

**MULTIAIR**  
Trelegy test results



**PULINNO**  
innovative healthcare

# TEST RESULTS

## INTRODUCTION:

- We have performed comparative analysis of originators' *fluticasone furoate+umeclidinium bromide+vilanterol* (Trelegy) product on (i) Originator's Ellipta device and (ii) MultiAir device.
- For sake of tests the blister strips were retracted from Ellipta and inserted into MultiAir Device.
- The test included: APDS, Resistance Test, Delivered Dose Uniformity Tests

## RESISTANCE RESULTS:

- The airflow resistance results for all tested inhalers fall within  $\pm 15\%$  of the average resistance of the reference inhaler.
- All tested inhalers are comparable in terms of airflow resistance (average of 3 measurements per inhaler).
- Differences in inhaler resistance are observed over its lifecycle; measurements taken after the 15th dose are generally higher than those at the first and last doses.

## APSD RESULTS:

- The inhalation drug-specific parameters (FPD, FPF, MMAD, GSD) were very well reproduced in tested MultiAir inhalers compared with the reference inhaler Trelegy (flow rate 30 L/min).
- The drug mass deposited at individual stages of the NGI impactor is at a satisfactory level relative to the reference product.
- The results obtained for the two tested inhalers are consistent and reproducible

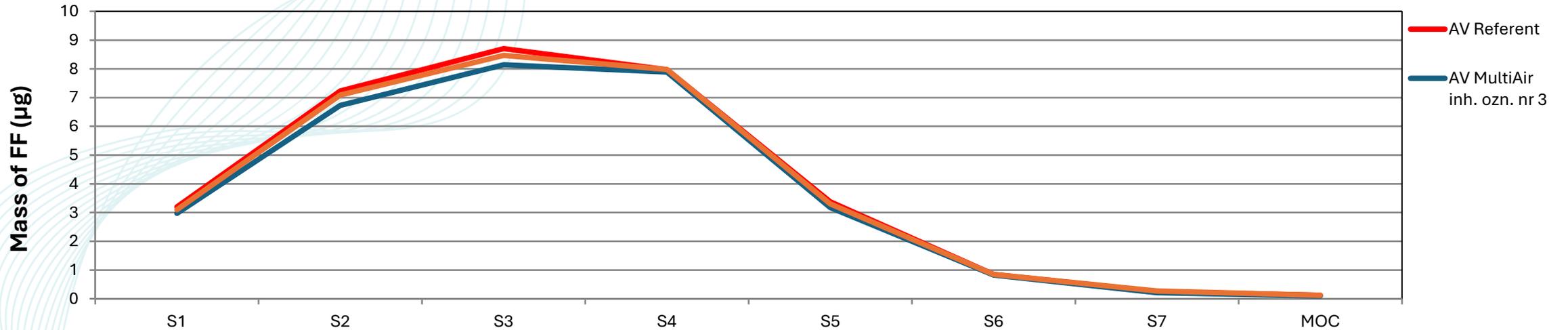
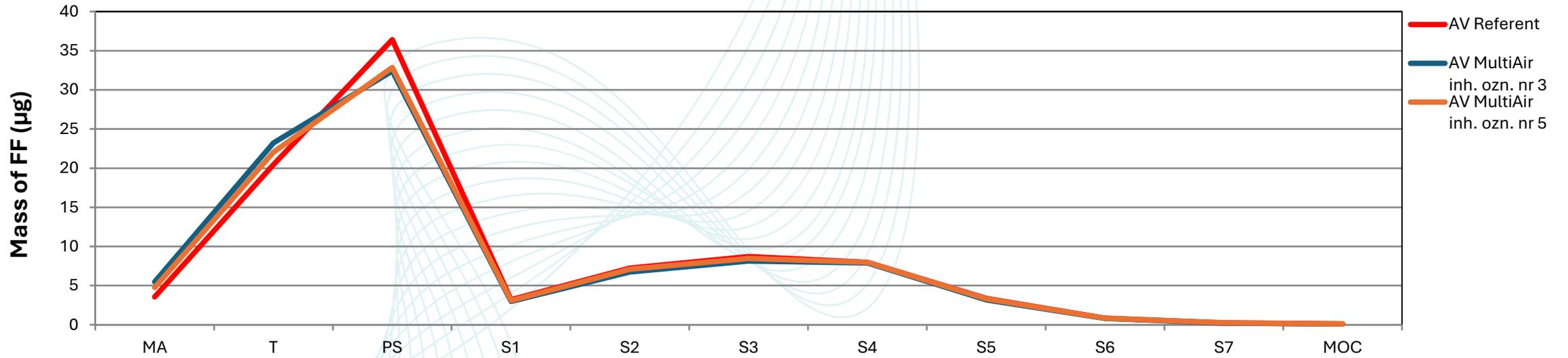
## DDU RESULTS

