1.0 Object

1.1 To test the performance of Rossmax NE100 nebulizer

2.0 Equipment List

2.1 Rossmax NE100 Nebulizer*2

2.2 Rossmax Nebulizer kit*2

2.3 Malvern Spraytec particle size analyer

2.4 Marple 298 Cascade Impactor

2.5 Chroma 61602 Programmable AC Source

2.6 Shimadzu AUW120D microbalance

2.7 A.P. Buck, Inc. Libra Plus LP-5 sampling pump

2.8 SSI P51-6BarS-A-MD-20mA pressure meter

2.9 Golden Mountain Enterprise Co. Ltd. F33L0096 flow meter

2.10 Humidity/Temperature Meter

2.11 Taiwan Biotech Co., Ltd 0.9% Saline solution

2.12 2.5% NaF solution

2.13 Atrovent Ipratropium Bromide

2.14 Atrovent Flixotide

2.15 AstraZeneca Terbutaline Sulphate

2.16 Ventoline (2.5mg) Salbutamol/Sulphate

2.17 Casio Timer

3.0 Testing Items

3.1 Aerosol Particle Size Distribution Testing(By Malvern Spraytec)

3.2 Aerosol Particle Size Distribution Testing(By Marple 298 Cascade Impactor)

3.3 Nebulization Rate Testing(Including drugs testing)

3.4 Residual Volume Testing

3.5 Reliability Test

4.0 Testing Procedure

4.1 Aerosol Particle Size Distribution Testing(By Malvern Spraytec)

4.1.1 Each sample should be tested with 2.5ml 0.9% saline solution for 3 minutes.

4.1.2 Add 2.5ml 0.9% saline solution into the nebulizer kit,

4.1.3 Connect the nebulizer kit with NE100 and put at the testing site, the nebulizer kit's outlet must be kept at 3.0 cm from the laser beam.

4.1.4 Start recording Spraytec for more than 15 secs, then start NE100 for testing.

4.1.5 After 3.0 minutes have been reached, stop the NE100 and then stop Spraytec.
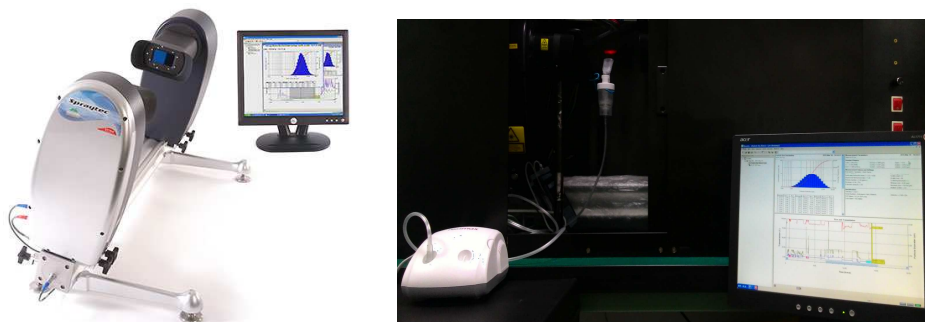
4.1.6 Checks Spraytec records

Fig 1. Malvern Spraytec and Testing site

4.2 Aerosol Particle Size Distribution Testing(By Marple 298 Cascade Impactor)

4.2.1 Each sample should be tested with 2.5 ml 2.5% NaF solution.

4.2.2 Add 2.5 ml 2.5% NaF solution into the nebulizer kit, measure the weight before and after the testing.

4.2.3 Connect suction and sampling pumps to the cascade impactor testing module as see in the Fig 2.

4.2.4 Connect the nebulizer kit with NE100 and connect the nebulizer kit outlet to cascade impactor inlet.(Fig 2.)

4.2.5 The suction and sampling pumps are turned on and allowed to stabilize at required flows.

4.2.6 Finally start the NE100.(Sampling times can be varied for different nebulizers to allow for maximum deposit on each stage without coverloading stages.)

4.2.7 After sampling for the required time, NE100 is switched off, followed a few seconds later by the sampling pump and then the suction pump.

