

CALIBRATION CERTIFICATE

Certificate Number 830

Model: S3100

Serial Number: 190304023

Sensor ID: 190304-023

Customer name: Balkan Pharmaceuticals

Date of Calibration: September 27, 2024

Next calibration on this instrument is due: September 27, 2025

Calibration Method Calibration has been accomplished as described in ISO 21501-4:2018. All work performed is in accordance with Lighthouse Worldwide Solutions Calibration Procedure Document 462810617-1 and is recorded and maintained as such.

Traceability The measurements have been executed using standards traceable to the International System of Units in order to ensure continued accuracy and measurement traceability within the level of uncertainty reported by our laboratory.

Uncertainty The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor of $k = 2$, which provides a confidence level of approximately 95%. The values and test criteria are applied using Simple Acceptance; Shared Risk approach.

Results This certifies the above named instrument conforms to the original specifications in effect at date of manufacture and test.

Environmental Conditions Ambient temperature 24.4 °C Relative humidity 53 %

Test Equipment

Standards	Model	Mfg	Serial#	Cal Date	Cal Due
DMM	P3320	Peak Tech	140821704	13-06-24	13-06-25
MCA	8000D	AmpTek	1116	02-09-24	02-09-25
Flow Meter	DCL-H	Bios	7065	24-05-24	24-05-25
Test Standard	Solair	LWS	160699001	29-11-23	29-11-24

Particle Size Standards

Nominal Size	Particle Size	Tolerance (nm)	Lot No.	Manufacturer	Expiration Date
0.30µm	0.30µm	+/-3	257546	Thermo Scientific	01-08-25
0.40µm	0.40µm	+/-3	258557	Thermo Scientific	01-09-25
0.50µm	0.51µm	+/-4	255494	Thermo Scientific	01-06-25
1.00µm	1.03µm	+/-6	260019	Thermo Scientific	01-10-25
3.00µm	2.92µm	+/-15	257549	Thermo Scientific	01-08-25
5.00µm	5.02µm	+/-20	276198	Thermo Scientific	01-01-27
10.00µm	9.99µm	+/-40	261682	Thermo Scientific	01-12-25

Counting Efficiency Particle Size Standards

Nominal Size	Particle Size	Tolerance (nm)	Lot No.	Manufacturer	Expiration Date
0.30µm	0.30µm	+/-3	257546	Thermo Scientific	01-08-25
0.50µm	0.51µm	+/-4	255494	Thermo Scientific	01-06-25

Size Calibrations as Left

Channel	Chnl Size	Threshold	Expanded Uncertainty	As Left Size Error
1	0.30µm	54mV	0.016 µm	0%
2	0.50µm	431mV	0.01 µm	0%
3	1.00µm	986mV	0.015 µm	0%
4	3.00µm	3080mV	0.033 µm	0%
5	5.00µm	3580mV	0.041 µm	0%
6	10.00µm	4503mV	0.092 µm	0%

Measurements as Left

Nominal Flow Rate:		Measured Flow:		Expanded Uncertainty	Result
28.30 LPM		28.32 LPM	(limit ±5% of nominal)	0.8L/min	Pass
False Count Rate:		Observed Cts:	0	(≤ 1 ct max / 5 min.)	Pass
JIS B 9921 Zero Count		Observed Cts:	0	Upper confidence level	21
ISO21501-4 False Count Rate		Observed Cts:	0		Particles/m3
Counting Efficiency 50%:		Size	0.303 µm	41.0% (limit 30% - 70%)	Expanded Uncertainty 4.8 %
					Result Pass
Counting Efficiency 100%:		Size	0.508 µm	99.4% (limit 90% - 110%)	29.8 %
					Result Pass
Size Resolution:		Size	0.401 µm	11.48% (limit 15%)	1.5 %
					Result Pass

Size Calibrations as Found

Channel	Size(μm)	As Rec'd Threshold Settings	As Rec'd size (μm)	Percent size error (%)	Percent size error tolerance	Expanded Uncertainty	Pass/Fail
1	0.3	54	0.300	0.0%	+/- 10%	0.016 μm	Pass
2	0.5	431	0.499	-0.2%	+/- 10%	0.01 μm	Pass
3	1	1048	1.054	5.4%	+/-10%	0.015 μm	Pass
4	3	3023	2.844	-5.2%	+/-10%	0.033 μm	Pass
5	5	3657	5.330	6.6%	+/-10%	0.041 μm	Pass
6	10	4506	9.989	-0.1%	+/-10%	0.092 μm	Pass

Measurements as Found

Nominal Flow Rate:		Measured Flow:		Expanded Uncertainty	Result
28.30 LPM		27.16 LPM		(limit ±5% of nominal) 0.8 L/min	Pass
False Count Rate:		Observed Cts:		(≤ 1 ct max / 5 min.)	Pass
JIS B 9921 Zero Count		0		Upper confidence	
ISO21501-4 False Count Rate		Observed Cts:		level	21
		0			Particles/m3
Counting Efficiency 50%:		Size		Expanded Uncertainty	Result
		0.303 μm		3.4 %	Pass
Counting Efficiency 100%:		Size		Expanded Uncertainty	Result
		0.508 μm		4.9 %	Fail
Size Resolution:		Size		Expanded Uncertainty	Result
		0.401 μm		1.5 %	Pass

Signature:
Calibration Tech/Engineer:

Olga Pirya

INCOTECH
S.R.L.