

## 1.0 Object

- 1.1 To test the performance of Rossmax NB60Q nebulizer

## 2.0 Equipment List

- 2.1 Rossmax NB60Q Nebulizer\*2
- 2.2 Rossmax Nebulizer kit\*2
- 2.3 Malvern Spraytec particle size analyzer
- 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 Atrovent Ipratropium Bromide
- 2.13 Atrovent Flixotide
- 2.14 AstraZeneca Terbutaline Sulphate
- 2.15 Ventoline (2.5mg) Salbutamol/Sulphate
- 2.16 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 NB60Q 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 NB60Q for testing.
- 4.1.5 After 3.0 minutes have been reached, stop the NB60Q and then stop Spraytec.
- 4.1.6 Checks Spraytec records

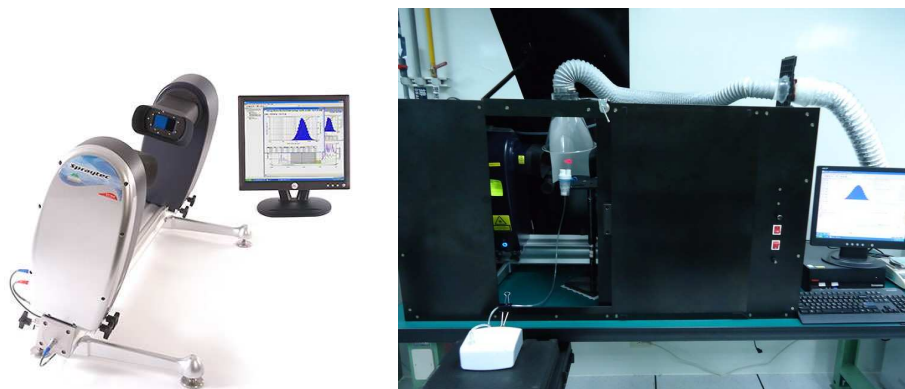


Fig 1. Malvern Spraytec and Testing site

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

- 4.2.1 Each sample should be tested with 2.5 ml 0.9% saline solution.
- 4.2.2 Add 2.5 ml 0.9% saline 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 NB60Q 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 NB60Q.(Sampling times can be varied for different nebulizers to allow for maximum deposit on each stage without overloading stages.
- 4.2.7 After sampling for the required time, NB60Q is switched off, followed a few seconds later by the sampling pump and then the suction pump.
- 4.2.8 Dismount the cascade impactor from the testing module
- 4.2.9 Dismantle the impactor and determine the amount of NaCl on the individual stages of the impactor, the input connection and the outlet filter.

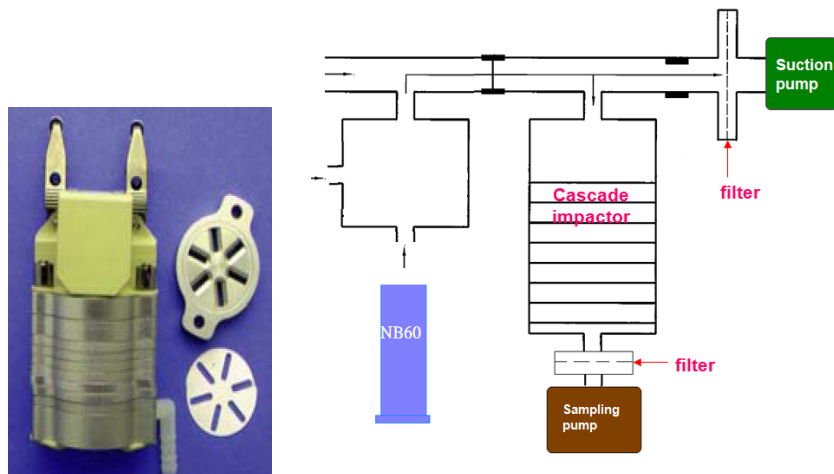


Fig 2. Cascade Impactor and Testing setup

## 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 NB60Q and then start NB60Q for testing.
- 4.3.4 After 1.0 minutes have been reached, stop the NB60Q
- 4.3.5 Calculates how many weight of the solution/drugs have been nebulized