- The measured masses of individual doses are comparable.
- The MultiAir inhaler performed as expected in most cases at both 30 L/min and 80 L/min flow rates, regardless of the type of blister installed.

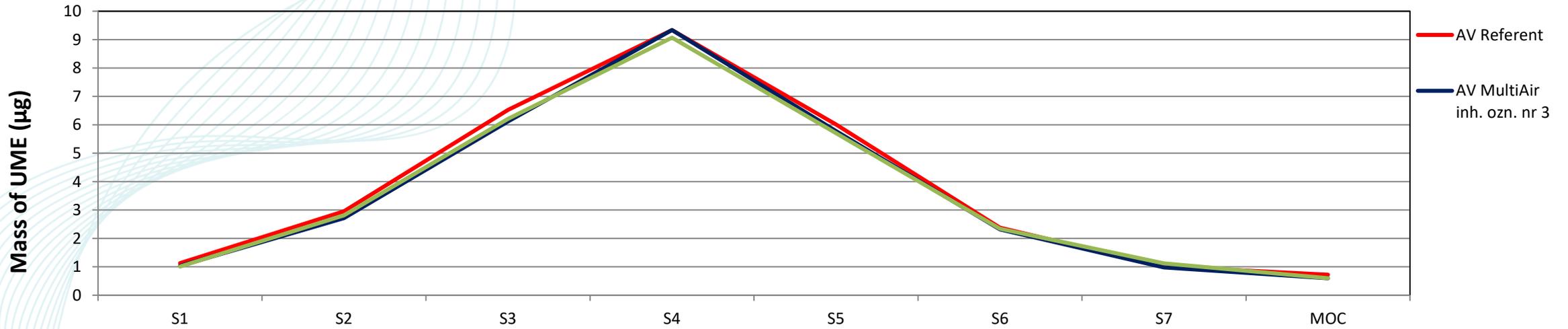
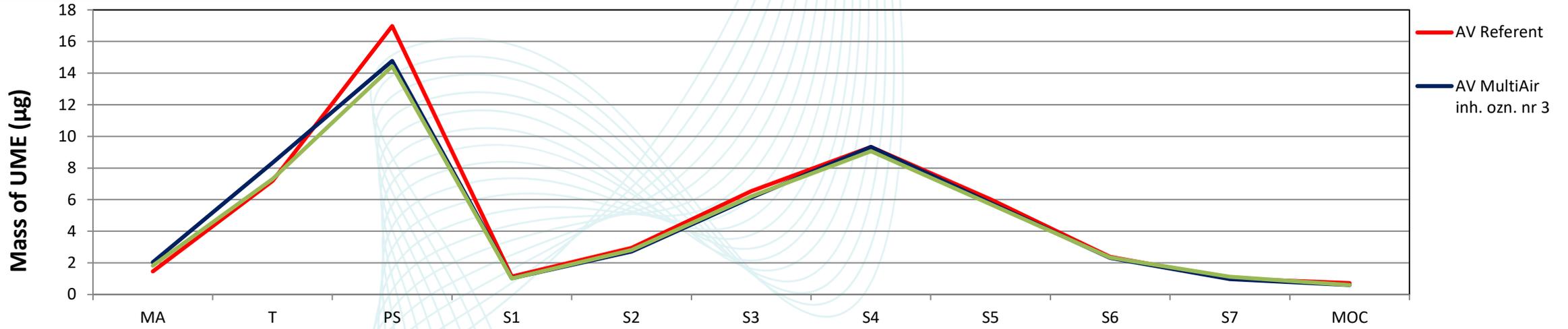
# TEST RESULTS : RESISTANCE

