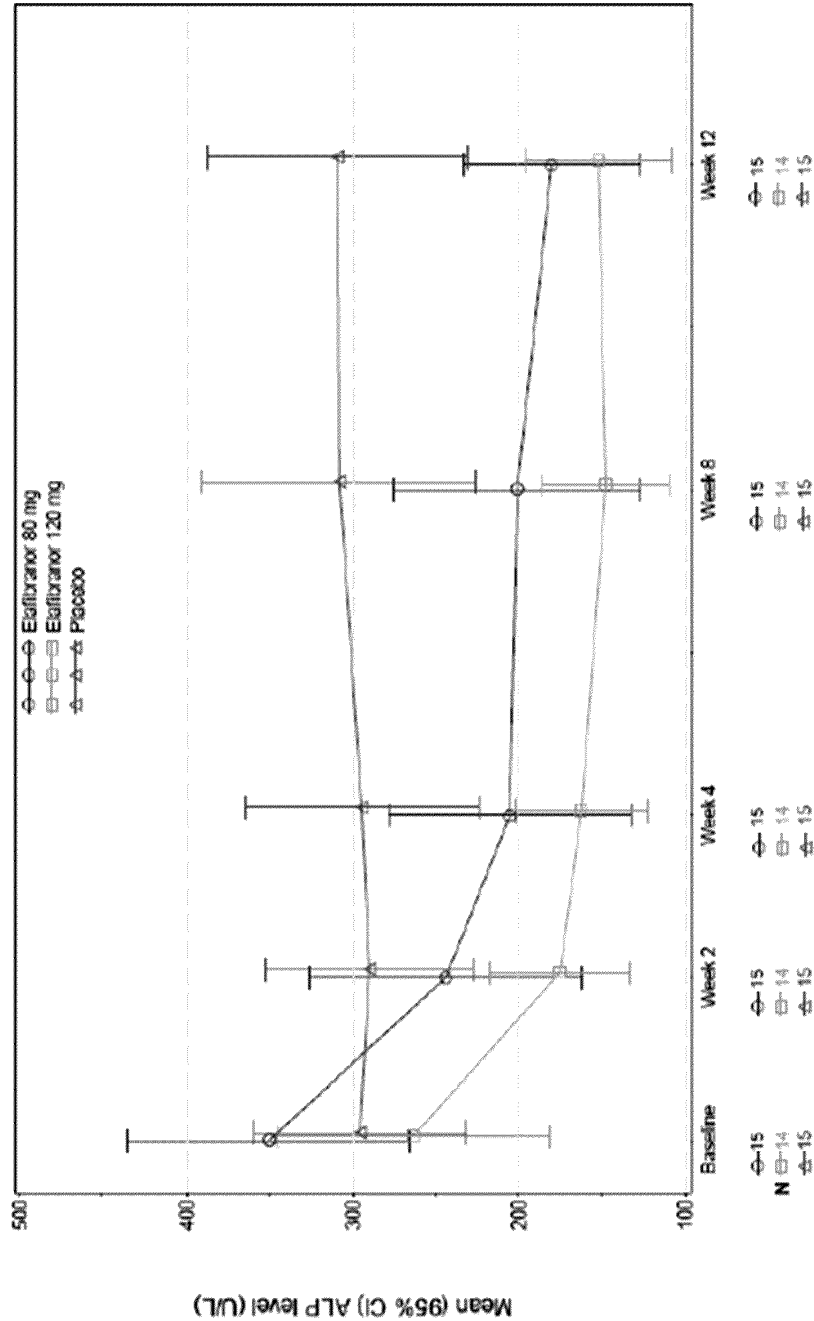


Figure 6

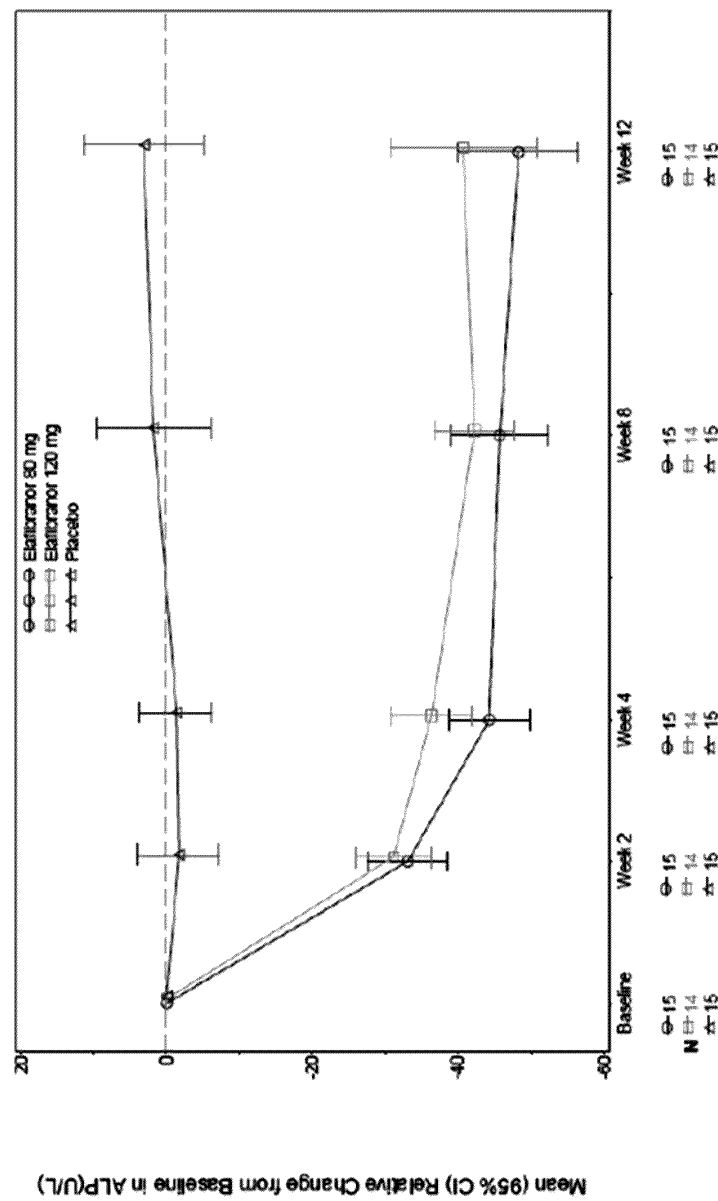


Figure 7

	Statistic	Elafibranor 80 mg N = 15	Elafibranor 120 mg N = 14	Placebo N = 15
10% Reduction in ALP levels				
Response rate from Baseline to Endpoint (Visit 5 or EOT), n (%)	Responder	14 (93.3)	13 (92.9)	2 (13.3)
	Non-responder	1 (6.7)	1 (7.1)	13 (86.7)
	Fishers exact p-value	< 0.001	< 0.001	-
20% Reduction in ALP levels				
Response rate from Baseline to Endpoint (Visit 5 or EOT), n (%)	Responder	14 (93.3)	13 (92.9)	1 (6.7)
	Non-responder	1 (6.7)	1 (7.1)	14 (93.3)
	Fishers exact p-value	< 0.001	< 0.001	-
40% Reduction in ALP levels				
Response rate from Baseline to Endpoint (Visit 5 or EOT), n (%)	Responder	13 (86.7)	8 (57.1)	0
	Non-responder	2 (13.3)	6 (42.9)	15 (100)
	Fishers exact p-value	< 0.001	< 0.001	-