## 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 NB60Q and put at the testing site,

- 4.4.4 Start NB60Q
- 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 NB60Q 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 NB60Q with a N1 nebulizer bottle as loading.
- 4.5.2 Set a timer to control power on(10 minutes)/off(10 minutes) of tested NB60Q 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)

NB60Q	Model	Testing times	Dv10	Dv50	Dv90	SMD	SR	
Sample 1	Open	1	1.903	3.967	7.918	3.386	<b>4.161</b>	
		2	1.908	3.989	7.990	3.400	<b>4.188</b>	
		3	1.892	3.965	7.948	3.376	<b>4.201</b>	Fig 3
		Mean	<b>1.901</b>	<b>3.974</b>	<b>7.952</b>	<b>3.387</b>	<b>4.183</b>	
		Std Dev	<b>0.008</b>	<b>0.013</b>	<b>0.036</b>	<b>0.012</b>	<b>0.020</b>	
	Closed	1	1.743	4.182	9.535	3.352	<b>5.470</b>	Fig 4
		2	1.802	4.356	9.924	3.474	<b>5.507</b>	
		3	1.905	4.793	11.420	3.731	<b>5.995</b>	
		Mean	<b>1.817</b>	<b>4.444</b>	<b>10.293</b>	<b>3.519</b>	<b>5.657</b>	
		Std Dev	<b>0.082</b>	<b>0.315</b>	<b>0.995</b>	<b>0.193</b>	<b>0.293</b>	
Sample 2	Open	1	2.074	4.101	7.811	3.574	<b>3.766</b>	
		2	2.070	4.056	7.656	3.547	<b>3.699</b>	Fig 5
		3	2.122	4.180	7.908	3.646	<b>3.727</b>	
		Mean	<b>2.089</b>	<b>4.112</b>	<b>7.792</b>	<b>3.589</b>	<b>3.730</b>	
		Std Dev	<b>0.029</b>	<b>0.063</b>	<b>0.127</b>	<b>0.051</b>	<b>0.034</b>	
	Closed	1	1.950	4.310	9.120	3.591	<b>4.677</b>	
		2	1.972	4.393	9.356	3.648	<b>4.744</b>	
		3	1.933	4.239	8.901	3.544	<b>4.605</b>	Fig 6
		Mean	<b>1.952</b>	<b>4.314</b>	<b>9.126</b>	<b>3.594</b>	<b>4.675</b>	
		Std Dev	<b>0.020</b>	<b>0.077</b>	<b>0.228</b>	<b>0.052</b>	<b>0.070</b>	

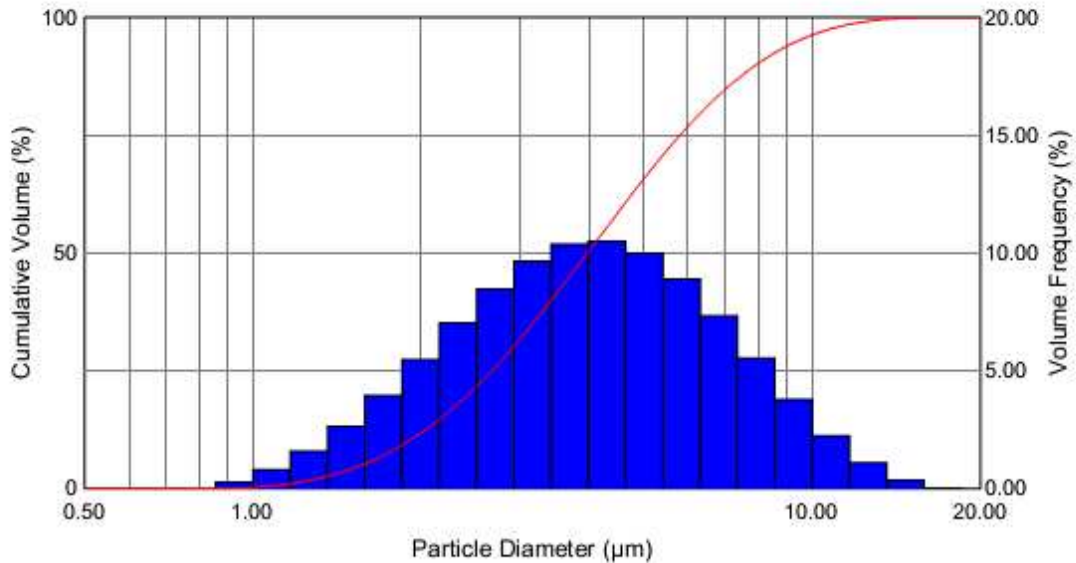
**Average Particle Size Distribution**  
 (average size distribution, weighted)  
 20131206.smea\Exp 001 - 2013 Dec 6\Averages\NB60Q\_01\_Open\_03 1 1.psd  
 Sample : NB60Q\_01\_Open\_03  
 Start+7 (s) :: +1:00 (s)