Inhaler	Analysis date	Resistance	AV Res Inh	T/R	AV T/R - Inh	flow at 4kPa [L/min]
inhalator : inhalator Pulinno Multiair - inh 1- blistry - Trelegy s.999X dose "1"	16.01.2026	0,024956	0,025738	97%	100%	80,6
inhalator : inhalator Pulinno Multiair - inh 1- blistry - Trelegy s.999X dose "15"	16.01.2026	0,027217		106%		73,1
inhalator : inhalator Pulinno Multiair - inh 1- blistry - Trelegy s.999X dose "30"	16.01.2026	0,025041		97%		79,2
inhalator : inhalator Pulinno Multiair - inh 2- blistry - Trelegy s.999X dose "1"	16.01.2026	0,024821	0,024821	96%	96%	81,6
inhalator : inhalator Pulinno Multiair - inh 3- blistry - Trelegy s.999X dose "1"	21.01.2026	0,024821	0,026211	96%	102%	77,3
inhalator : inhalator Pulinno Multiair - inh 3- blistry - Trelegy s.999X dose "15"	21.01.2026	0,027141		105%		73,6
inhalator : inhalator Pulinno Multiair - inh 3- blistry - Trelegy s.999X dose "30"	21.01.2026	0,026671		103%		74,4
inhalator : inhalator Pulinno Multiair - inh 4- blistry - Trelegy s.999X dose "1"	21.01.2026	0,026341	0,026914	102%	104%	76,5
inhalator : inhalator Pulinno Multiair - inh 4- blistry - Trelegy s.999X dose "15"	21.01.2026	0,027871		108%		71,9
inhalator : inhalator Pulinno Multiair - inh 4- blistry - Trelegy s.999X dose "30"	21.01.2026	0,026529		103%		76,1
inhalator : inhalator Pulinno Multiair - inh 5- blistry - Trelegy s.999X dose "1"	23.01.2026	0,025170	0,026325	98%	102%	80,6
inhalator : inhalator Pulinno Multiair - inh 5- blistry - Trelegy s.999X dose "15"	23.01.2026	0,026868		104%		74,5
inhalator : inhalator Pulinno Multiair - inh 5- blistry - Trelegy s.999X dose "30"	23.01.2026	0,026938		105%		74,5
inhalator : inhalator Pulinno Multiair - inh 6- blistry - Relvar s.GC4N dose "1"	22.01.2026	0,025301	0,026444	98%	103%	79,5
inhalator : inhalator Pulinno Multiair - inh 6- blistry - Relvar s.GC4N dose "15"	22.01.2026	0,027969		109%		71,6
inhalator : inhalator Pulinno Multiair - inh 6- blistry - Relvar s.GC4N dose "30"	22.01.2026	0,026061		101%		76,8
inhalator : inhalator Pulinno Multiair - inh 7- blistry - Relvar s.GC4N dose "1"	22.01.2026	0,025687	0,026369	100%	102%	78,9
inhalator : inhalator Pulinno Multiair - inh 7- blistry - Relvar s.GC4N dose "15"	22.01.2026	0,026707		104%		74,9
inhalator : inhalator Pulinno Multiair - inh 7- blistry - Relvar s.GC4N dose "30"	22.01.2026	0,026713		104%		74,9
inhalator : inhalator Pulinno Multiair - inh 8- blistry - Relvar s.GC4N dose "1"	27.01.2026	0,026622	0,026756	103%	104%	75,9
inhalator : inhalator Pulinno Multiair - inh 8- blistry - Relvar s.GC4N dose "15"	27.01.2026	0,028291		110%		70,6
inhalator : inhalator Pulinno Multiair - inh 8- blistry - Relvar s.GC4N dose "30"	27.01.2026	0,025356		98%		78,8
inhalator : inhalator Pulinno Multiair - inh 9- blistry - Relvar s.GC4N dose "1"	23.01.2026	0,025693	0,025642	100%	99%	78,6
inhalator : inhalator Pulinno Multiair - inh 9- blistry - Relvar s.GC4N dose "15"	27.01.2026	0,026092		101%		76,1
inhalator : inhalator Pulinno Multiair - inh 9- blistry - Relvar s.GC4N dose "30"	27.01.2026	0,025141		98%		80,2
	MEAN	<b>0,026241</b>	<b>0,026136</b>	<b>102%</b>		<b>76,41</b>
	%RSD	3,9				
	<b>Referent's Resistance</b>	<b>0,025777</b>				