Figure 8

GGT (U/L)	Statistic	Elafibranor 80 mg N = 15	Elafibranor 120 mg N = 14	Placebo N = 15
Baseline	Mean ± SD	282.3 ± 215.7	158.5 ± 144.6	229.6 ± 115.9
	Median	225.0	114.0	201.0
Endpoint (Visit 5 or EOT value)	Mean ± SD	190.8 ± 171.2	96.6 ± 90.8	230.2 ± 125.3
	Median	118.0	58.0	169.0
Absolute change from baseline to Endpoint	Mean ± SD	-91.5 ± 95.3	-61.9 ± 70.8	0.6 ± 54.4
	Median	-48.0	-46.5	-4.0
Treatment effect (vs placebo) ^a	Estimate	-77.7	-82	-
	95% CI	[-123.4 ; -32.0]	[-128.8 ; -35.1]	
	p-value	0.001	0.001	
Interaction: Baseline*trt	p-value	0.093		
Relative change from baseline to Endpoint (%)	Mean ± SD	-37.1 ± 25.5	-40.0 ± 24.1	0.2 ± 26.0
	Median	-41.0	-40.7	-2.8
Treatment effect (vs placebo) ^b	Estimate	-38.6	-39.9	-
	95% CI	[-56.8 ; -20.4]	[-58.1 ; -21.6]	
	p-value	0.001	0.002	

Figure 9

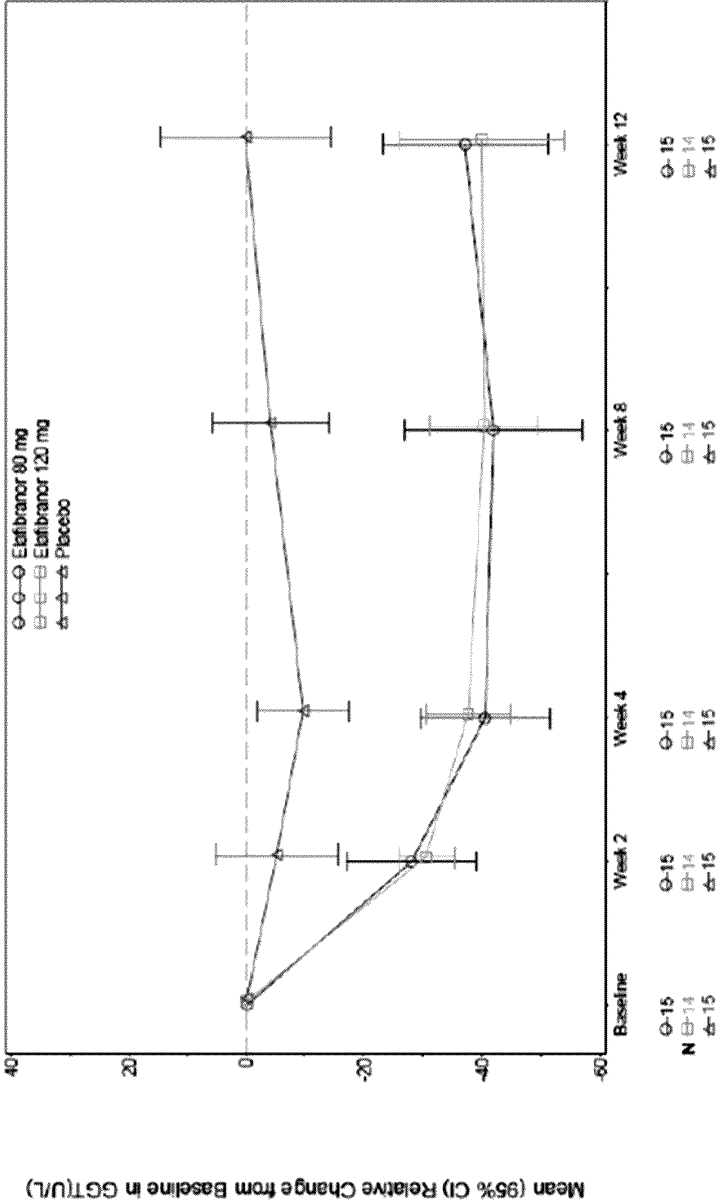


Figure 10