2013 Dec 6 - 10:31:05

**Standard Values:**  
 Trans = 92.6 (%)  
 Cv = 0.4618 (PPM)  
 SSA = 1.777 (m<sup>2</sup>/cc)

Dv(10) = 1.892 (μm)  
 Dv(50) = 3.965 (μm)  
 Dv(90) = 7.948 (μm)

Span = 1.527  
 D[3][2] = 3.376 (μm)  
 D[4][3] = 4.522 (μm)



Size (μm)	% V <	% V	Size (μm)	% V <	% V	Size (μm)	% V <	% V
0.117	0.00	0.00	2.51	21.76	7.03	54.12	100.00	0.00
0.136	0.00	0.00	2.93	30.25	8.48	63.10	100.00	0.00
0.158	0.00	0.00	3.41	39.90	9.65	73.56	100.00	0.00
0.185	0.00	0.00	3.98	50.27	10.37	85.77	100.00	0.00
0.215	0.00	0.00	4.64	60.77	10.50	100.00	100.00	0.00
0.251	0.00	0.00	5.41	70.77	10.00	116.59	100.00	0.00
0.293	0.00	0.00	6.31	79.66	8.89	135.94	100.00	0.00
0.341	0.00	0.00	7.36	86.99	7.33	158.49	100.00	0.00
0.398	0.00	0.00	8.58	92.53	5.54	184.79	100.00	0.00
0.464	0.00	0.00	10.00	96.30	3.77	215.44	100.00	0.00
0.541	0.00	0.00	11.66	98.54	2.24	251.19	100.00	0.00
0.631	0.00	0.00	13.59	99.63	1.09	292.87	100.00	0.00
0.736	0.00	0.00	15.85	99.99	0.36	341.46	100.00	0.00
0.858	0.00	0.00	18.48	100.00	0.01	398.11	100.00	0.00
1.00	0.26	0.26	21.54	100.00	0.00	464.16	100.00	0.00
1.17	1.06	0.80	25.12	100.00	0.00	541.17	100.00	0.00
1.36	2.65	1.59	29.29	100.00	0.00	630.96	100.00	0.00
1.58	5.29	2.64	34.15	100.00	0.00	735.64	100.00	0.00
1.85	9.26	3.96	39.81	100.00	0.00	857.70	100.00	0.00
2.15	14.73	5.47	46.42	100.00	0.00	1000.00	100.00	0.00

Fig 3. Sample 1 testing result (Valve fully open)