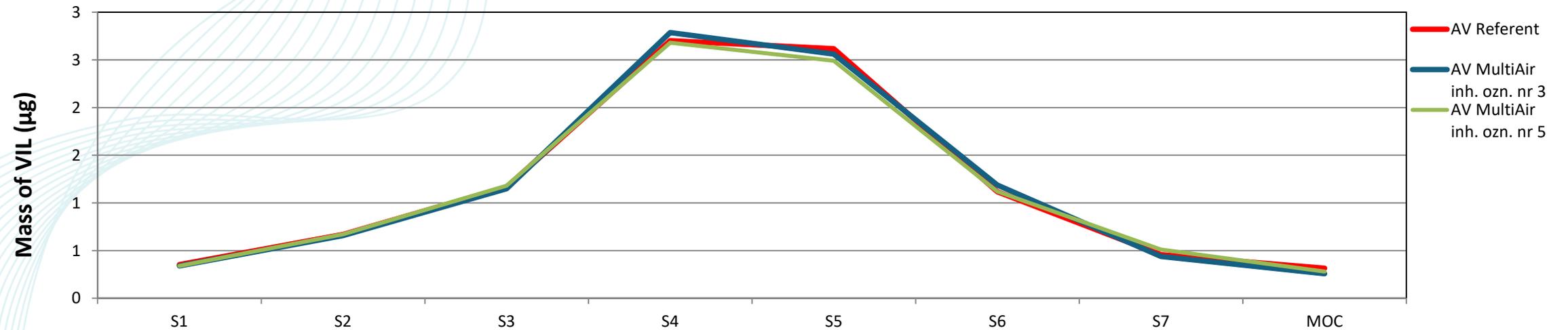
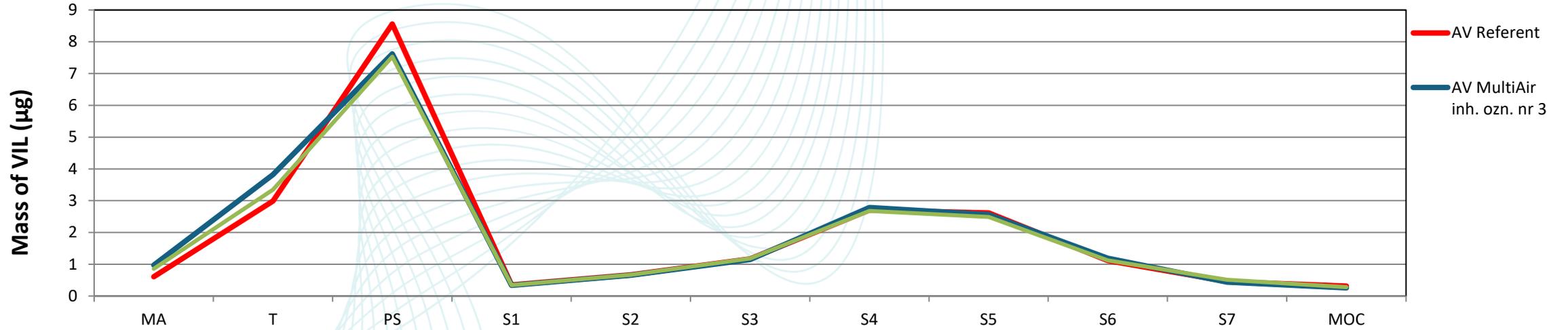
# TEST RESULTS : APSD 30L (Fluticasone fuorate)



