

Table 14.2.4.10.2: Summary of FEV₁ Percentage of Predicted Normal Value on Day 1 – Change from Baseline (ITT Population)

Day	Time Point		CHF 5259 pMDI (N=97)	Placebo pMDI (N=98)
Day 42	T-45': 45 min pre-dose	n	97	97
		Mean (SD)	3.8 (8.7)	0.4 (7.3)
		95% CI [1]	2.1 - 5.6	-1.0 - 1.9
		Median	4.0	0.5
		Min - Max	-16 - 37	-24 - 20
Day 42	T-15': 15 min pre-dose	n	97	96
		Mean (SD)	4.9 (8.8)	1.7 (7.5)
		95% CI [1]	3.1 - 6.6	0.2 - 3.2
		Median	4.5	1.5
		Min - Max	-15 - 38	-22 - 19
	T15': 15 min post-dose	n	96	96
		Mean (SD)	6.5 (8.4)	1.8 (7.5)
		95% CI [1]	4.8 - 8.2	0.3 - 3.4
		Median	5.8	1.3
		Min - Max	-12 - 39	-22 - 23
	T30': 30 min post-dose	n	94	94
		Mean (SD)	7.7 (8.6)	2.3 (8.2)
		95% CI [1]	5.9 - 9.5	0.6 - 3.9
		Median	6.5	0.5
		Min - Max	-14 - 40	-24 - 22

Day 42	T45': 45 min post-dose	n	93	96
		Mean (SD)	8.0 (8.4)	2.9 (8.2)
		95% CI [1]	6.3 - 9.7	1.2 - 4.5
		Median	7.0	3.0
		Min - Max	-14 - 39	-22 - 24
	T1H: 1 hour post-dose	n	96	95
		Mean (SD)	8.1 (9.0)	3.6 (8.4)
		95% CI [1]	6.2 - 9.9	1.9 - 5.3
		Median	6.8	3.5
		Min - Max	-17 - 39	-16 - 28
	T2H: 2 hours post-dose	n	97	97
		Mean (SD)	8.1 (9.0)	4.0 (8.8)
		95% CI [1]	6.3 - 9.9	2.3 - 5.8
		Median	7.5	3.0
		Min - Max	-12 - 37	-19 - 35
Day 42	T3H: 3 hours post-dose	n	97	97
		Mean (SD)	8.9 (8.7)	4.5 (8.8)
		95% CI [1]	7.1 - 10.6	2.8 - 6.3
		Median	7.5	4.5
		Min - Max	-8 - 36	-15 - 31
	T4H: 4 hours post-dose	n	96	97
		Mean (SD)	8.1 (8.8)	5.3 (8.7)
		95% CI [1]	6.3 - 9.8	3.5 - 7.0
		Median	8.0	4.0
		Min - Max	-15 - 40	-14 - 25

Day 42	T6H: 6 hours post-dose	n	96	96
		Mean (SD)	7.6 (8.9)	4.5 (9.0)
		95% CI [1]	5.8 - 9.4	2.6 - 6.3
		Median	7.0	4.0
		Min - Max	-12 - 39	-24 - 31
	T8H: 8 hours post-dose	n	96	97
		Mean (SD)	7.5 (9.1)	3.5 (8.7)
		95% CI [1]	5.6 - 9.3	1.7 - 5.2
		Median	6.3	2.0
		Min - Max	-16 - 38	-19 - 26
	T11H30': 11 hours and 30 min post-dose	n	96	96
		Mean (SD)	6.3 (8.7)	2.2 (9.0)
		95% CI [1]	4.5 - 8.0	0.3 - 4.0
		Median	6.0	1.8
		Min - Max	-22 - 38	-17 - 32
	T12H: 12 hours post-dose	n	95	96
		Mean (SD)	5.8 (8.9)	2.9 (8.5)
		95% CI [1]	4.0 - 7.6	1.2 - 4.7
		Median	5.5	1.5
		Min - Max	-23 - 34	-15 - 28