**Average Particle Size Distribution**  
(average size distribution, weighted)

2013 Dec 6 - 10:37:25

20131206.smea\Exp 001 - 2013 Dec 6\Averages\NB60Q\_01\_Closed\_01 1 1.psd

Sample : NB60Q\_01\_Closed\_01

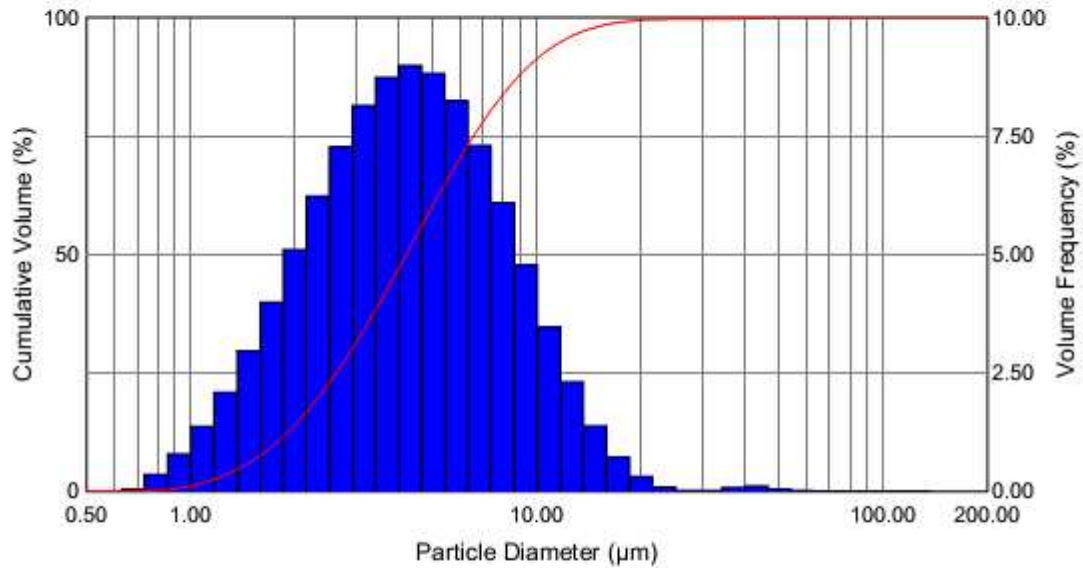
Start+9 (s) :: +1:00 (s)

**Standard Values:**

Trans = 93.8 (%)  
Cv = 0.3713 (PPM)  
SSA = 1.790 (m<sup>2</sup>/cc)

Dv(10) = 1.743 (μm)  
Dv(50) = 4.182 (μm)  
Dv(90) = 9.535 (μm)

Span = 1.863  
D[3][2] = 3.352 (μm)  
D[4][3] = 5.167 (μm)



Size (μm)	% V <	% V	Size (μm)	% V <	% V	Size (μm)	% V <	% V
0.117	0.00	0.00	2.51	22.98	6.23	54.12	99.94	0.06
0.136	0.00	0.00	2.93	30.25	7.27	63.10	99.96	0.02
0.158	0.00	0.00	3.41	38.39	8.14	73.56	99.97	0.01
0.185	0.00	0.00	3.98	47.13	8.74	85.77	99.98	0.01
0.215	0.00	0.00	4.64	56.11	8.98	100.00	99.99	0.01
0.251	0.00	0.00	5.41	64.93	8.82	116.59	99.99	0.01
0.293	0.00	0.00	6.31	73.17	8.24	135.94	100.00	0.00
0.341	0.00	0.00	7.36	80.48	7.30	158.49	100.00	0.00
0.398	0.00	0.00	8.58	86.57	6.10	184.79	100.00	0.00
0.464	0.00	0.00	10.00	91.34	4.77	215.44	100.00	0.00
0.541	0.00	0.00	11.66	94.81	3.47	251.19	100.00	0.00
0.631	0.00	0.00	13.59	97.12	2.31	292.87	100.00	0.00
0.736	0.05	0.05	15.85	98.51	1.39	341.46	100.00	0.00
0.858	0.41	0.36	18.48	99.24	0.73	398.11	100.00	0.00
1.00	1.21	0.80	21.54	99.56	0.32	464.16	100.00	0.00
1.17	2.58	1.37	25.12	99.65	0.10	541.17	100.00	0.00
1.36	4.68	2.09	29.29	99.68	0.02	630.96	100.00	0.00
1.58	7.65	2.97	34.15	99.69	0.02	735.64	100.00	0.00
1.85	11.64	3.99	39.81	99.77	0.08	857.70	100.00	0.00
2.15	16.75	5.11	46.42	99.88	0.11	1000.00	100.00	0.00

Fig4. Sample 1 testing result (Valve Closed)



**Average Particle Size Distribution**

(average size distribution, weighted)

20131206.smea\Exp 002 - 2013 Dec 6\Averages\NB60Q\_02\_Open\_02 1 1.psd

Sample : NB60Q\_02\_Open\_02

Start+9 (s) :: +58 (s)

2013 Dec 6 - 10:52:43

**Standard Values:**

Trans = 89.9 (%)

Cv = 0.6941 (PPM)

SSA = 1.692 (m<sup>2</sup>/cc)

Dv(10) = 2.07 (μm)