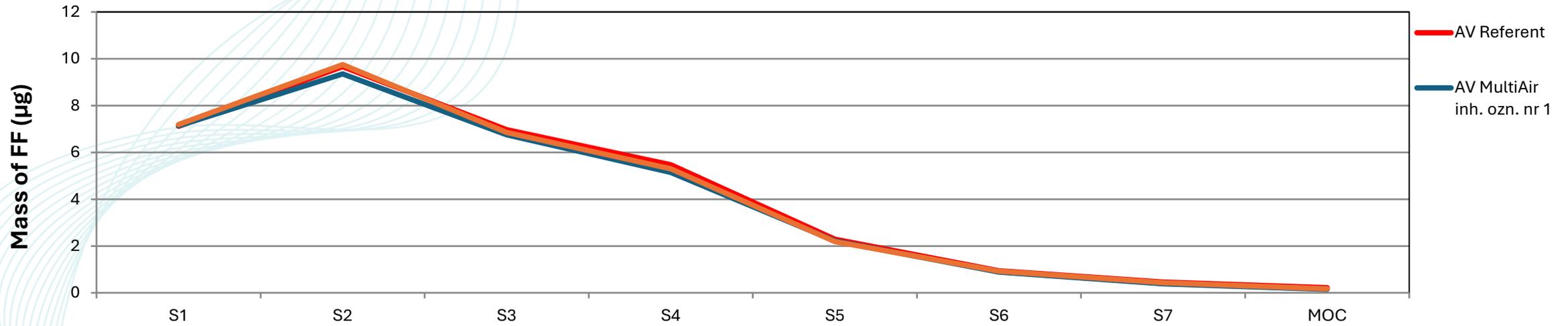
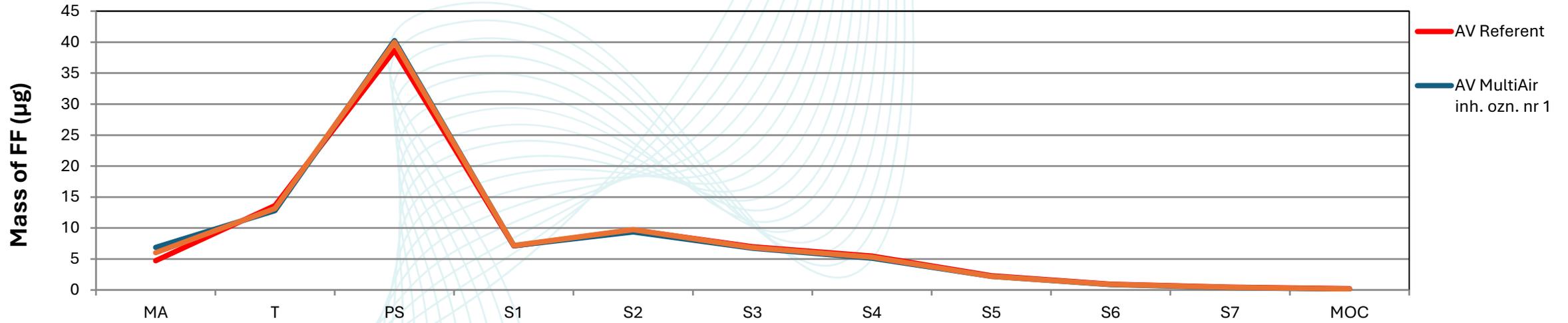
# TEST RESULTS : APSD 30L (Umeclidinium)



