

1.0 Object

- 1.1 To test the performance of Rossmax NI60 nebulizer

2.0 Equipment List

- 2.1 Rossmax NI60 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 NI60 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 NI60 for testing.
- 4.1.5 After 3.0 minutes have been reached, stop the NI60 and then stop Spraytec.
- 4.1.6 Checks Spraytec records

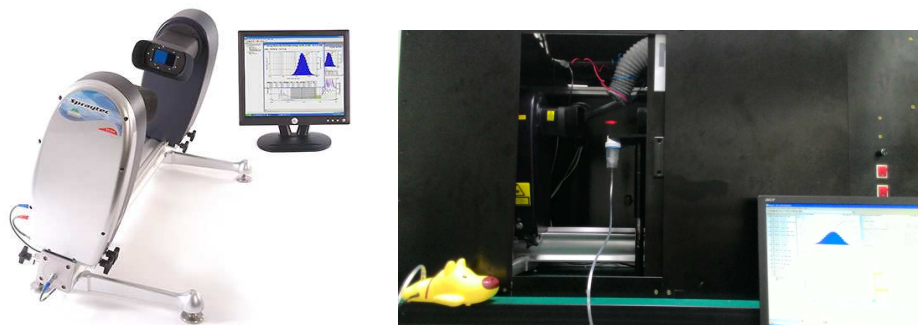


Fig 1. Malvern Spraytec and Testing site

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 NI60 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 NI60.(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, NI60 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.

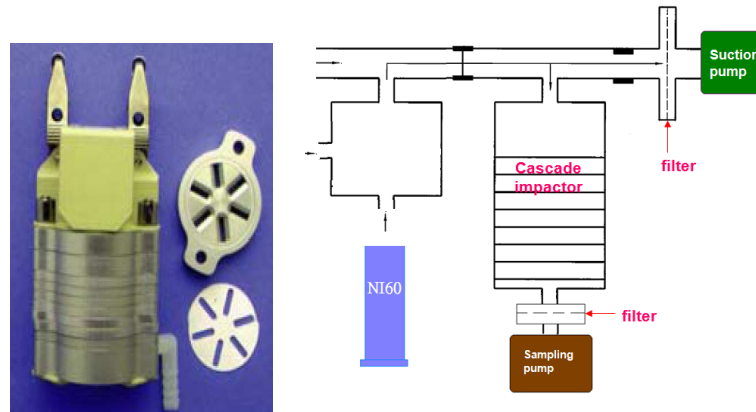


Fig 2. Cascade Impactor and Testing setup

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 NI60 and then start NI60 for testing.
- 4.3.4 After 1.0 minutes have been reached, stop the NI60
- 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 NI60 and put at the testing site,
- 4.4.4 Start NI60
- 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 NI60 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 NI60 with a N1 nebulizer bottle as loading.

4.5.2 Set a timer to control power on(10 minutes)/off(10 minutes) of tested NI60 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

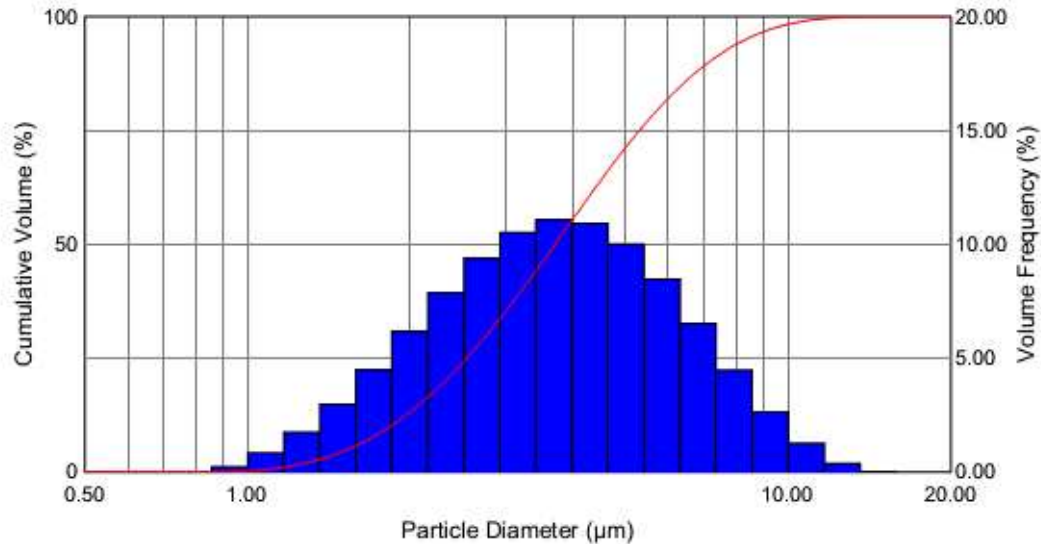
5.1 Aerosol Particle Size Distribution Testing(By Malvern Spraytec)

