

1.0 Object

- 1.1 To test the performance of Rossmax NH60 nebulizer

2.0 Equipment List

- 2.1 Rossmax NH60 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 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 NH60 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 NH60 for testing.
- 4.1.5 After 3.0 minutes have been reached, stop the NH60 and then stop Spraytec.
- 4.1.6 Checks Spraytec records

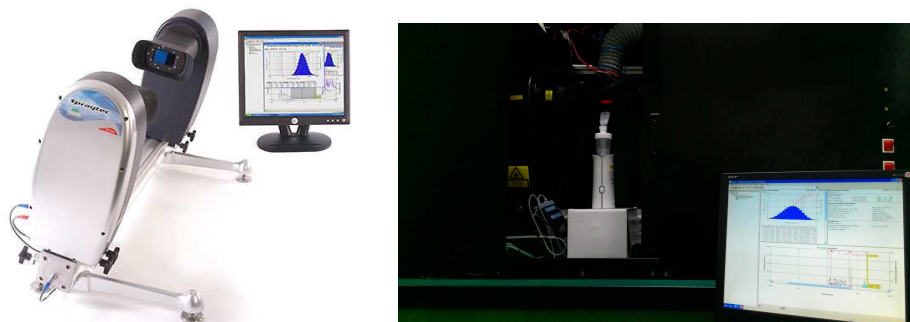


Fig 1. Malvern Spraytec and Testing site

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 NH60 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 NH60.(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, NH60 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 NaF on the individual stages of the impactor, the input connection and the outlet filter.

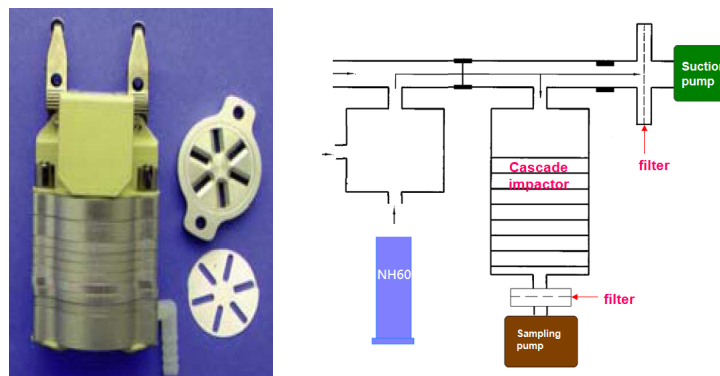


Fig 2. Cascade Impactor and Testing setup

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 NH60 and then start NH60 for testing.
- 4.3.4 After 1.0 minutes have been reached, stop the NH60
- 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 NH60 and put at the testing site,
- 4.4.4 Start NH60
- 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 NH60 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 NH60 with a nebulizer kit as loading.

4.5.2 Set a timer to control power on(10 minutes)/off(10 minutes) of tested NH60 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)

NH60	Valve Status	Testing times	Dv10	Dv50	Dv90	SMD	SR	
Sample 1	Fully Open	1	1.907	3.984	7.951	3.398	4.169	
		2	1.898	3.976	7.971	3.388	4.200	
		3	1.886	3.934	7.862	3.359	4.169	Fig 3
		Mean	1.897	3.965	7.928	3.382	4.179	
		Std Dev	0.011	0.027	0.058	0.020	0.018	
	Closed	1	1.942	4.905	11.510	3.812	5.927	Fig 4
		2	1.975	4.998	11.720	3.875	5.934	
		3	1.972	4.992	11.750	3.872	5.958	
		Mean	1.963	4.965	11.660	3.853	5.940	
		Std Dev	0.018	0.052	0.131	0.036	0.017	
Sample 2	Fully Open	1	1.942	4.063	8.115	3.461	4.179	
		2	1.925	4.016	8.017	3.428	4.165	
		3	1.922	3.990	7.930	3.412	4.126	Fig 5
		Mean	1.930	4.023	8.021	3.434	4.156	
		Std Dev	0.011	0.037	0.093	0.025	0.027	
	Closed	1	1.960	4.960	11.650	3.855	5.944	
		2	1.971	4.952	11.570	3.863	5.870	Fig 6
		3	1.982	4.981	11.650	3.884	5.878	
		Mean	1.971	4.964	11.623	3.867	5.897	
		Std Dev	0.011	0.015	0.046	0.015	0.041	

Average Particle Size Distribution

2015 Jan 15 - 17:20:54

(average size distribution, weighted)

