



Study: Independent performance characterisation of the BIBO Pulmifier® equine nebuliser system (WLA Health & Care AG)		
INTERNAL REFERENCE: WLA-RMACL	REVIEW/APPROVAL/REPORTING: Internal review/Internal approval/ Open reporting	TEST PERIOD: Session - July/Aug 2026

1.0 Executive Summary

Performance characterisation of the 'BIBO Pulmifier® equine nebuliser system' (WLA Health & Care AG) was conducted in line with the international ISO test standard ISO 27427:2023 (Anaesthetic and respiratory equipment — Nebulizing systems and components), and established test protocols appropriate for the characterisation of the performance of actively vibrating mesh nebulisers.

Nebulisers tested were selected at random and therefore considered representative of the production population. All testing was conducted in an academic laboratory setting by researchers skilled in nebuliser performance characterisation. All test equipment used was within calibration. Testing was conducted with the intention only of verifying whether claims around product performance were met in an independent test laboratory.

No device malfunctions were noted during testing and the novel 'end of dose' feature operated as intended for all doses.

Summarised;

Performance metric	Acceptance Criteria	Test Result	Pass/Fail
Aerosol flow rate (mL/min)	0.8 – 1.2 mL/min when measured with 0.9% saline	1.006 ± 0.010	Pass
Aerosol droplet size (microns)	1 – 5 microns when measured with 0.9% saline using laser diffraction (Malvern Spraytec)	3.456	Pass
Fine particle Fraction ≤5 microns (%)	≥ 50 %	73.3	Pass
Medication temperature	≤ 10degC rise over the starting temperature	9.3 ± 0.44	Pass

In additional 'report only' testing, beyond verifying the product performance claims, the aerosol flow rate for fifteen (15) undiluted commercially available medications for inhalation, and excellent flow rate performance noted with each.

Overall findings: In this independent study, the Bibo Pulmifier equine nebuliser system met all acceptance criteria set out by the manufacturer in the product literature (Instruction manual version 2.1) and demonstrated broad compatibility with a wide selection of medications commonly delivered by inhalation.

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2.0 Test Materials

2.1 Nebuliser system

The nebuliser system under test was the 'BIBO Pulmifier® equine nebuliser system' (WLA Health & Care AG). Three separate nebuliser systems were included in the study and were fully charged using the AC/DC charger provided, prior to commencement of testing.

All testing was conducted in triplicate.

All test equipment used was within calibration, where applicable.

3.0 Methods and Results

3.1 Aerosol flow rate

Aerosol flow rate testing was conducted with sixteen (16) commonly used medications for inhalation. These medications were selected following a review of the literature and a web-based search for commercially available products, intended for delivery to the equine airway by inhalation.

The flow rate, expressed as mL of drug aerosolised per minute, was measured using a calibrated stopwatch. The standard labelled dose of each medication was placed into the nebuliser's medication cup, with the nebuliser and the stopwatch started concurrently. The stopwatch was stopped as soon as the aerosol generation visibly ended, and the time recorded. Medications were nebulised neat, straight from the nebule, vial or bottle, with no dilution of the manufacturer's stated concentration.

The acceptance criteria for flow rate when measured with 0.9% saline is presented in Table 1;

Table 1: Aerosol flow rate acceptance criteria.

Performance metric	Acceptance Criteria
Aerosol flow rate (mL/min)	0.8 – 1.2 mL/min when measured with 0.9% saline.

Flow rate was calculated by dividing the starting nominal dose volume by the time taken to nebulise the dose fully and expressed as mL nebulised per minute. Each test was conducted in triplicate, and the results are presented below in Table 2.



Table 2: Individual datapoints and summary statistics for aerosol flow rate recorded with the BIBO Pulmifier® across sixteen (16) nebulised medications commonly prescribed for delivery to the equine airway via inhalation.

Type	Tradename	Concentration	Run 1	Run 2	Run 3	Average (mL/min)	Standard Deviation
Airway Hydration/QC test solution	Saline for inhalation	0.09%	1.017	1.000	1.000	1.006	0.010
h2-adrenergic receptor agonist	Salbutair	2.5mg/2.5mL	1.034	1.034	1.017	1.029	0.010
Anticholinergic bronchodilator	Ipratropium	250mcg/mL	1.017	1.017	1.034	1.023	0.010
Airway Hydration	Emser Hyperton	4%	1.017	1.015	1.017	1.016	0.001
Airway Hydration	Dead Sea Brine	1%	1.053	1.034	1.053	1.047	0.010
Airway Hydration	Mucoclear	6%	1.053	1.053	1.034	1.047	0.010
Airway Hydration	BiTop Equilung	0.9% saline + 1.3% E	1.000	1.017	1.017	1.011	0.010
Airway Hydration	BiTop Equilung Complete Plus	3% saline + 1.3% Bi-	1.000	1.017	1.017	1.011	0.010
Mucolytic	Mucosolvan	15mg/2mL	1.091	1.071	1.053	1.072	0.019
Mucolytic	Acetylcystine		0.857	0.870	0.857	0.861	0.007
Mucolytic	Flumicil	10%	0.857	0.845	0.857	0.853	0.007
Anti-inflammatory	Dexamethasone	4mg/mL	0.923	0.938	0.923	0.928	0.008
Anti-inflammatory	Fluticasone	250mcg/mL	0.923	0.923	0.938	0.928	0.008
Anti-inflammatory	Pulmicort	1mg/2mL	0.968	0.968	0.984	0.973	0.009
Antimicrobial	Silvalex	100ppm	1.034	1.053	1.071	1.053	0.018
Antibiotic	Genta	100mg/mL	0.469	0.480	0.472	0.474	0.006

Findings: The acceptance criteria for aerosol flow rate were met in full.