4.2.8 Dismount the cascaade impactor from the testing module

4.2.9 Dismantle the impactor and determine the amount of NaF on the individual stages of the impactor, the input connection and the outlet filter.
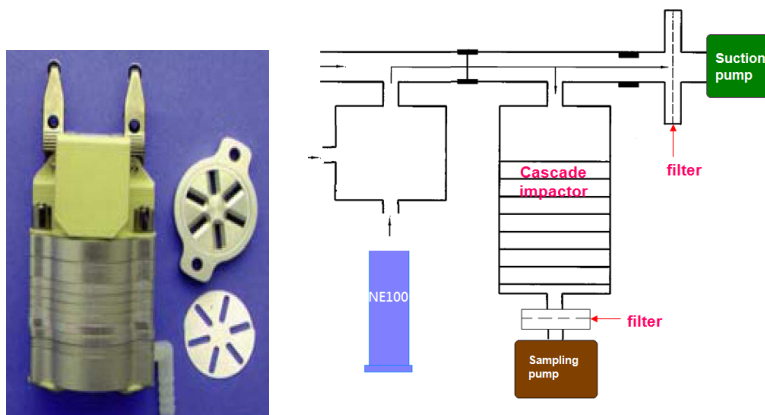

Fig 2. Cascade Impactor and Testing setup

4.3 Nebulization Rate Testing(Including Drug Testings)

4.3.1 Each sample should be tested with 2.0 ml 0.9% saline solution, Atrovent Ipratropium Bromide, Atrovent Flixotide, AstraZeneca Terbutaline Sulphate and Ventoline (2.5mg) Salbutamol/Sulphate for 1 minutes.

4.3.2 Add 2.0ml 0.9% saline solution/drugs into the nebulizer kit, measure the weight before and after the testing.

4.3.3 Connect the nebulizer kit with NE100 and then start NE100 for testing.

4.3.4 After 1.0 minutes have been reached, stop the NE100

4.3.5 Calculates how many weight of the solution/drugs have been nebulizered

4.4 Residual Volume Testing

4.4.1 Each sample should be tested with 2.0ml 0.9% saline solution and nebulized till the bottle is empty.

4.4.2 Add 2.0ml 0.9% saline solution into the nebulizer kit, measure the weight before and after the testing.

4.4.3 Connect the nebulizer kit with NE100 and put at the testing site,

4.4.4 Start NE100

4.4.5 Shakes the nebulizer kit one or two times during nebulizing if there has large droplet stick on the wall inside the nebulizer kit.

4.4.6 After the nebulizer kit is empty, stop NE100 and measure the mass of the tested bottle

4.4.7 Calculates the Residual Volume

4.5 Reliability Test

4.5.1 Connect the tested NE100 with a nebulizer kit as loading.

4.5.2 Set a timer to control power on(30 minutes)/off(5 minutes) of tested NE100 to repeat the working cycle as test specification request.

4.5.3 Before life test, and after every cumulative 100 working hours, check and record the working pressure, working flow, current draw and the nebulization performance.

5.0 Testing Results

5.1 Aerosol Particle Size Distribution Testing(By Malvern Spraytec)

NE100	Testing times	Dv10	Dv50	Dv90	SMD	SR	
Sample 1	1	1.751	4.388	11.410	3.488	**6.516**	
	2	1.694	4.232	11.580	3.389	**6.836**	
	3	1.672	4.170	11.660	3.348	**6.974**	Fig 3
	Mean	**1.706**	**4.263**	**11.550**	**3.408**	**6.775**	
	Std Dev	**0.041**	**0.112**	**0.128**	**0.072**	**0.235**	
Sample 2	1	1.756	4.511	12.690	3.564	**7.227**	Fig 4
	2	1.723	4.521	14.010	3.558	**8.131**	
	3	1.710	4.531	14.820	3.561	**8.667**	
	Mean	**1.730**	**4.521**	**13.840**	**3.561**	**8.008**	
	Std Dev	**0.024**	**0.010**	**1.075**	**0.003**	**0.728**	