20150115-Ken.smea\Exp 005 - 2015 Jan 15\Averages\NH60-A Open+N1 4.psd

Sample : NH60-A Open +N1

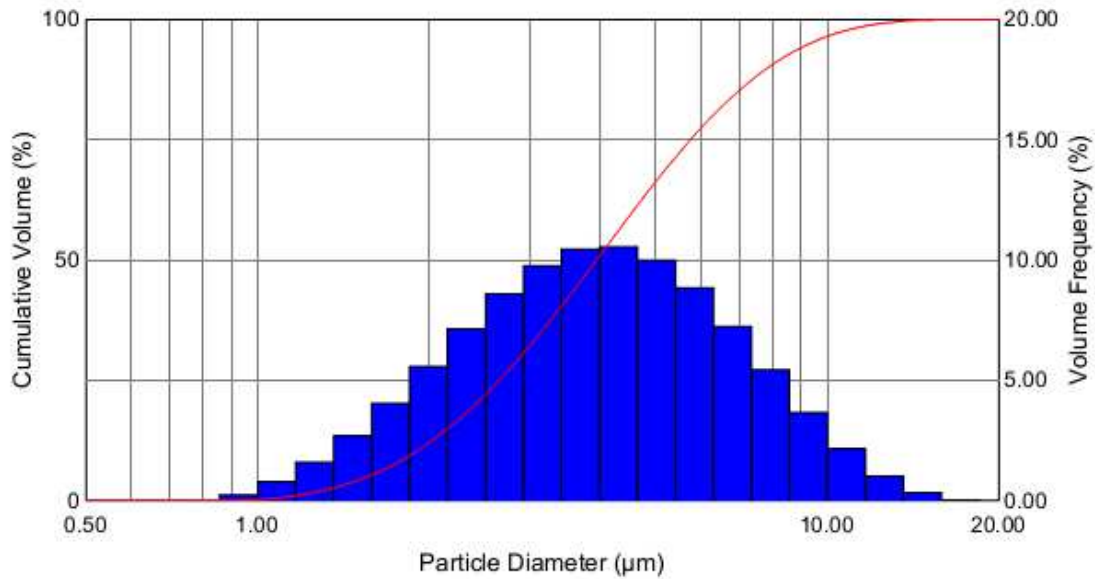
Start+3:59 (s) : +5:29 (s)

Standard Values:

Trans = 88.4 (%)
Cv = 3.693 (PPM)
SSA = 1.786 (m²/cc)

Dv(10) = 1.886 (μm)
Dv(50) = 3.934 (μm)
Dv(90) = 7.862 (μm)

Span = 1.519
D[3][2] = 3.359 (μm)
D[4][3] = 4.484 (μm)



Size (μm)	% V <	% V	Size (μm)	% V <	% V	Size (μm)	% V <	% V
0.117	0.00	0.00	2.51	22.04	7.14	54.12	100.00	0.00
0.136	0.00	0.00	2.93	30.63	8.59	63.10	100.00	0.00
0.158	0.00	0.00	3.41	40.38	9.75	73.56	100.00	0.00
0.185	0.00	0.00	3.98	50.82	10.45	85.77	100.00	0.00
0.215	0.00	0.00	4.64	61.37	10.54	100.00	100.00	0.00
0.251	0.00	0.00	5.41	71.36	9.99	116.59	100.00	0.00
0.293	0.00	0.00	6.31	80.20	8.84	135.94	100.00	0.00
0.341	0.00	0.00	7.36	87.43	7.24	158.49	100.00	0.00
0.398	0.00	0.00	8.58	92.86	5.42	184.79	100.00	0.00
0.464	0.00	0.00	10.00	96.51	3.65	215.44	100.00	0.00
0.541	0.00	0.00	11.66	98.65	2.14	251.19	100.00	0.00
0.631	0.00	0.00	13.59	99.67	1.02	292.87	100.00	0.00
0.736	0.00	0.00	15.85	99.99	0.32	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	0.22	0.22	21.54	100.00	0.00	464.16	100.00	0.00
1.17	1.01	0.78	25.12	100.00	0.00	541.17	100.00	0.00
1.36	2.60	1.60	29.29	100.00	0.00	630.96	100.00	0.00
1.58	5.29	2.69	34.15	100.00	0.00	735.64	100.00	0.00
1.85	9.33	4.04	39.81	100.00	0.00	857.70	100.00	0.00
2.15	14.90	5.57	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

