

Table 9: ANCOVA Model on the Change in FEV₁ From Post-diluent to 1, 10, 20 and 30 Minutes After Study Drug Intake (ITT Population)

Change in FEV ₁	CHF1535 100/6 µg NEXThaler® (Test) N=63	CHF1535 100/6 µg pMDI (Reference) N=62	Placebo N=63
1 minute			
Adjusted mean (95% CI)	-0.645 (-0.684;-0.605)	-0.647 (-0.687;-0.608)	-0.842 (-0.881;-0.802)
Test vs Reference			
Adj. mean difference (95% CI)	0.003 (-0.053;0.059)	-	-
p-value	0.919	-	-
Active treatments vs placebo			
Adj. mean difference (95% CI)	0.197 (0.141;0.253)	0.194 (0.139;0.250)	-
p-value	<0.001	<0.001	-
10 minutes			
Adjusted mean (95% CI)	-0.352 (-0.399;-0.305)	-0.390 (-0.437;-0.343)	-0.616 (-0.662;-0.570)
Test vs Reference			
Adj. mean difference (95% CI)	0.037 (-0.029;0.104)	-	-
p-value	0.267	-	-
Active treatments vs placebo			
Adj. mean difference (95% CI)	0.264 (0.198;0.330)	0.226 (0.161;0.292)	-
p-value	<0.001	<0.001	-
20 minutes			
Adjusted mean (95% CI)	-0.208 (-0.250;-0.166)	-0.239 (-0.281;-0.196)	-0.471 (-0.513;-0.430)
Test vs Reference			
Adj. mean difference (95% CI)	0.031 (-0.029;0.090)	-	-
p-value	0.314	-	-
Active treatments vs placebo			
Adj. mean difference (95% CI)	0.263 (0.204;0.323)	0.233 (0.174;0.291)	-
p-value	<0.001	<0.001	-
30 minutes			
Adjusted mean (95% CI)	-0.093 (-0.137;-0.050)	-0.126 (-0.169;-0.082)	-0.363 (-0.406;-0.320)
Test vs Reference			
Adj. mean difference (95% CI)	0.032 (-0.029;0.094)	-	-
p-value	0.296	-	-
Active treatments vs placebo			
Adj. mean difference (95% CI)	0.270 (0.209;0.331)	0.237 (0.177;0.298)	-
p-value	<0.001	<0.001	-

N = number of subjects in the population

Source: [Table 14.2.1.7](#)