Malvern

Average Particle Size Distribution
(average size distribution, weighted)
20150107_N1N4.smea\Exp 001 - 2015 Jan 7\Averages\NE100_N4 1 3.psd
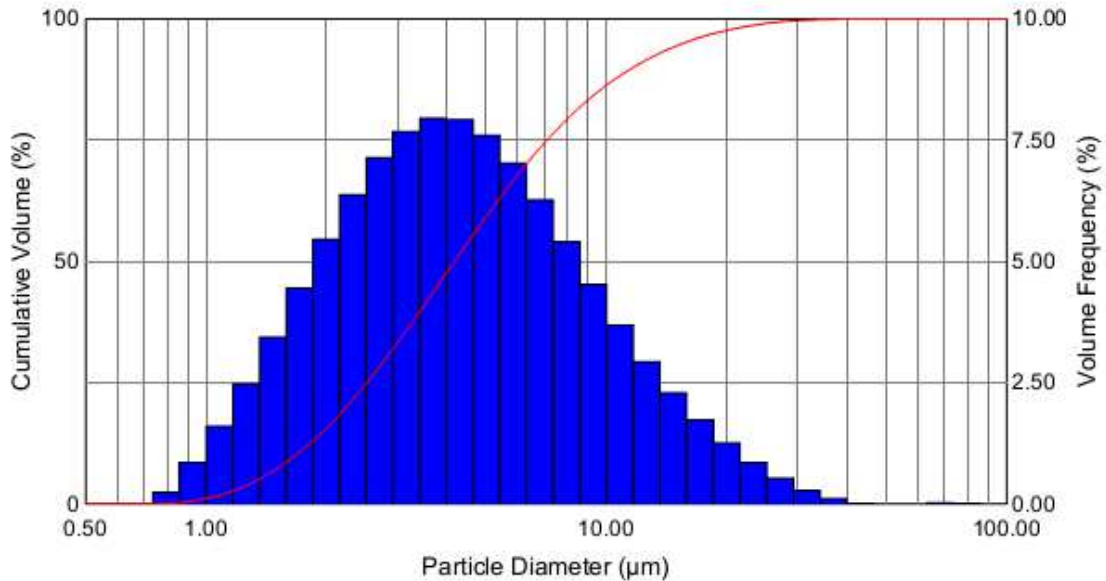Sample : N1N4
Start+1:28:03 (s) :: +1:28:25 (s)

2015 Jan 7 - 16:34:19

Standard Values:

Trans = 77.7 (%)	Dv(10) = 1.672 (µm)	Span = 2.395
Cv = 7.147 (PPM)	Dv(50) = 4.17 (µm)	D[3][2] = 3.348 (µm)
SSA = 1.792 (m²/cc)	Dv(90) = 11.66 (µm)	D[4][3] = 5.713 (µm)

Size (µm)	% V <	% V	Size (µm)	% V <	% V	Size (µm)	% V <	% V
0.117	0.00	0.00	2.51	24.84	6.37	54.12	99.98	0.00
0.136	0.00	0.00	2.93	31.97	7.13	63.10	99.98	0.00
0.158	0.00	0.00	3.41	39.65	7.68	73.56	100.00	0.02
0.185	0.00	0.00	3.98	47.60	7.95	85.77	100.00	0.00
0.215	0.00	0.00	4.64	55.51	7.91	100.00	100.00	0.00
0.251	0.00	0.00	5.41	63.11	7.60	116.59	100.00	0.00
0.293	0.00	0.00	6.31	70.13	7.02	135.94	100.00	0.00
0.341	0.00	0.00	7.36	76.39	6.26	158.49	100.00	0.00
0.398	0.00	0.00	8.58	81.80	5.40	184.79	100.00	0.00
0.464	0.00	0.00	10.00	86.32	4.52	215.44	100.00	0.00
0.541	0.00	0.00	11.66	90.01	3.69	251.19	100.00	0.00
0.631	0.00	0.00	13.59	92.94	2.93	292.87	100.00	0.00
0.736	0.00	0.00	15.85	95.22	2.28	341.46	100.00	0.00
0.858	0.23	0.23	18.48	96.95	1.73	398.11	100.00	0.00
1.00	1.08	0.85	21.54	98.20	1.25	464.16	100.00	0.00
1.17	2.67	1.60	25.12	99.06	0.86	541.17	100.00	0.00
1.36	5.14	2.46	29.29	99.58	0.53	630.96	100.00	0.00
1.58	8.57	3.43	34.15	99.86	0.28	735.64	100.00	0.00
1.85	13.01	4.45	39.81	99.97	0.11	857.70	100.00	0.00
2.15	18.47	5.45	46.42	99.98	0.01	1000.00	100.00	0.00

