ULTRA *A-I-R*

NE-U17-E Ultrasonic Nebuliser
Aerosol Output (by weight)
&
Aerosol Size

report to

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Introduction

3 ULTRA *A-I-R* ultrasonic nebulisers (model NE-U17-E) were received from OMRON UK and tested for aerosol output (by weight) and aerosol output (NGI cascade impaction).

lab number	serial number
1	4600039A
2	4600040A
3	4500013A

Methods

Aerosol Output

The ULTRA *A-I-R* ultrasonic nebulisers were analyzed at a combination of 10 flow volumes X 10 nebulization frequencies (i.e. 100 permutations) by measuring the weight loss of water. The water tank was filled to the required level with tap water. The nebulization section was weighed on a tarred balance as one whole unit which comprised: the medication cup cover, the medication cup and the medication cup holder. This was filled to approximately 100 ml by adding approximately 100g of deionized distilled water. The inhalation time was set for 1 minute and each permutation (10x10=100 per nebulizer) was nebulized for 1 minute. After each minute the inhalation hose was held in a vertical position and the large droplets were shaken out and allowed to return to the medication cup. The nebulization section was taken out of the water tank, the exterior was dried, and re-weighed. The weight loss was recorded, and the balance re-tarred. This procedure was repeated for each permutation. A detailed set of results for each of n=3 nebulizers are presented in the appendix.

Aerosol Size

One of the ULTRA *A-I-R* ultrasonic nebulisers was tested for aerosol size at mid-frequency (setting 5) at 3 flow rates settings (1, 5 & 10) on n=1 nebulizer (number 3, serial 4500013A). Aerosol size was measured using the New Generation Impactor (NGI) cascade impactor. A flow rate of 15 L/minute was drawn through the NGI. A T-piece was used for additional make-up air an the end of the corrugated tubing (ie between tubing and impactor 'throat'). Nebulizer #3 was tested using the following matrix. The nebulization time as selected so as to collect suffient aerosol for analysis but not overload the capacity of the NGI impactor.

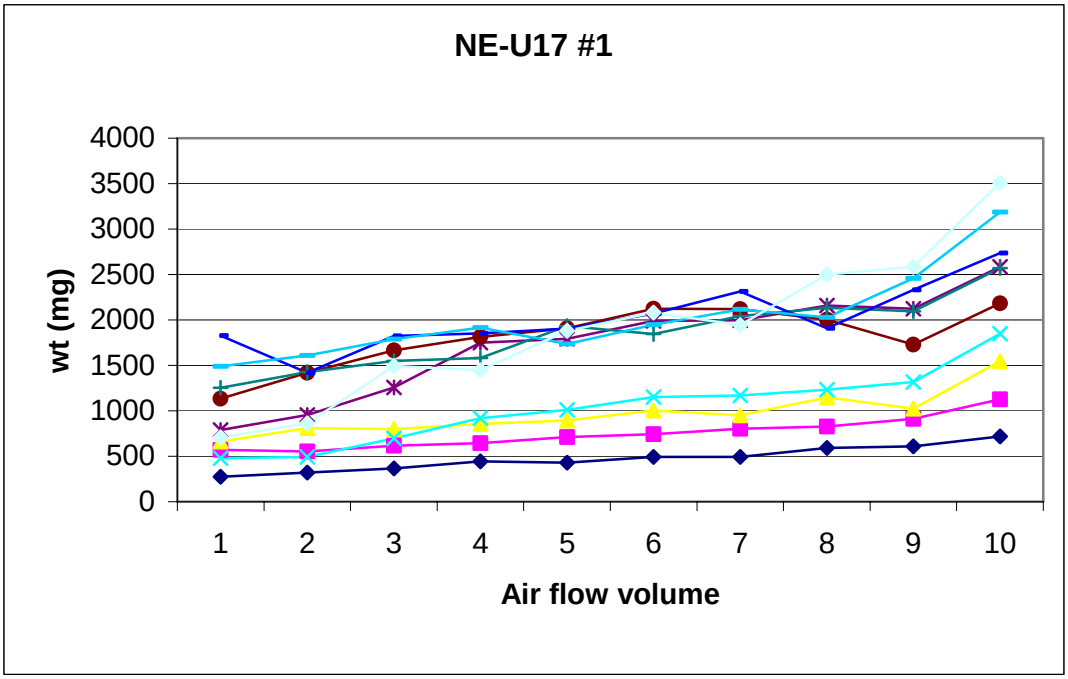
Frequency	flow rate	collection time (sec)
5	1	60
5	5	40
5	10	20