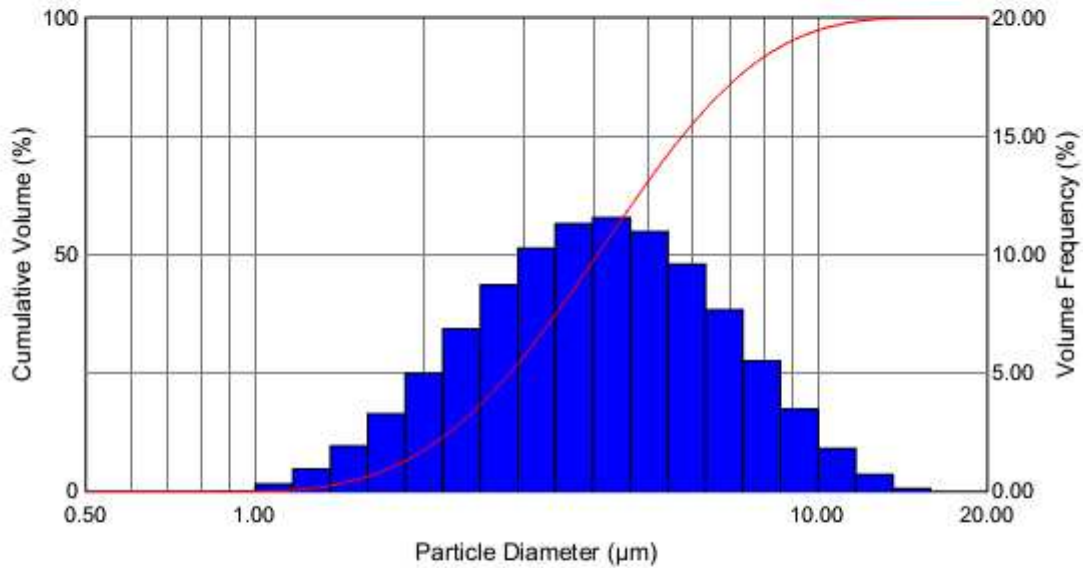
Dv(50) = 4.056 (μm)

Dv(90) = 7.656 (μm)

Span = 1.377

D[3][2] = 3.547 (μm)

D[4][3] = 4.528 (μm)



Size (μm)	% V <	% V	Size (μm)	% V <	% V	Size (μm)	% V <	% V
0.117	0.00	0.00	2.51	18.33	6.86	54.12	100.00	0.00
0.136	0.00	0.00	2.93	27.03	8.71	63.10	100.00	0.00
0.158	0.00	0.00	3.41	37.30	10.27	73.56	100.00	0.00
0.185	0.00	0.00	3.98	48.59	11.29	85.77	100.00	0.00
0.215	0.00	0.00	4.64	60.14	11.55	100.00	100.00	0.00
0.251	0.00	0.00	5.41	71.11	10.97	116.59	100.00	0.00
0.293	0.00	0.00	6.31	80.71	9.60	135.94	100.00	0.00
0.341	0.00	0.00	7.36	88.37	7.67	158.49	100.00	0.00
0.398	0.00	0.00	8.58	93.88	5.50	184.79	100.00	0.00
0.464	0.00	0.00	10.00	97.34	3.46	215.44	100.00	0.00
0.541	0.00	0.00	11.66	99.16	1.82	251.19	100.00	0.00
0.631	0.00	0.00	13.59	99.87	0.71	292.87	100.00	0.00
0.736	0.00	0.00	15.85	100.00	0.13	341.46	100.00	0.00
0.858	0.00	0.00	18.48	100.00	0.00	398.11	100.00	0.00
1.00	0.01	0.01	21.54	100.00	0.00	464.16	100.00	0.00
1.17	0.33	0.32	25.12	100.00	0.00	541.17	100.00	0.00
1.36	1.27	0.94	29.29	100.00	0.00	630.96	100.00	0.00
1.58	3.19	1.92	34.15	100.00	0.00	735.64	100.00	0.00
1.85	6.48	3.28	39.81	100.00	0.00	857.70	100.00	0.00
2.15	11.46	4.98	46.42	100.00	0.00	1000.00	100.00	0.00

Fig 5. Sample 2 testing result (Valve fully open)