	Testing times	Dv10	Dv50	Dv90	SMD	SR	
#1 Open	1	1.831	3.700	7.124	3.198	3.891	Fig 3
	2	1.928	3.869	7.411	3.349	3.844	
	3	1.962	3.931	7.511	3.404	3.828	
	Mean	1.907	3.833	7.349	3.317	3.854	
	Std Dev	0.068	0.120	0.201	0.107	0.033	
#1 Closed	1	2.010	4.684	9.941	3.787	4.946	Fig 4
	2	2.032	4.748	10.090	3.833	4.966	
	3	2.049	4.803	10.230	3.875	4.993	
	Mean	2.030	4.745	10.087	3.832	4.968	
	Std Dev	0.020	0.060	0.145	0.044	0.024	
#2 Open	1	1.917	3.885	7.508	3.350	3.917	Fig 5
	2	1.957	3.962	7.645	3.417	3.906	
	3	2.002	4.044	7.774	3.488	3.883	
	Mean	1.959	3.964	7.642	3.418	3.902	
	Std Dev	0.043	0.080	0.133	0.069	0.017	
#2 Closed	1	2.108	5.050	11.060	4.020	5.247	Fig 6
	2	2.125	5.100	11.190	4.051	5.266	
	3	2.149	5.171	11.350	4.101	5.282	
	Mean	2.127	5.107	11.200	4.057	5.265	
	Std Dev	0.021	0.061	0.145	0.041	0.017	

Average Particle Size Distribution
 (average size distribution, weighted)
 20141110.smea\Exp 001 - 2014 Nov 10\Averages\NI60_Open_01 1 1.psd
 Sample : NI60_Open_01
 Start+13 (s) :: +1.47 (s)

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Standard Values:
 Trans = 87.0 (%) Dv(10) = 1.831 (µm) Span = 1.43
 Cv = 3.936 (PPM) Dv(50) = 3.7 (µm) D[3][2] = 3.198 (µm)
 SSA = 1.876 (m²/cc) Dv(90) = 7.124 (µm) D[4][3] = 4.153 (µm)



Size (µm)	% V <	% V	Size (µm)	% V <	% V	Size (µm)	% V <	% V
0.117	0.00	0.00	2.51	24.33	7.87	54.12	100.00	0.00
0.136	0.00	0.00	2.93	33.71	9.38	63.10	100.00	0.00
0.158	0.00	0.00	3.41	44.23	10.52	73.56	100.00	0.00
0.185	0.00	0.00	3.98	55.31	11.08	85.77	100.00	0.00
0.215	0.00	0.00	4.64	66.22	10.91	100.00	100.00	0.00
0.251	0.00	0.00	5.41	76.23	10.01	116.59	100.00	0.00
0.293	0.00	0.00	6.31	84.69	8.46	135.94	100.00	0.00
0.341	0.00	0.00	7.36	91.21	6.52	158.49	100.00	0.00
0.398	0.00	0.00	8.58	95.69	4.48	184.79	100.00	0.00
0.464	0.00	0.00	10.00	98.34	2.66	215.44	100.00	0.00
0.541	0.00	0.00	11.66	99.60	1.26	251.19	100.00	0.00
0.631	0.00	0.00	13.59	99.99	0.39	292.87	100.00	0.00
0.736	0.00	0.00	15.85	100.00	0.01	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	0.22	0.22	21.54	100.00	0.00	464.16	100.00	0.00
1.17	1.06	0.84	25.12	100.00	0.00	541.17	100.00	0.00
1.36	2.82	1.76	29.29	100.00	0.00	630.96	100.00	0.00
1.58	5.81	2.99	34.15	100.00	0.00	735.64	100.00	0.00
1.85	10.29	4.49	39.81	100.00	0.00	857.70	100.00	0.00
2.15	16.46	6.17	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)
 20141110.smea\Exp 001 - 2014 Nov 10\Averages\NI60_Closed_01 1 1.psd
 Sample : NI60_Closed_01
 Start+20 (s) :: +1:51 (s)

