

# Certificate

Vacuum Conveyor System  
piFlow\_p7l

SMEPAC

**OEB4**

The SMEPAC (Standardized Measurement of Equipment Particulate Airborne Concentration) test was performed in accordance with the ISPE Good Practice Guide: SMEPAC, 3rd edition (2024) to assess particulate emissions of containment systems and processes.

SMEPAC testing is applied in the manufacture of pharmaceutical products and active ingredients, as well as biotechnological and chemical substances, and in sectors with stringent hygiene requirements. It ensures both the protection of the product from contamination and the prevention of particulate emissions during the handling of materials or highly potent agents thereby safeguarding operator health, safety and the surrounding environment.

Equipment tested: **piFlow\_p7l**  
Test performed at: Syntegon Technology GmbH  
Stuttgarter Str. 130,  
71332 Waiblingen  
Test date: 20.May.2025 – 21.May 2025

Containment Performance Target: **10,0 µg/m<sup>3</sup> (OEB 4)**

SMEPAC testing was performed in accordance with the **ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment, 3<sup>rd</sup> Edition, 2024.**

Three consecutive runs were performed with simulated production conditions. Lactose monohydrate was used as surrogate material. Each run included one sample at rest and six samples in operation.

The tested **piFlow\_p7l** setup was equipped with a secondary class U16 filter according to *DIN EN 779 / DIN EN 1822-1:1998*).

Total number of samples: 18  
Maximum (µg/m<sup>3</sup>): 8,726  
Average (µg/m<sup>3</sup>): 0,914  
Standard deviation (µg/m<sup>3</sup>): 1,527  
Conformity Statement: Acceptance criteria for **OEB 4** classification were fulfilled for SMEPAC results of tested equipment.

Frankfurt/Main, 14.Oct.2025

14.OCT.2025,   
Ilker Köse, Valicare GmbH  
nominated SMEPAC Quality Assurance Responsible

**- Results -**

<b>Summary of results:</b>				
	Run 1	Run 2	Run 3	Avg (Run 1 - Run 3)
min [ $\mu\text{g}/\text{m}^3$ ]	0,023	0,023	0,023	0,023
max [ $\mu\text{g}/\text{m}^3$ ]	3,607	8,726	0,358	4,230
avg [ $\mu\text{g}/\text{m}^3$ ]	1,036	1,636	0,071	0,914
SD [ $\mu\text{g}/\text{m}^3$ ]	1,527	2,937	0,117	1,527
SD [%]	147,4	179,5	164,0	163,9
number of samples	6	6	6	6
<b>Baseline [<math>\mu\text{g}/\text{m}^3</math>]</b>				
	0,02	0,02	0,03	0,02

**- Acceptance criteria -**

No.	Criteria in adherence to EN 689:1996	Result	<input checked="" type="checkbox"/> - Yes <input type="checkbox"/> - N/A
1.	One or more measurements are taken and at least one value exceeds the CPT.	Device fails	<input type="checkbox"/>
2.	Only one measurement is taken, and it is less than 10% of CPT	Device passes	<input type="checkbox"/>
3.	Three or more measurements are less than 25% of the CPT	Device passes	<input type="checkbox"/>
4.	Some measurements are greater than 25% of CPT, but all are less than the CPT and the Geometric Mean of any given set of measurements is less than 50% of the CPT	Device passes	<input checked="" type="checkbox"/>
5.	Some measurements are greater than 25% of CPT, but all are less than the CPT and the Geometric Mean of any given set of measurements is greater than 50% of the CPT	Device fails	<input type="checkbox"/>

Conformity Statement: **Devices passes**  
based on acceptance criteria No. 4.

### - Single Results -

#### Run1

Sampling date	Sampling mode <sup>1)</sup>	Sampling time [sec]	Sampling time [min]	Sampling flow [L/min]	Sampling volume [L]	Run 1	
						Mass on the filter [µg]	Mass in air [µg/m <sup>3</sup> ]
20.May.2025	B <sub>R</sub>	3240	54	2	108,0	0,0025	0,0231
20.May.2025	B	3240	54	2	108,0	0,0072	0,0667
20.May.2025	S	3360	56	2	112,0	0,4040	3,6071
20.May.2025	S	3420	57	2	114,0	0,0106	0,0930
20.May.2025	S	3420	57	2	114,0	0,0127	0,1114
20.May.2025	S	3420	57	2	114,0	0,0076	0,0667
20.May.2025	S	3480	58	2	116,0	0,3810	3,2845

1) B<sub>Rest</sub> = Baseline at Rest, B = Baseline, S = Stationary

#### Run 2

Sampling date	Sampling mode <sup>1)</sup>	Sampling time [sec]	Sampling time [min]	Sampling flow [L/min]	Sampling volume [L]	Run 2	
						Mass on the filter [µg]	Mass in air [µg/m <sup>3</sup> ]
21.May.2025	B <sub>R</sub>	3240	54	2	108,0	0,0025	0,0231
21.May.2025	B	3120	52	2	104,0	0,0052	0,0500
21.May.2025	S	3120	52	2	104,0	0,1610	1,5481
21.May.2025	S	3120	52	2	104,0	0,0726	0,6981
21.May.2025	S	3180	53	2	106,0	0,0128	0,1208
21.May.2025	S	3120	52	2	104,0	0,0298	0,2865
21.May.2025	S	3180	53	2	106,0	0,9250	8,7264

1) B<sub>Rest</sub> = Baseline at Rest, B = Baseline, S = Stationary

#### Run 3

Sampling date	Sampling mode <sup>1)</sup>	Sampling time [sec]	Sampling time [min]	Sampling flow [L/min]	Sampling volume [L]	Run 3	
						Mass on the filter [µg]	Mass in air [µg/m <sup>3</sup> ]
21.May.2025	B <sub>R</sub>	3000	50	2	100,0	0,0025	0,0250
21.May.2025	B	3240	54	2	108,0	0,0025	0,0231
21.May.2025	S	3240	54	2	108,0	0,0025	0,0231
21.May.2025	S	3180	53	2	106,0	0,0025	0,0236
21.May.2025	S	3240	54	2	108,0	0,0025	0,0231
21.May.2025	S	3180	53	2	106,0	0,0025	0,0236
21.May.2025	S	3240	54	2	108,0	0,0387	0,3583

1) B<sub>Rest</sub> = Baseline at Rest, B = Baseline, S = Stationary

- End of the certificate -