**Average Particle Size Distribution**  
(average size distribution, weighted)

2013 Dec 6 - 10:57:07

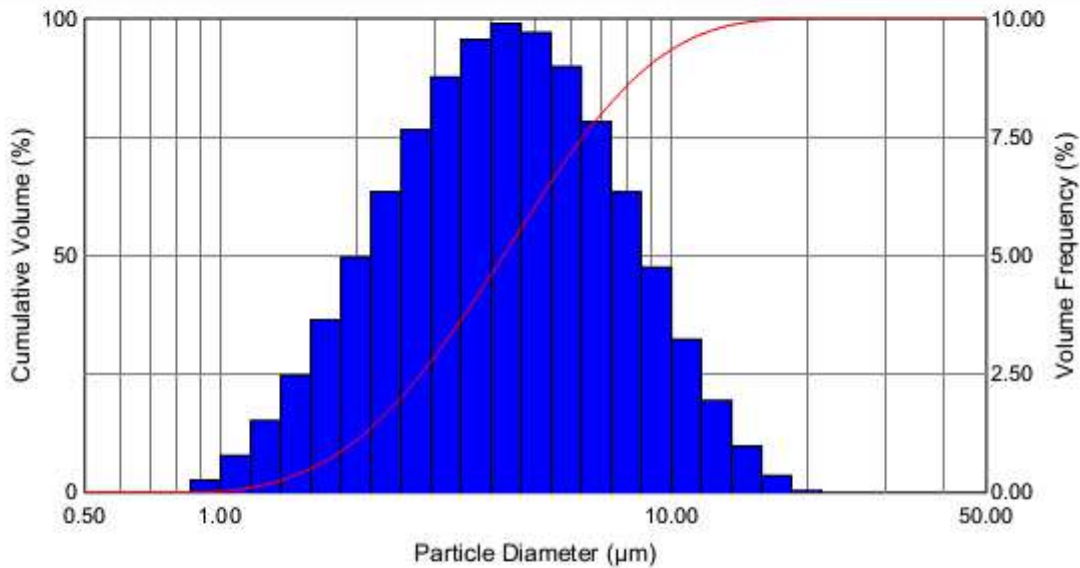
20131206.smea\Exp 002 - 2013 Dec 6\Averages\NB60Q\_02\_Closed\_03 1 1.psd  
Sample : NB60Q\_02\_Closed\_03  
Start+11 (s) :: +1:00 (s)

**Standard Values:**

Trans = 90.6 (%)  
Cv = 0.6201 (PPM)  
SSA = 1.693 (m<sup>2</sup>/cc)

Dv(10) = 1.933 (μm)  
Dv(50) = 4.239 (μm)  
Dv(90) = 8.901 (μm)

Span = 1.644  
D[3][2] = 3.544 (μm)  
D[4][3] = 4.93 (μm)



Size (μm)	% V <	% V	Size (μm)	% V <	% V	Size (μm)	% V <	% V
0.117	0.00	0.00	2.51	20.00	6.34	54.12	100.00	0.00
0.136	0.00	0.00	2.93	27.65	7.65	63.10	100.00	0.00
0.158	0.00	0.00	3.41	36.42	8.77	73.56	100.00	0.00
0.185	0.00	0.00	3.98	45.97	9.56	85.77	100.00	0.00
0.215	0.00	0.00	4.64	55.86	9.89	100.00	100.00	0.00
0.251	0.00	0.00	5.41	65.57	9.70	116.59	100.00	0.00
0.293	0.00	0.00	6.31	74.55	8.98	135.94	100.00	0.00
0.341	0.00	0.00	7.36	82.37	7.82	158.49	100.00	0.00
0.398	0.00	0.00	8.58	88.71	6.34	184.79	100.00	0.00
0.464	0.00	0.00	10.00	93.46	4.75	215.44	100.00	0.00
0.541	0.00	0.00	11.66	96.69	3.23	251.19	100.00	0.00
0.631	0.00	0.00	13.59	98.63	1.94	292.87	100.00	0.00
0.736	0.00	0.00	15.85	99.60	0.98	341.46	100.00	0.00
0.858	0.00	0.00	18.48	99.96	0.36	398.11	100.00	0.00
1.00	0.27	0.27	21.54	100.00	0.04	464.16	100.00	0.00
1.17	1.05	0.79	25.12	100.00	0.00	541.17	100.00	0.00
1.36	2.57	1.52	29.29	100.00	0.00	630.96	100.00	0.00
1.58	5.05	2.47	34.15	100.00	0.00	735.64	100.00	0.00
1.85	8.69	3.64	39.81	100.00	0.00	857.70	100.00	0.00
2.15	13.65	4.96	46.42	100.00	0.00	1000.00	100.00	0.00