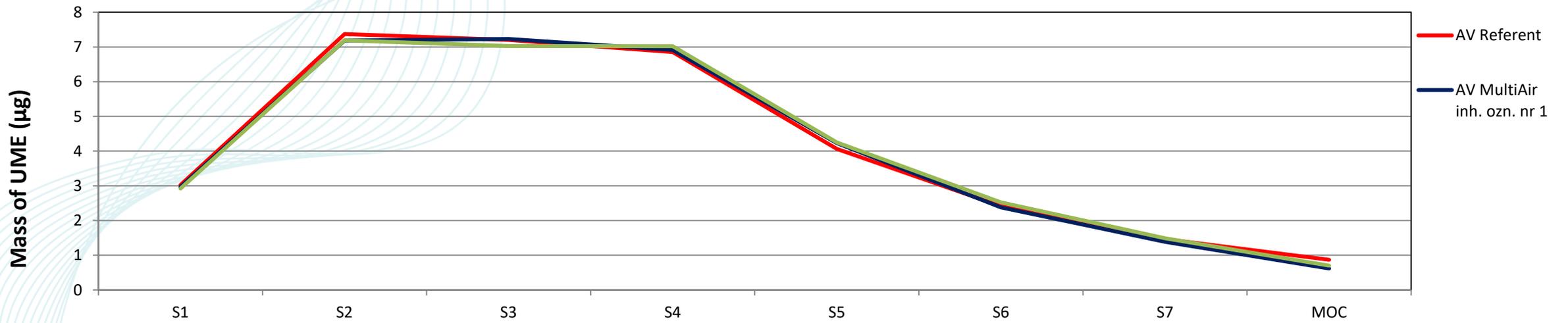
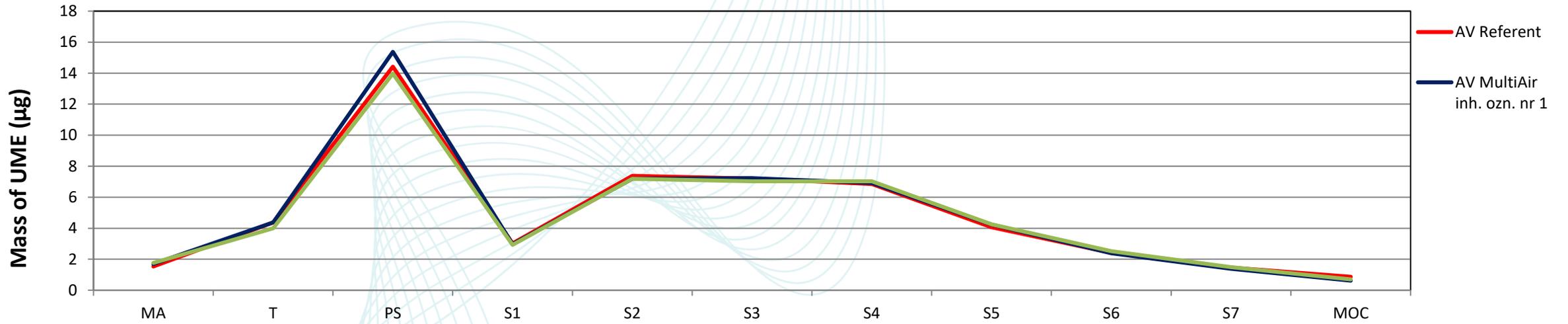
# TEST RESULTS : APSD 30L (Vilanterole)