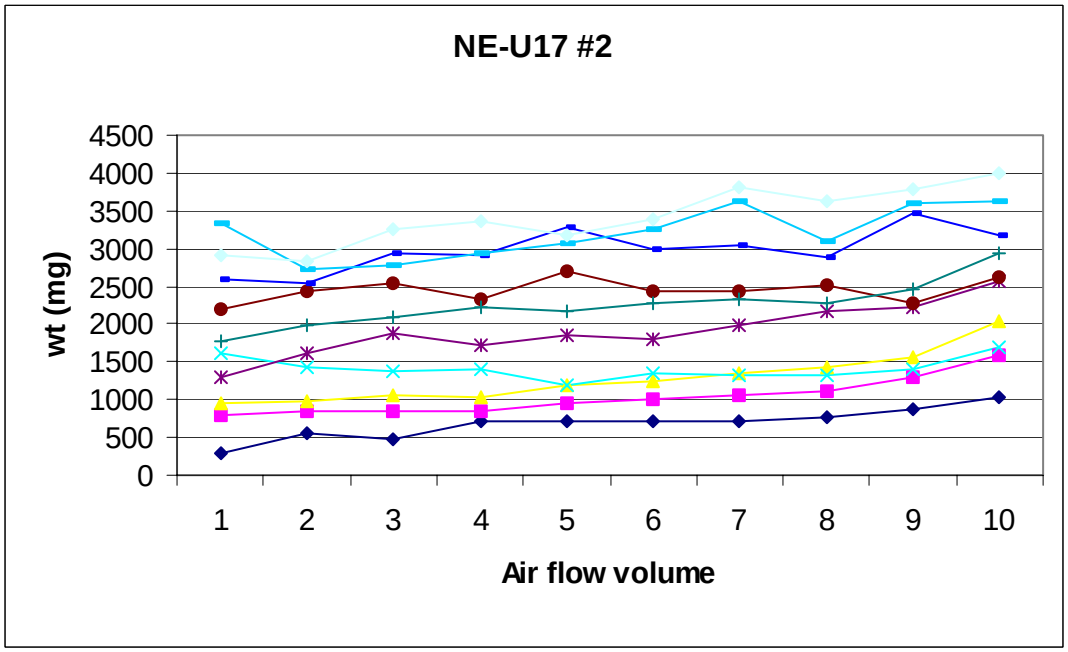
Detailed results are presented in the appendix.

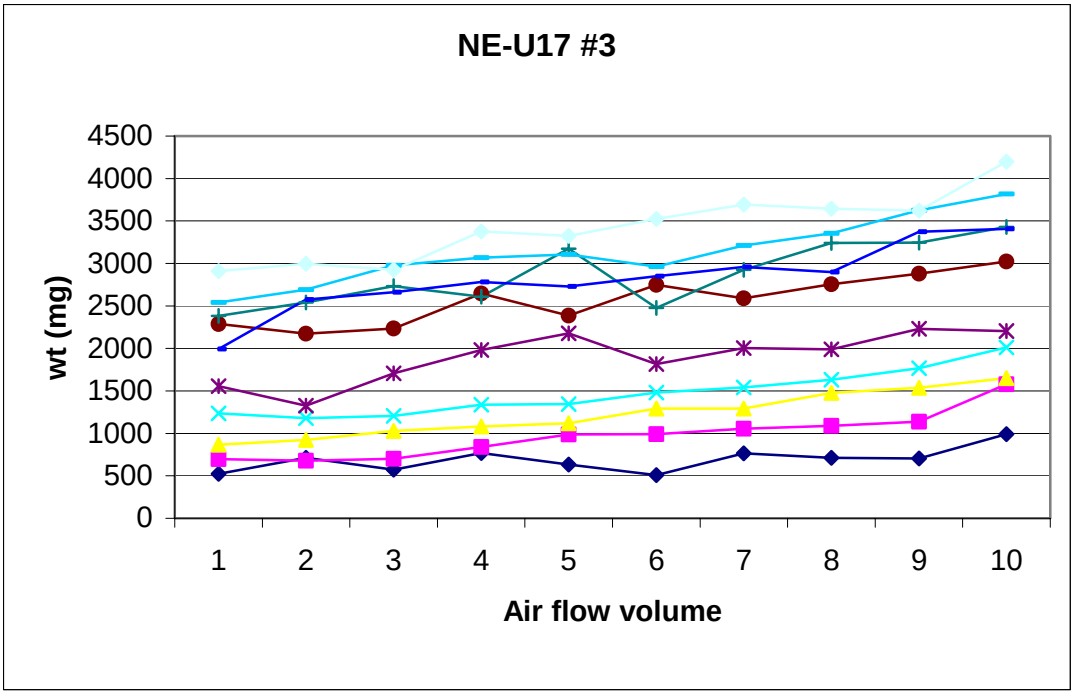
Results

All three nebulizers were within the recommended nebulization rate of greater than 2.37 ml/min at the maximum flow volume (setting 10) and maximum nebulization frequency (setting 10) as described in the U17 compliance check document (section 10) attached in the appendix.