2015 Jan 15 - 17:40:19

(average size distribution, weighted)

20150115-Ken.smea\Exp 006 - 2015 Jan 15\Averages\NH60-A Closed+N1 2.psd

Sample : NH60-A Closed +N1

Start+23 (s) :: +2:14 (s)

Standard Values:

Trans = 84.7 (%)

Dv(10) = 1.942 (µm)

Span = 1.95

Cv = 5.547 (PPM)

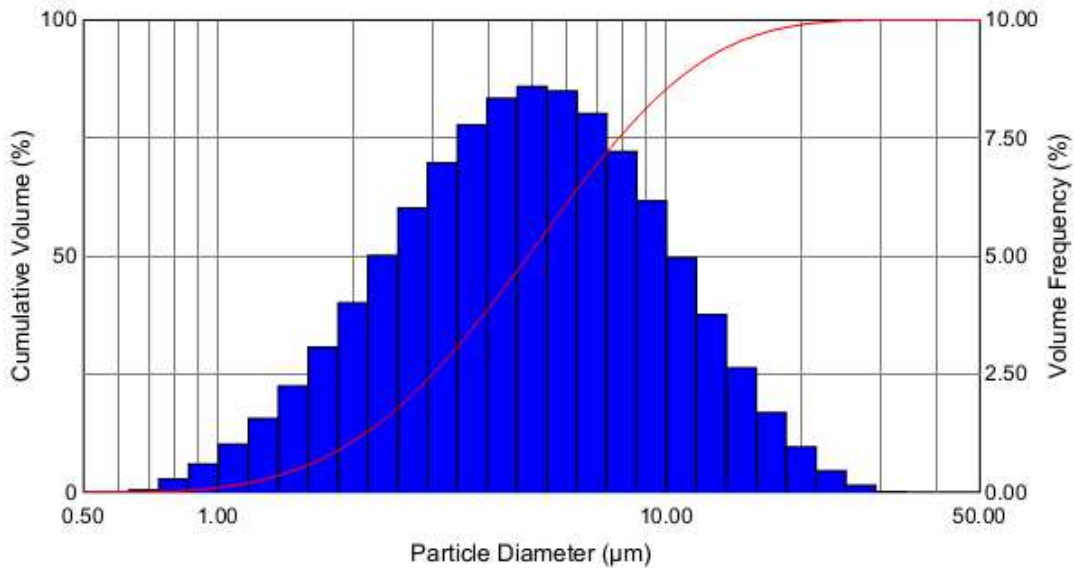
Dv(50) = 4.905 (µm)

D[3][2] = 3.812 (µm)

SSA = 1.574 (m²/cc)

Dv(90) = 11.51 (µm)

D[4][3] = 5.985 (µm)



Size (µm)	% V <	% V	Size (µm)	% V <	% V	Size (µm)	% V <	% V
0.117	0.00	0.00	2.51	17.83	5.01	54.12	100.00	0.00
0.136	0.00	0.00	2.93	23.85	6.02	63.10	100.00	0.00
0.158	0.00	0.00	3.41	30.81	6.97	73.56	100.00	0.00
0.185	0.00	0.00	3.98	38.59	7.77	85.77	100.00	0.00
0.215	0.00	0.00	4.64	46.93	8.34	100.00	100.00	0.00
0.251	0.00	0.00	5.41	55.52	8.60	116.59	100.00	0.00
0.293	0.00	0.00	6.31	64.01	8.49	135.94	100.00	0.00
0.341	0.00	0.00	7.36	72.04	8.02	158.49	100.00	0.00
0.398	0.00	0.00	8.58	79.25	7.22	184.79	100.00	0.00
0.464	0.00	0.00	10.00	85.42	6.16	215.44	100.00	0.00
0.541	0.00	0.00	11.66	90.38	4.97	251.19	100.00	0.00
0.631	0.00	0.00	13.59	94.14	3.75	292.87	100.00	0.00
0.736	0.05	0.05	15.85	96.77	2.63	341.46	100.00	0.00
0.858	0.33	0.28	18.48	98.45	1.68	398.11	100.00	0.00
1.00	0.93	0.60	21.54	99.40	0.95	464.16	100.00	0.00
1.17	1.95	1.02	25.12	99.85	0.45	541.17	100.00	0.00
1.36	3.51	1.56	29.29	99.99	0.14	630.96	100.00	0.00
1.58	5.75	2.24	34.15	100.00	0.01	735.64	100.00	0.00
1.85	8.81	3.06	39.81	100.00	0.00	857.70	100.00	0.00
2.15	12.82	4.00	46.42	100.00	0.00	1000.00	100.00	0.00