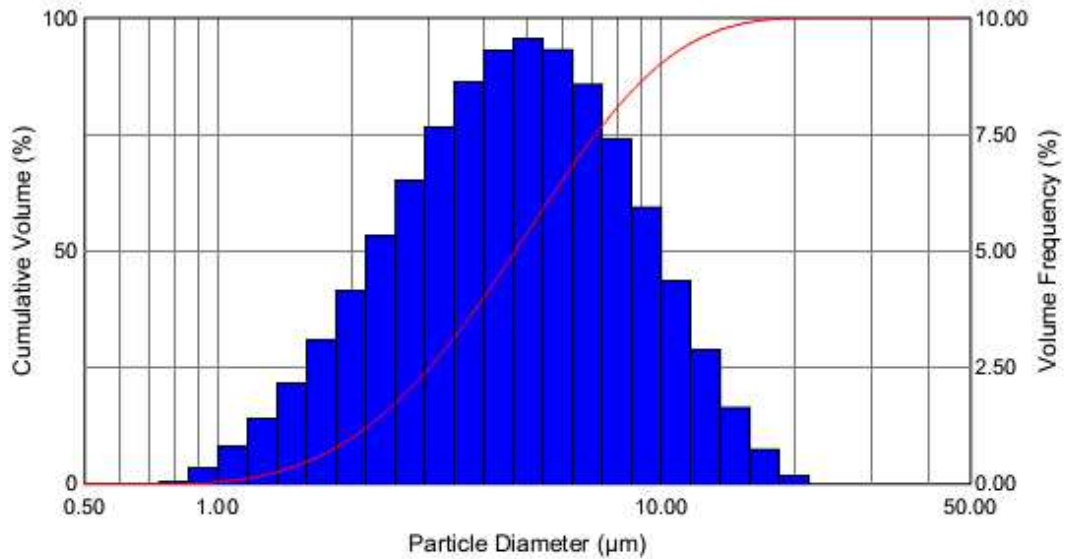
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Standard Values:

Trans = 81.5 (%)
 Cv = 6.919 (PPM)
 SSA = 1.584 (m²/cc)

Dv(10) = 2.01 (μm)
 Dv(50) = 4.684 (μm)
 Dv(90) = 9.941 (μm)

Span = 1.693
 D[3][2] = 3.787 (μm)
 D[4][3] = 5.437 (μm)



Size (μm)	% V <	% V	Size (μm)	% V <	% V	Size (μm)	% V <	% V
0.117	0.00	0.00	2.51	17.34	5.32	54.12	100.00	0.00
0.136	0.00	0.00	2.93	23.86	6.52	63.10	100.00	0.00
0.158	0.00	0.00	3.41	31.51	7.65	73.56	100.00	0.00
0.185	0.00	0.00	3.98	40.14	8.63	85.77	100.00	0.00
0.215	0.00	0.00	4.64	49.43	9.30	100.00	100.00	0.00
0.251	0.00	0.00	5.41	58.98	9.55	116.59	100.00	0.00
0.293	0.00	0.00	6.31	68.30	9.31	135.94	100.00	0.00
0.341	0.00	0.00	7.36	76.87	8.57	158.49	100.00	0.00
0.398	0.00	0.00	8.58	84.27	7.40	184.79	100.00	0.00
0.464	0.00	0.00	10.00	90.21	5.94	215.44	100.00	0.00
0.541	0.00	0.00	11.66	94.57	4.37	251.19	100.00	0.00
0.631	0.00	0.00	13.59	97.45	2.88	292.87	100.00	0.00
0.736	0.00	0.00	15.85	99.09	1.64	341.46	100.00	0.00
0.858	0.05	0.05	18.48	99.82	0.73	398.11	100.00	0.00
1.00	0.40	0.35	21.54	100.00	0.18	464.16	100.00	0.00
1.17	1.21	0.81	25.12	100.00	0.00	541.17	100.00	0.00
1.36	2.61	1.41	29.29	100.00	0.00	630.96	100.00	0.00
1.58	4.78	2.16	34.15	100.00	0.00	735.64	100.00	0.00
1.85	7.86	3.09	39.81	100.00	0.00	857.70	100.00	0.00
2.15	12.02	4.15	46.42	100.00	0.00	1000.00	100.00	0.00

Fig4. Sample 1 testing result (Valve Closed)

Average Particle Size Distribution
 (average size distribution, weighted)
 20141110.smea\Exp 002 - 2014 Nov 10\Averages\NI60_Open_02 1 1.psd
 Sample : NI60_Open_01_02
 Start+4 (s) :: +1:30 (s)

