

Certificate

Vacuum Conveyor System
piFlow_p64

SMEPAC

OEB5

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_p64**
Test performed at: Syntegon Technology GmbH
Stuttgarter Str. 130,
71332 Waiblingen

Test date: 19.May.2025 – 20.May 2025

Containment Performance Target: **1,0 µg/m³ (OEB 5)**

SMEPAC testing was performed in accordance with the **ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment, 3rd 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_p64** 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 ³):	0,111
Average (µg/m ³):	0,030
Standard deviation (µg/m ³):	0,012
Conformity Statement:	Acceptance criteria for OEB 5 classification were fulfilled for SMEPAC results of tested equipment.

Frankfurt/Main, 14.Oct.2025

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

- Results -

Summary of results:				
	Run 1	Run 2	Run 3	Avg (Run 1 - Run 3)
min [$\mu\text{g}/\text{m}^3$]	0,022	0,023	0,025	0,023
max [$\mu\text{g}/\text{m}^3$]	0,111	0,043	0,025	0,060
avg [$\mu\text{g}/\text{m}^3$]	0,039	0,027	0,025	0,030
SD [$\mu\text{g}/\text{m}^3$]	0,030	0,007	0,000	0,012
SD [%]	76,5	25,8	0,0	34,1
number of samples	6	6	6	6
Baseline [$\mu\text{g}/\text{m}^3$]	0,02	0,04	0,00	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 ¹⁾	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 ³]
19.May.2025	B _R	3420	57	2	114,0	0,0025	0,0219
20.May.2025	B	3240	54	2	108,0	0,0045	0,0417
20.May.2025	S	3300	55	2	110,0	0,0025	0,0227
20.May.2025	S	3240	54	2	108,0	0,0030	0,0278
20.May.2025	S	3300	55	2	110,0	0,0122	0,1109
20.May.2025	S	3300	55	2	110,0	0,0025	0,0227
20.May.2025	S	3300	55	2	110,0	0,0029	0,0264

1) B_{Rest} = Baseline at Rest, B = Baseline, S = Stationary

Run 2

Sampling date	Sampling mode ¹⁾	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 ³]
20.May.2025	B _R	3180	53	2	106,0	0,0046	0,0434
20.May.2025	B	3180	53	2	106,0	0,0025	0,0236
20.May.2025	S	3180	53	2	106,0	0,0031	0,0292
20.May.2025	S	3240	54	2	108,0	0,0025	0,0231
20.May.2025	S	3180	53	2	106,0	0,0025	0,0236
20.May.2025	S	3240	54	2	108,0	0,0025	0,0231
20.May.2025	S	3240	54	2	108,0	0,0025	0,0231

1) B_{Rest} = Baseline at Rest, B = Baseline, S = Stationary

Run 3

Sampling date	Sampling mode ¹⁾	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 ³]
20.May.2025	B _R	3060	51	2	102,0	0025	0,0245
20.May.2025	B	3060	51	2	102,0	0025	0,0245
20.May.2025	S	3060	51	2	102,0	0025	0,0245
20.May.2025	S	3060	51	2	102,0	0025	0,0245
20.May.2025	S	3060	51	2	102,0	0025	0,0245
20.May.2025	S	3060	51	2	102,0	0025	0,0245
20.May.2025	S	3060	51	2	102,0	0025	0,0245

1) B_{Rest} = Baseline at Rest, B = Baseline, S = Stationary

- End of the certificate -