3.2 Droplet size characterisation: Volume Median Diameter (VMD) and fine particle fraction

Using the Spraytec™ laser diffraction system (Malvern Panalytical, UK), the aerosol droplet size reported as Volume Median Diameter (VMD) was characterised using 0.9% saline. The percentage fraction of aerosol droplets less than or equal to 5 microns (i.e., the fine particle fraction, FPF) was derived from the raw data, using the Spraytec software (Version 4).

The acceptance criteria for both metrics when measured with 0.9% saline is presented in Table 3;

Table 3: Droplet size and fine particle fraction acceptance criteria.

Performance metric	Acceptance Criteria
Aerosol droplet size (Dv50) (microns)	1 – 5 microns when measured with 0.9% saline using laser diffraction (Malvern Spraytec)
Fine particle Fraction $\leq$ 5 microns (%)	$\geq$ 50 %

The results of testing are presented in Table 4 and Figure 1 below;

Table 4: Droplet size characteristics following testing with 0.9% saline.

Standard Values: Trans = 49.8 (%) Cv = 57.09 (PPM) SSA = 2.088 (m ² /cc)	Dv(10) = 1.562 (μm) Dv(50) = 3.456 (μm) Dv(90) = 7.044 (μm)	Span = 1.586 D[3][2] = 2.874 (μm) D[4][3] = 3.946 (μm)
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The VMD (Dv50) was 3.456 microns.

The Fine Particle Fraction of droplets less than or equal to 5 microns was 73.3%

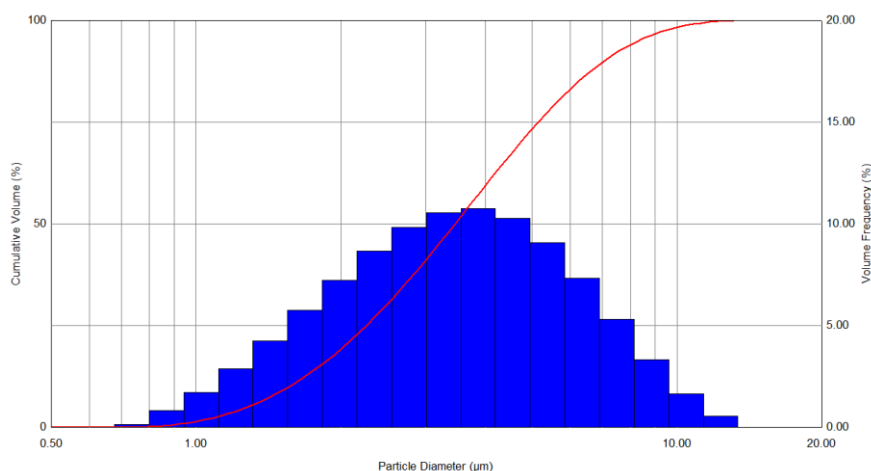


Figure 1: Droplet size (volumetric mean diameter (VMD)) distribution for Bibo Pulmifier nebuliser, tested with 0.9% saline.



Findings: The acceptance criteria for both droplet size (VMD) and Fine Particle Fraction (FPF $\leq 5\mu\text{m}$) were met in full.

NOTE: differences in measurement equipment setup and test solution will impact the recorded droplet size and thus these results are only directly comparable to others recorded on the same equipment, software settings and experimental setup.

3.3 Medication temperature

The temperature of the medication in the medication cup of the nebuliser during nebulisation was recorded using a J-type thermocouple and calibrated datalogger. A 10mL dose of 0.9% saline was added to the medication cup, and temperature readings were taken on the minute, each minute until the dose was completed.

The acceptance criteria when measured with 0.9% saline is presented in Table 5;

Table 5: Droplet size and fine particle fraction acceptance criteria.

Performance metric	Acceptance Criteria
Medication temperature	$\leq 10\text{degC}$ rise over the starting temperature when measured with 0.9% saline.

The results of testing are presented in Table 6 below;

Table 6: Individual datapoints and summary statistics for medication temperature change. NOTE: all three runs had a dose duration of 08:11 and 08:30 (mins:secs).

Time (min)	Temperature (degC)		
	Run 1	Run 2	Run 3
0	20.9	20.6	20.8
1	21.8	21.5	21.8
2	22.7	22.5	22.5
3	23.3	23.5	23.3
4	24.3	23.9	24.5
5	25.0	24.7	24.9
6	25.9	25.7	26.0
7	27.6	27.4	27.6
8	29.5	30.0	29.8
After Nebulisation (°C)	29.7	30.2	30.3
Δ Temp (°C)	8.80	9.60	9.50
Average		9.30	
STDEV		0.44	

Findings: The acceptance criteria for medication temperature were met in full.