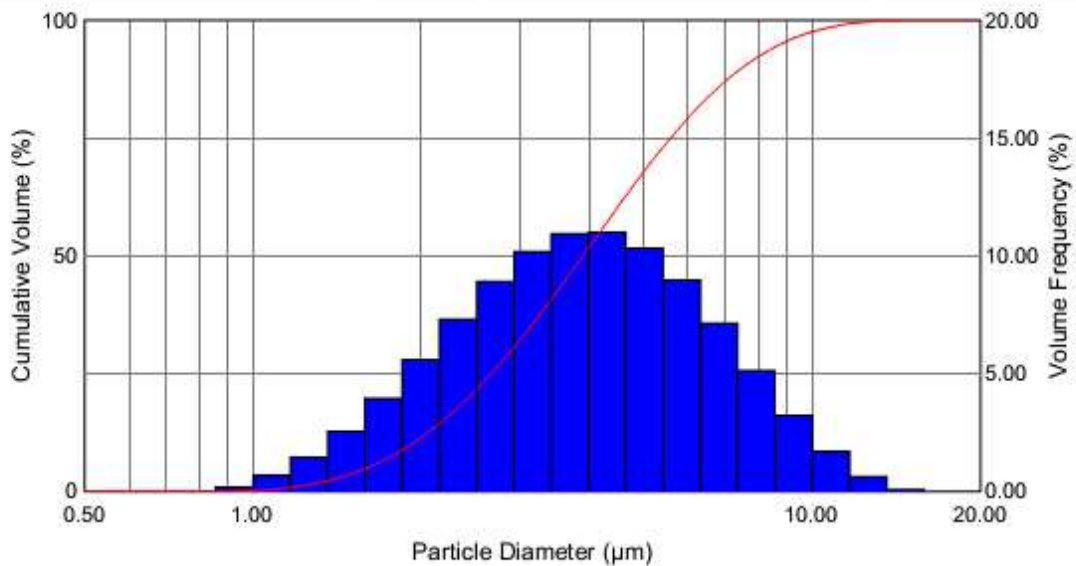
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Standard Values:

Trans = 90.1 (%)
 Cv = 3.122 (PPM)
 SSA = 1.791 (m²/cc)

Dv(10) = 1.917 (μm)
 Dv(50) = 3.885 (μm)
 Dv(90) = 7.508 (μm)

Span = 1.439
 D[3][2] = 3.35 (μm)
 D[4][3] = 4.366 (μm)



Size (μm)	% V <	% V	Size (μm)	% V <	% V	Size (μm)	% V <	% V
0.117	0.00	0.00	2.51	21.72	7.31	54.12	100.00	0.00
0.136	0.00	0.00	2.93	30.62	8.91	63.10	100.00	0.00
0.158	0.00	0.00	3.41	40.81	10.19	73.56	100.00	0.00
0.185	0.00	0.00	3.98	51.76	10.94	85.77	100.00	0.00
0.215	0.00	0.00	4.64	62.76	11.01	100.00	100.00	0.00
0.251	0.00	0.00	5.41	73.09	10.33	116.59	100.00	0.00
0.293	0.00	0.00	6.31	82.07	8.97	135.94	100.00	0.00
0.341	0.00	0.00	7.36	89.22	7.15	158.49	100.00	0.00
0.398	0.00	0.00	8.58	94.35	5.13	184.79	100.00	0.00
0.464	0.00	0.00	10.00	97.59	3.24	215.44	100.00	0.00
0.541	0.00	0.00	11.66	99.28	1.69	251.19	100.00	0.00
0.631	0.00	0.00	13.59	99.92	0.64	292.87	100.00	0.00
0.736	0.00	0.00	15.85	100.00	0.08	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	0.17	0.17	21.54	100.00	0.00	464.16	100.00	0.00
1.17	0.85	0.67	25.12	100.00	0.00	541.17	100.00	0.00
1.36	2.30	1.46	29.29	100.00	0.00	630.96	100.00	0.00
1.58	4.86	2.55	34.15	100.00	0.00	735.64	100.00	0.00
1.85	8.81	3.96	39.81	100.00	0.00	857.70	100.00	0.00
2.15	14.41	5.59	46.42	100.00	0.00	1000.00	100.00	0.00