Fig 3. Sample 1 testing result

Average Particle Size Distribution
(average size distribution, weighted)
20150107_N1N4.smea\Exp 001 - 2015 Jan 7\Averages\NE100_N4 1 4.psd
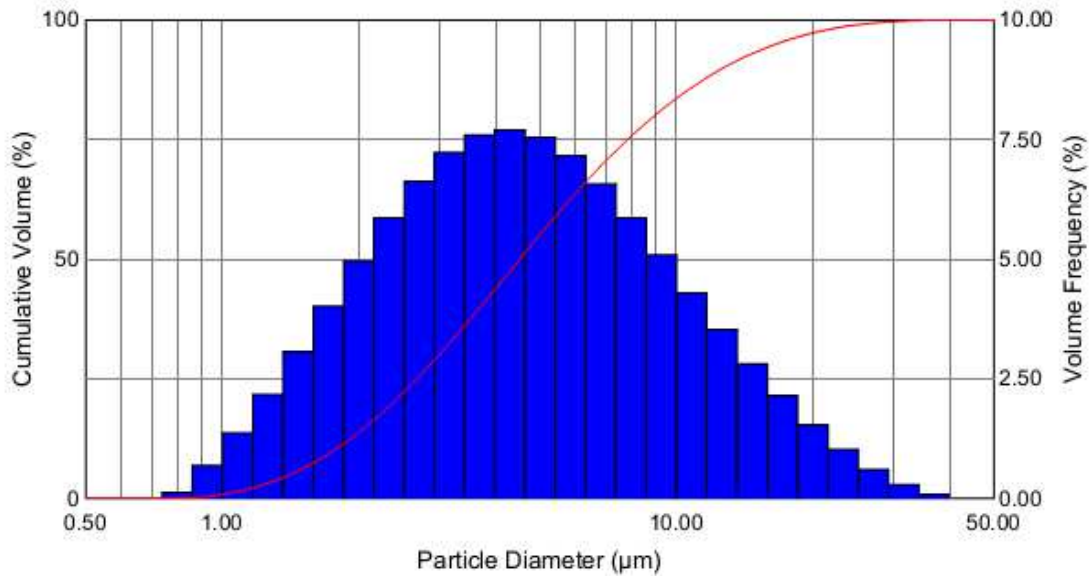Sample : N1N4
Start+1:31:27 (s) :: +1:32:11 (s)

2015 Jan 7 - 16:38:05

Standard Values:

Trans = 77.5 (%)	Dv(10) = 1.756 (µm)	Span = 2.423
Cv = 7.759 (PPM)	Dv(50) = 4.511 (µm)	D[3][2] = 3.564 (µm)
SSA = 1.684 (m²/cc)	Dv(90) = 12.69 (µm)	D[4][3] = 6.121 (µm)

Size (µm)	% V <	% V	Size (µm)	% V <	% V	Size (µm)	% V <	% V
0.117	0.00	0.00	2.51	22.27	5.86	54.12	100.00	0.00
0.136	0.00	0.00	2.93	28.90	6.63	63.10	100.00	0.00
0.158	0.00	0.00	3.41	36.13	7.23	73.56	100.00	0.00
0.185	0.00	0.00	3.98	43.73	7.60	85.77	100.00	0.00
0.215	0.00	0.00	4.64	51.43	7.70	100.00	100.00	0.00
0.251	0.00	0.00	5.41	58.98	7.55	116.59	100.00	0.00
0.293	0.00	0.00	6.31	66.14	7.16	135.94	100.00	0.00
0.341	0.00	0.00	7.36	72.71	6.58	158.49	100.00	0.00
0.398	0.00	0.00	8.58	78.58	5.86	184.79	100.00	0.00
0.464	0.00	0.00	10.00	83.67	5.09	215.44	100.00	0.00
0.541	0.00	0.00	11.66	87.97	4.30	251.19	100.00	0.00
0.631	0.00	0.00	13.59	91.50	3.53	292.87	100.00	0.00
0.736	0.00	0.00	15.85	94.31	2.81	341.46	100.00	0.00
0.858	0.13	0.13	18.48	96.46	2.15	398.11	100.00	0.00
1.00	0.81	0.69	21.54	98.00	1.55	464.16	100.00	0.00
1.17	2.19	1.37	25.12	99.03	1.03	541.17	100.00	0.00
1.36	4.36	2.17	29.29	99.63	0.60	630.96	100.00	0.00
1.58	7.42	3.06	34.15	99.92	0.29	735.64	100.00	0.00
1.85	11.44	4.01	39.81	100.00	0.08	857.70	100.00	0.00
2.15	16.40	4.97	46.42	100.00	0.00	1000.00	100.00	0.00

