

Chemi S.p.A.
Protocol LF-PB/11/04

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Table 14.2.2.1
Analysis of Secondary Endpoint: Daily Volume (mL) of Lymph Collected when Drain is in Place
Summary Statistics for each day
ITT Population

Parameter	Statistic	Placebo (N=28)	LF-PB 10 mg (N=29)	LF-PB 20 mg (N=29)	LF-PB 30 mg (N=28)
Day 2	n	27	29	29	26
	Mean	91.1	118.6	105.7	98.8
	SD	55.68	68.70	68.25	52.77
	Median	70.0	100.0	80.0	100.0
	Min, Max	10.0, 200.0	40.0, 300.0	20.0, 300.0	10.0, 250.0
Day 3	n	28	29	28	28
	Mean	87.9	95.4	93.6	101.7
	SD	43.49	45.01	101.05	64.54
	Median	90.0	80.0	60.0	87.5
	Min, Max	25.0, 170.0	45.0, 200.0	0.0, 450.0	20.0, 300.0
Day 4	n	27	28	25	27
	Mean	91.3	80.5	92.2	89.4
	SD	58.73	37.88	59.85	39.23
	Median	75.0	80.0	90.0	90.0
	Min, Max	10.0, 250.0	0.0, 150.0	5.0, 250.0	40.0, 180.0
Day 5	n	23	28	23	25
	Mean	74.7	72.0	105.4	78.2
	SD	39.69	35.65	121.52	39.05
	Median	60.0	60.0	75.0	75.0
	Min, Max	25.0, 170.0	25.0, 180.0	20.0, 600.0	25.0, 165.0

Reference: Listing(s): 16.2.6.1
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Day 6	n	20	24	22	21
	Mean	72.8	81.7	113.5	86.2
	SD	39.62	56.85	125.76	39.71
	Median	65.0	72.5	82.5	90.0
	Min, Max	25.0, 150.0	0.0, 280.0	12.0, 600.0	30.0, 160.0
Day 7	n	16	22	21	20
	Mean	55.6	79.8	93.7	75.0
	SD	40.34	44.81	73.02	41.58
	Median	45.0	75.0	70.0	70.0
	Min, Max	10.0, 140.0	0.0, 180.0	18.0, 300.0	20.0, 150.0
Day 8	n	13	18	16	18
	Mean	66.7	81.2	94.4	70.1
	SD	41.97	47.22	53.75	40.04
	Median	49.0	65.0	85.0	67.5
	Min, Max	20.0, 140.0	27.0, 200.0	25.0, 200.0	1.0, 150.0
Day 9	n	8	16	15	14
	Mean	89.0	93.4	86.3	81.1
	SD	45.46	49.90	49.51	43.15
	Median	87.5	77.5	75.0	67.5
	Min, Max	20.0, 150.0	27.0, 200.0	15.0, 200.0	0.0, 160.0

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Parameter	Statistic	Placebo (N=28)	LF-PB 10 mg (N=29)	LF-PB 20 mg (N=29)	LF-PB 30 mg (N=28)
Day 10	n	6	15	12	13
	Mean	112.5	80.5	74.6	75.2
	SD	71.95	35.65	39.40	40.65
	Median	85.0	80.0	75.0	80.0
	Min, Max	40.0, 240.0	30.0, 150.0	10.0, 130.0	0.0, 135.0
Day 11	n	6	14	10	13
	Mean	98.3	84.3	89.5	167.5
	SD	41.19	46.49	26.08	374.57
	Median	80.0	75.0	100.0	75.0
	Min, Max	60.0, 150.0	30.0, 200.0	50.0, 120.0	10.0, 1409.0
Day 12	n	6	13	9	11
	Mean	79.2	77.2	89.4	68.5
	SD	33.53	34.54	31.67	34.03
	Median	70.0	70.0	100.0	60.0
	Min, Max	40.0, 135.0	40.0, 150.0	40.0, 130.0	20.0, 130.0
Day 13	n	5	10	9	10
	Mean	72.0	77.0	71.1	66.5
	SD	13.04	48.43	16.91	37.64
	Median	70.0	62.5	70.0	55.0
	Min, Max	60.0, 90.0	25.0, 180.0	40.0, 100.0	25.0, 140.0

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Day 14	n	5	10	8	8
	Mean	74.6	70.9	73.8	73.1
	SD	29.59	39.26	24.46	39.27
	Median	70.0	72.5	80.0	67.5
	Min, Max	48.0, 125.0	20.0, 150.0	40.0, 100.0	25.0, 125.0
Day 15	n	4	5	8	4
	Mean	70.0	68.0	67.5	92.5
	SD	55.83	23.87	23.30	29.86
	Median	55.0	70.0	75.0	100.0
	Min, Max	20.0, 150.0	40.0, 100.0	30.0, 95.0	50.0, 120.0

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