

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 1	T15': 15 min post-dose	n	94	97
		Mean (SD)	4.5 (5.2)	2.1 (5.0)
		95% CI [1]	3.4 - 5.6	1.1 - 3.1
		Median	3.8	1.0
		Min - Max	-7 - 30	-9 - 25
	T30': 30 min post-dose	n	95	95
		Mean (SD)	6.2 (6.4)	2.1 (5.1)
		95% CI [1]	4.9 - 7.5	1.0 - 3.1
		Median	5.0	1.0
		Min - Max	-13 - 35	-10 - 18
	T45': 45 min post-dose	n	95	96
		Mean (SD)	7.1 (6.3)	3.0 (5.3)
		95% CI [1]	5.8 - 8.4	1.9 - 4.0
		Median	6.0	2.0
		Min - Max	-9 - 35	-10 - 21
Day 1	T1H: 1 hour post-dose	n	96	97
		Mean (SD)	8.3 (6.6)	3.1 (5.3)
		95% CI [1]	7.0 - 9.6	2.0 - 4.1
		Median	7.5	2.5
		Min - Max	-6 - 38	-10 - 18

	T2H: 2 hours post-dose	n	97	98
		Mean (SD)	8.3 (7.1)	3.6 (5.9)
		95% CI [1]	6.8 - 9.7	2.5 - 4.8
		Median	7.0	2.8
		Min - Max	-8 - 39	-13 - 20
	T3H: 3 hours post-dose	n	97	98
		Mean (SD)	8.5 (7.4)	4.6 (6.2)
		95% CI [1]	7.0 - 10.0	3.3 - 5.8
		Median	8.0	5.0
		Min - Max	-5 - 38	-13 - 18
Day 1	T4H: 4 hours post-dose	n	96	97
		Mean (SD)	8.7 (7.6)	4.8 (6.5)
		95% CI [1]	7.2 - 10.2	3.4 - 6.1
		Median	8.0	4.0
		Min - Max	-4 - 38	-11 - 23

	T6H: 6 hours post-dose	n	97	97
		Mean (SD)	7.8 (7.4)	4.7 (7.2)
		95% CI [1]	6.3 - 9.3	3.2 - 6.1
		Median	6.5	3.5
		Min - Max	-8 - 36	-12 - 25
	T8H: 8 hours post-dose	n	97	98
		Mean (SD)	6.4 (7.5)	3.6 (7.4)
		95% CI [1]	4.9 - 7.9	2.1 - 5.1
		Median	6.0	3.5
		Min - Max	-9 - 37	-16 - 21
Day 1	T11H30': 11 hours and 30 min post-dose	n	97	96
		Mean (SD)	4.8 (7.5)	1.8 (7.5)
		95% CI [1]	3.3 - 6.3	0.2 - 3.3
		Median	4.0	1.5
		Min - Max	-13 - 33	-16 - 23
	T12H: 12 hours post-dose	n	97	97
		Mean (SD)	5.1 (8.1)	2.9 (7.5)
		95% CI [1]	3.4 - 6.7	1.4 - 4.4
		Median	4.0	2.5
		Min - Max	-18 - 35	-13 - 21