Fig4. Sample 1 testing result (Valve Closed)

Average Particle Size Distribution

2015 Jan 15 - 16:01:29

(average size distribution, weighted)

20150115-Ken.smea\Exp 003 - 2015 Jan 15\Averages\NH60-B Open+N1 1 3.psd

Sample : NH60-B +N1 open

Start+4:15 (s) : +5:38 (s)

Standard Values:

Trans = 89.9 (%)

Dv(10) = 1.922 (µm)

Span = 1.506

Cv = 3.254 (PPM)

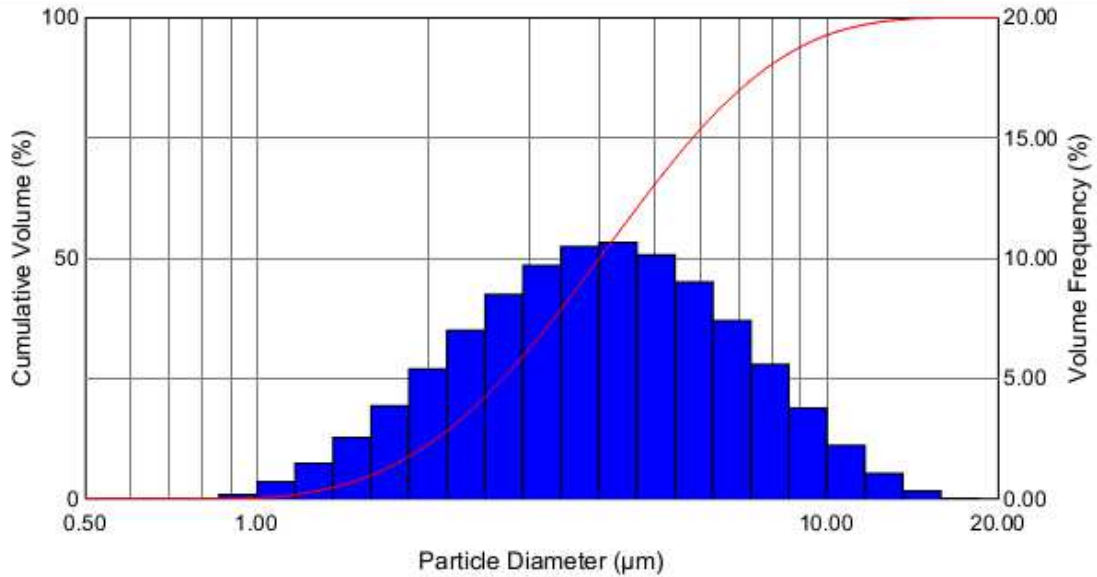
Dv(50) = 3.99 (µm)

D[3][2] = 3.412 (µm)

SSA = 1.758 (m²/cc)

Dv(90) = 7.93 (µm)

D[4][3] = 4.538 (µm)



Size (µm)	% V <	% V	Size (µm)	% V <	% V	Size (µm)	% V <	% V
0.117	0.00	0.00	2.51	21.15	6.99	54.12	100.00	0.00
0.136	0.00	0.00	2.93	29.64	8.49	63.10	100.00	0.00
0.158	0.00	0.00	3.41	39.36	9.71	73.56	100.00	0.00
0.185	0.00	0.00	3.98	49.84	10.48	85.77	100.00	0.00
0.215	0.00	0.00	4.64	60.48	10.64	100.00	100.00	0.00
0.251	0.00	0.00	5.41	70.62	10.14	116.59	100.00	0.00
0.293	0.00	0.00	6.31	79.63	9.01	135.94	100.00	0.00
0.341	0.00	0.00	7.36	87.05	7.41	158.49	100.00	0.00
0.398	0.00	0.00	8.58	92.62	5.57	184.79	100.00	0.00
0.464	0.00	0.00	10.00	96.38	3.76	215.44	100.00	0.00
0.541	0.00	0.00	11.66	98.59	2.21	251.19	100.00	0.00
0.631	0.00	0.00	13.59	99.65	1.06	292.87	100.00	0.00
0.736	0.00	0.00	15.85	99.99	0.34	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	0.18	0.18	21.54	100.00	0.00	464.16	100.00	0.00
1.17	0.87	0.70	25.12	100.00	0.00	541.17	100.00	0.00
1.36	2.35	1.48	29.29	100.00	0.00	630.96	100.00	0.00
1.58	4.89	2.54	34.15	100.00	0.00	735.64	100.00	0.00
1.85	8.76	3.87	39.81	100.00	0.00	857.70	100.00	0.00
2.15	14.16	5.40	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