The aerosol output results are shown in the graphs below.







Results of Aerosol size are summarized in the table below.

mid-frequency	setting 5	MMAD	GSD
Low Flow	setting 1	4.0	1.8
Medium Flow	setting 5	3.9	1.8
High Flow	setting 10	3.9	1.8

Aerosol size remains is constant across the 3 flow rates tested at the mid-point frequency setting.

Appendix A

Index:

1. Requirements:

1) Small cup (disposable coffee-cup), on which medication cup can be placed when weighing, see photo.
2) Stopwatch
3) Calibrated weigh scale (0 ~ 150 grams, 2 digits behind decimal point)
4) Air compressor (including oil-particles filter!)
5) Calculator
6) Distilled or demineralised water
7) Saline (0.9% NaCl solution)

2. Test conditions:

1)	Ambient temperature:	15° to 35° C
2)	Ambient humidity:	45 to 85% RH
3)	Atmospheric pressure:	860 to 1.060 hPa
4)	Power supply voltage:	AC 230V ±2%
5)	Power supply voltage:	50 ± 2.5 Hz

3. Nebulisation rate test :

1) Take out the nebulisation set (3~8) from the unit.
2) Fill water tank in NE-U17 with **tap** water until indicated water level mark.
3) Take off the blue medication cup cover (3) from the medication cup holder (8) by rotating it slightly to the left.
4) Place the medication cup holder back in the unit.
5) Place the 'coffee' cup on the weigh scale and switch on the weigh scale.
6) Take out the medication cup (7) from the medication cup holder (8).
7) Place the medication cup in the 'coffee' cup and fill it with **distilled** water until the weigh scale indicates approx. 100 gr. (not critical). Refer to the photo on the right.

8) Note this weight as W1.
9) Place the medication cup including the water in the medication cup holder in (8) in the unit; be careful not to spoil any water!
10) Place the blue medication cover (3) on the medication cup holder (8).
11) Lock the nebulisation set by rotating the white lever (15) to the right position.
12) Connect the 50 cm flexible hose to the blue medication cup cover (make sure the hose is dry. If required, use compressor to blow dry).
13) Connect the mains cable to the main unit and to the mains. Switch on the main switch on NE-U17 and check (listen) that the ventilator is rotating.

14) Adjust both **Airflow volume knob** and **Nebulisation volume knob** on the main unit to max. clockwise **position '10'**.
15) Adjust the **timer knob** ('timer (min)') until the display indicates **3 minutes.**
16) Press the **START / STOP** button and check that the unit starts nebulisation.
17) Check that the hose is placed in a upwards, vertical position.
18) After 3 minutes, the units stops nebulisation and an audible signal (beep) is produced.
19) Switch off the main switch on NE-U17 and remove the mains cable from the unit and from the mains.
20) Hold the hose in a vertical position and move/shake it in such a way so that the big droplets return to the medication cup.
21) Remove the hose from the blue medication cup cover (3).
22) Rotate the white lever to the left and take out the nebulisationset (3~8) in a vertical direction.
23) Take off the blue medication cup cover from the medication cup holder and allow the major droplets to return to the medication cup by gentle shaking.
24) Take the medication cup (7) from the medication cup holder (8) and dry the **exterior only** of the cup by means of a tissue.
25) Place the white cup on the weigh scale and switch off and on the weigh scale.
26) Place the medication cup with the left-over water in the white cup. Be sure not to spoil any water ! Read out the weight.
27) Note this weight as W2.
28) Calculate the nebulisation rate (ml/min or mgr/min) from (W1 – W2) : 3
Nebulisation rate should be higher than 2.37 ml/min. If not, check U17 unit and repair if necessary.
29) Empty the water tank by holding the main unit upside down and by detaching the drainage tube on the left side of the unit.
30) Place the main unit on it's front side, enabling drying the interior of the water tank by means of a tissue. Use compressed air to finalize drying process. Use compressed air to dry the drainage tube.
31) Dry all accessories and parts (blue cover, medication cup holder, hose, cup) by means of compressed air.
32) Let main unit and all part air-dry for approx. half an hour.
33) Attach drainage tube on left side of the main unit.
34) Place the blue medication cup cover (3) on the medication cup holder (8).
35) Place the nebulisation set in the main unit and lock by rotating the white lever to the right position.
36) Put the unit + accessories in it's original package.

4. Adjustments:

U17 has no adjustments.