Fig6. Sample 2 testing result (Valve Closed)

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

Tested with 0.9% saline solution

MMAD=2.497  $\mu\text{m}$

FPD(Fine Particle Dose)=76.31%(particle size less than 5.0  $\mu\text{m}$ )

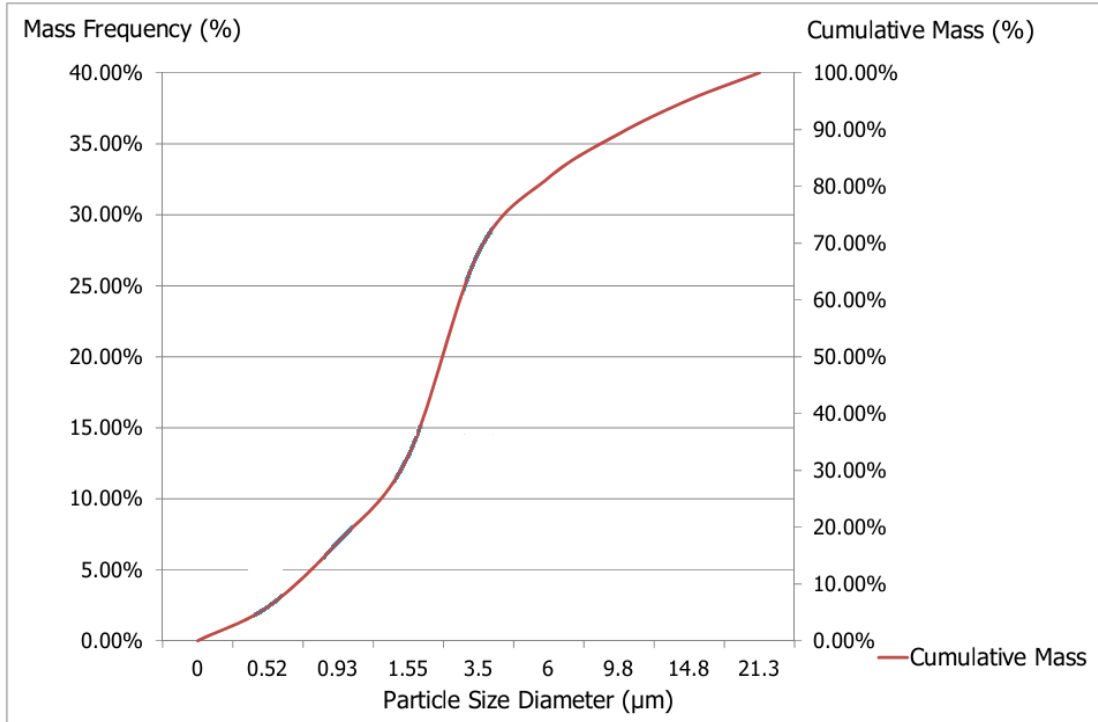


Fig 7. Aerodynamic particle size distribution

## 5.3 Nebulization Rate Testing(Including Drug Testings)

NB60Q	0.9% Saline		Atrovent Ipratropium Bromide		Atrovent Flixotide		AstraZeneca Terbutaline Sulphate		Ventoline(2.5mg) Salbutamol/ Sulphate	
	Open	Closed	Open	Closed	Open	Closed	Open	Closed	Open	Closed
ml/min	0.255	0.122	0.263	0.115	0.268	0.108	0.249	0.110	0.253	0.129
Dv(50) $\mu\text{m}$	4.430	4.831	4.721	4.932	4.855	5.003	4.777	4.983	4.562	4.487

## 5.4 Residual Volume Testing

	Sample 1		Sample 2	
Valve(Fully Open/Closed)	Open	Closed	Open	Closed
Residual Volume (ml)	0.63	0.66	0.64	0.65

## 5.5 Reliability Test

After hr	Neb Rate, ml/min	Particle size/MMAD, $\mu\text{m}$
0	0.29	2.43
100	0.26	2.77
200	0.27	2.53
300	0.26	2.53
400	0.28	2.68