2015 Jan 15 - 16:28:37

(average size distribution, weighted)

20150115-Ken.smea\Exp 004 - 2015 Jan 15\Averages\NH60-B Closed+N1 1 2.psd

Sample : NH60-B Closed +N1

Start+2:13 (s) : +3:56 (s)

Standard Values:

Trans = 85.9 (%)

Cv = 5.176 (PPM)

SSA = 1.553 (m²/cc)

Dv(10) = 1.971 (μm)

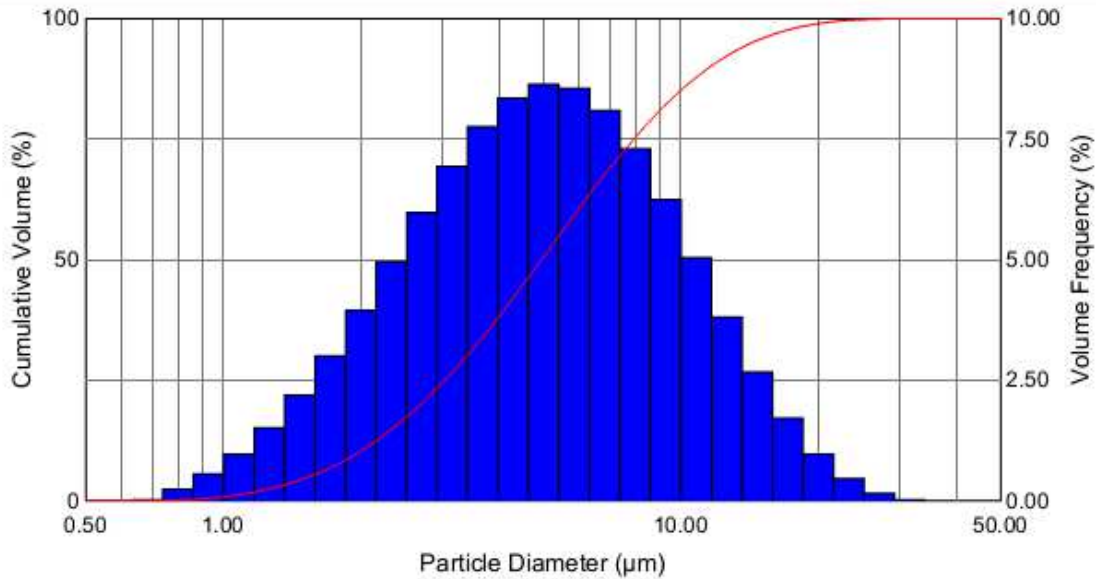
Dv(50) = 4.952 (μm)

Dv(90) = 11.57 (μm)

Span = 1.939

D[3][2] = 3.863 (μm)

D[4][3] = 6.034 (μm)



Size (μm)	% V <	% V	Size (μm)	% V <	% V	Size (μm)	% V <	% V
0.117	0.00	0.00	2.51	17.35	4.95	54.12	100.00	0.00
0.136	0.00	0.00	2.93	23.32	5.97	63.10	100.00	0.00
0.158	0.00	0.00	3.41	30.25	6.93	73.56	100.00	0.00
0.185	0.00	0.00	3.98	38.01	7.76	85.77	100.00	0.00
0.215	0.00	0.00	4.64	46.37	8.35	100.00	100.00	0.00
0.251	0.00	0.00	5.41	55.00	8.64	116.59	100.00	0.00
0.293	0.00	0.00	6.31	63.56	8.55	135.94	100.00	0.00
0.341	0.00	0.00	7.36	71.65	8.10	158.49	100.00	0.00
0.398	0.00	0.00	8.58	78.95	7.30	184.79	100.00	0.00
0.464	0.00	0.00	10.00	85.19	6.24	215.44	100.00	0.00
0.541	0.00	0.00	11.66	90.22	5.04	251.19	100.00	0.00
0.631	0.00	0.00	13.59	94.03	3.81	292.87	100.00	0.00
0.736	0.02	0.02	15.85	96.70	2.67	341.46	100.00	0.00
0.858	0.25	0.23	18.48	98.41	1.71	398.11	100.00	0.00
1.00	0.80	0.55	21.54	99.38	0.97	464.16	100.00	0.00
1.17	1.77	0.97	25.12	99.84	0.46	541.17	100.00	0.00
1.36	3.27	1.51	29.29	99.98	0.15	630.96	100.00	0.00
1.58	5.46	2.19	34.15	100.00	0.02	735.64	100.00	0.00
1.85	8.46	3.00	39.81	100.00	0.00	857.70	100.00	0.00
2.15	12.40	3.94	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 2.5% NaF solution