Fig4. Sample 2 testing result

5.2 Aerosol Particle Size Distribution Testing(By Marple 298 Cascade Impactor)
Tested with 2.5% NaF solution
MMAD=2.591 μ m
FPD(Fine Particle Dose)=81.69%(particle size less than 5.0 μ m)
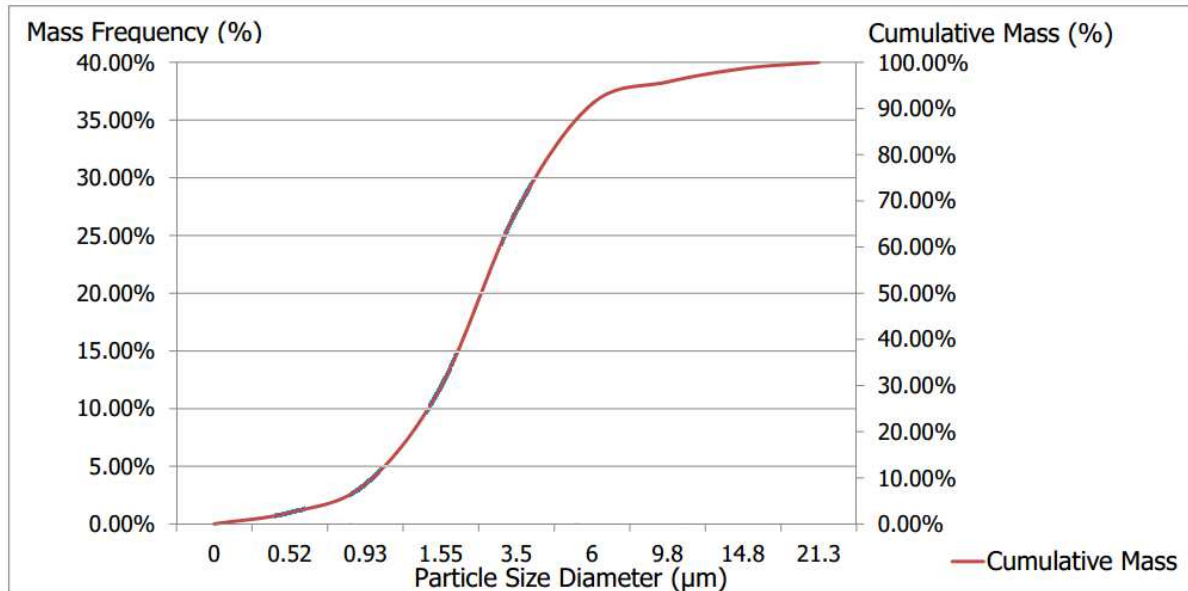

Fig 5. Aerodynamic particle size distribution

5.3 Nebulization Rate Testing(Including Drug Testings)

NE100	0.9% Saline	Atrovent Ipratropium Bromide	Atrovent Flixotide	AstraZeneca Terbutaline Sulphate	Ventoline(2.5mg) Salbutamol/ Sulphate
ml/min	0.365	0.381	0.315	0.371	0.377
MMAD, μm	2.551	2.753	2.562	2.934	2.717

5.4 Residual Volume Testing

	Sample 1	Sample 2
Residual Volume (ml)	0.61	0.58

5.5 Reliability Test

After hr	Neb Rate, ml/min	Particle size MMAD, μm	After hr	Neb Rate, ml/min	Particle size MMAD, μm
0	0.362	2.53	700	0.36	2.75
100	0.352	2.55	800	0.354	2.72
200	0.356	2.75	900	0.355	2.61
300	0.355	2.74	1,000	0.352	2.63
400	0.351	2.53	1,100	0.354	2.64
500	0.353	2.65	1,200	0.355	2.59
600	0.354	2.73			

NE100 Lifetest(1,200hrs)