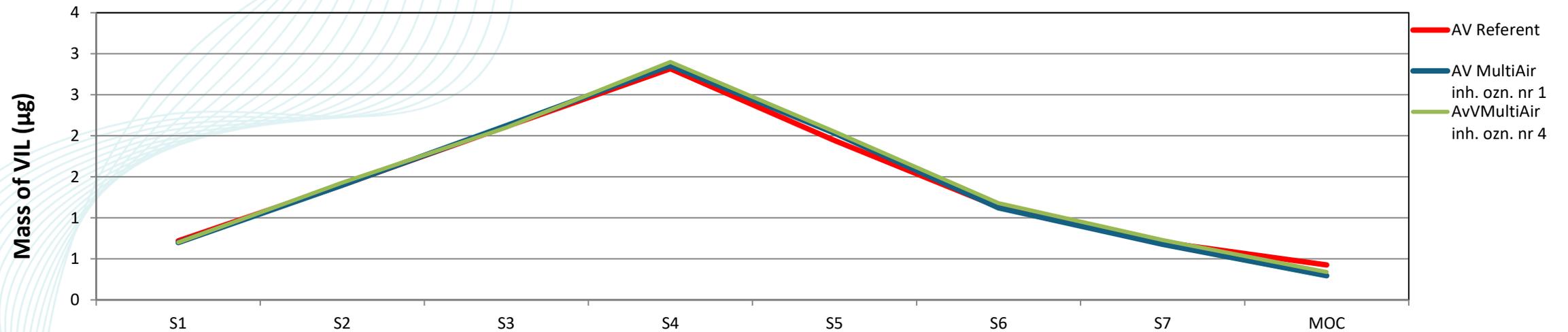
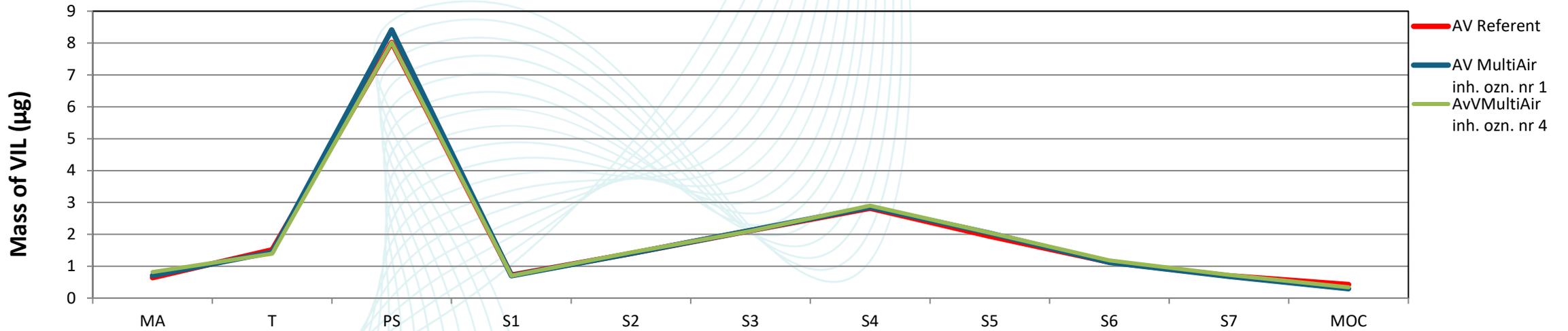
# TEST RESULTS APSD 80L (Fluticasone fuorate)



# TEST RESULTS APSD 80L (Umeclidinium)



# TEST RESULTS APSD 80L (Vilanterole)



# TEST RESULTS Delivered Dose Uniformity

	inhaler 1		inhaler 3		inhaler 4		inhaler 5				
seria:	Trelegy 92/55/22ug 999X										
przepływ	80 L/min		30 L/min		80 L/min		30 L/min				
dose	mass[mg]	anaylisis	masa[mg]	anaylisis	masa[mg]	anaylisis	masa[mg]	anaylisis			
1	23,9	DDU	21,0	DDU	24,4	DDU	23,2	DDU			
2	25,2		25,8		26,4		24,6				
3	25,9		26,5		25,1		24,7				
4	25,6		24,8		25,9		25,0				
5	25,8		26,2		26,0		25,2				
6	25,6		24,9		25,9		24,0				
7	25,8		26,1		25,4		24,5				
8	25,7		25,7		26,2		24,7				
9	25,6		26,0		25,7		24,8				
10	25,2		25,5		26,6		24,1				
11	26,0	APSD 1	23,8	APSD 1	26,0	APSD 1	25,2	APSD 1			
12	25,6		25,8		25,9		24,5				
13	25,6		25,7		25,8		24,8				
14	25,5		25,9		26,5		25,0				
15	24,8		25,8		25,5		25,4				
16	25,4	APSD 2	23,3	APSD 2	25,2	APSD 2	24,9	APSD 2			
17	25,2		28,0		26,7		24,4				
18	26,1		25,6		26,4		24,9				
19	25,8		23,0		25,3		25,1				
20	25,3		27,6		26,5		25,1				
21	26,0	APSD 3	26,1	APSD 3	27,3	APSD 3	24,6	APSD 3			
22	26,0		25,4		26,8		24,5				
23	25,7		25,3		26,2		24,5				
24	26,0		26,1		27,1		24,5				
25	25,1		25,8		25,4		25,4				
26		DDU-2 (every 2 dose)									
27	27,7		26,1		26,3		25,8				
28											
29	26,3		26,0		26,5		24,7				
30	22,7		25,4		24,5		25,3				
AV (dozy 1-25)	25,5		25,4		26,0		24,7				
RSD (dozy 1-25)	1,9		5,6		2,6		2,0				

- Results marked in red (inhalers No. 3) may be due to mass-measurement errors caused by electrostatic effects; these did not translate into the DDU or APSD results.