MMAD=2.430 μm

FPD(Fine Particle Dose)=76.48%(particle size less than 5.0 μm)

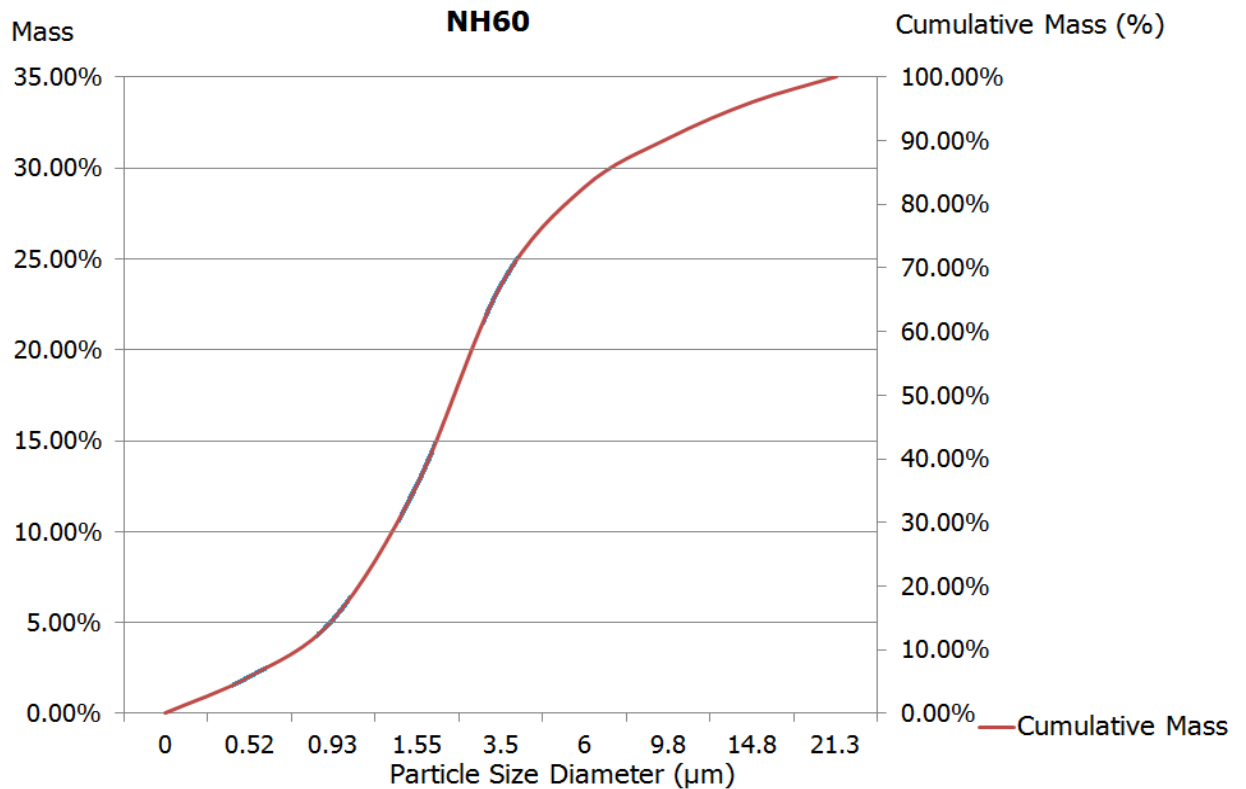


Fig 7. Aerodynamic particle size distribution

5.3 Nebulization Rate Testing(Including Drug Testings)

NH60	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
MMAD, μm	2.430	2.831	2.721	2.932	2.855	3.003	2.777	2.983	2.562	2.487

5.4 Residual Volume Testing

	Sample 1		Sample 2	
Valve(Fully Open/Closed)	Open	Closed	Open	Closed
Residual Volume (ml)	0.62	0.64	0.63	0.64

5.5 Reliability Test

After hr	Neb Rate, ml/min	Particle size/MMAD, μm
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