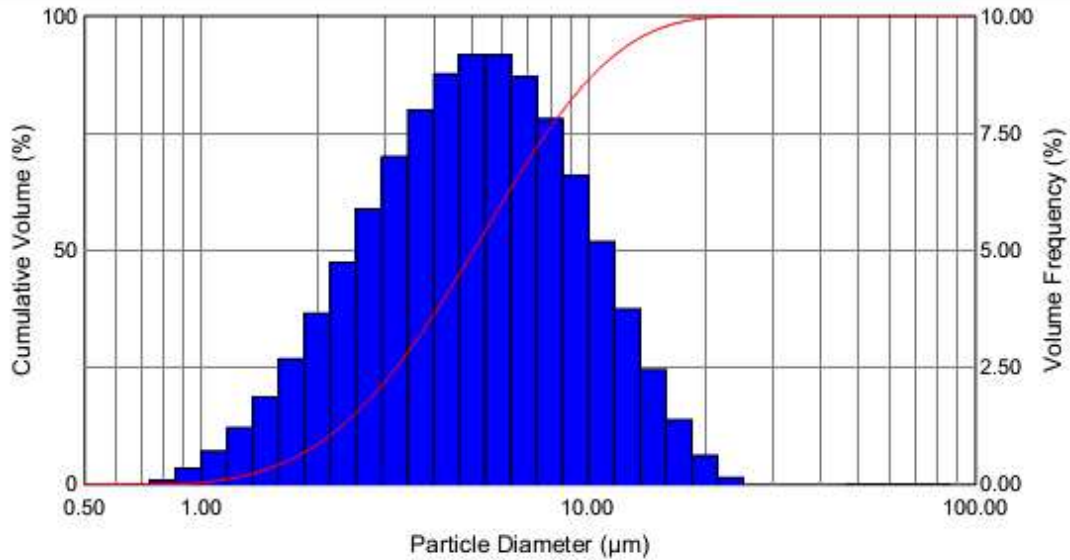
Fig 5. Sample 2 testing result (Valve fully open)

Average Particle Size Distribution
 (average size distribution, weighted)
 20141110.smeatExp 002 - 2014 Nov 10\Averages\N160_Closed_02 1 1.psd
 Sample : N160_Closed_01_02
 Start+12 (s) :: +1:30 (s)

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Standard Values:

Trans = 94.1 (%)	Dv(10) = 2.108 (µm)	Span = 1.773
Cv = 2.198 (PPM)	Dv(50) = 5.05 (µm)	D[3][2] = 4.02 (µm)
SSA = 1.492 (m ² /cc)	Dv(90) = 11.06 (µm)	D[4][3] = 5.958 (µm)



Size (µm)	% V <	% V	Size (µm)	% V <	% V	Size (µm)	% V <	% V
0.117	0.00	0.00	2.51	15.33	4.74	54.12	99.98	0.01
0.136	0.00	0.00	2.93	21.21	5.88	63.10	99.99	0.01
0.158	0.00	0.00	3.41	28.21	7.00	73.56	99.99	0.00
0.185	0.00	0.00	3.98	36.21	8.00	85.77	100.00	0.00
0.215	0.00	0.00	4.64	44.98	8.76	100.00	100.00	0.00
0.251	0.00	0.00	5.41	54.16	9.18	116.59	100.00	0.00
0.293	0.00	0.00	6.31	63.33	9.17	135.94	100.00	0.00
0.341	0.00	0.00	7.36	72.03	8.70	158.49	100.00	0.00
0.398	0.00	0.00	8.58	79.84	7.81	184.79	100.00	0.00
0.464	0.00	0.00	10.00	86.44	6.59	215.44	100.00	0.00
0.541	0.00	0.00	11.66	91.62	5.19	251.19	100.00	0.00
0.631	0.00	0.00	13.59	95.37	3.75	292.87	100.00	0.00
0.736	0.01	0.01	15.85	97.82	2.45	341.46	100.00	0.00
0.858	0.10	0.10	18.48	99.21	1.39	398.11	100.00	0.00
1.00	0.45	0.35	21.54	99.83	0.62	464.16	100.00	0.00
1.17	1.17	0.71	25.12	99.98	0.15	541.17	100.00	0.00
1.36	2.38	1.21	29.29	99.98	0.00	630.96	100.00	0.00
1.58	4.24	1.87	34.15	99.98	0.00	735.64	100.00	0.00
1.85	6.93	2.68	39.81	99.98	0.00	857.70	100.00	0.00
2.15	10.58	3.66	46.42	99.98	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 μ m

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

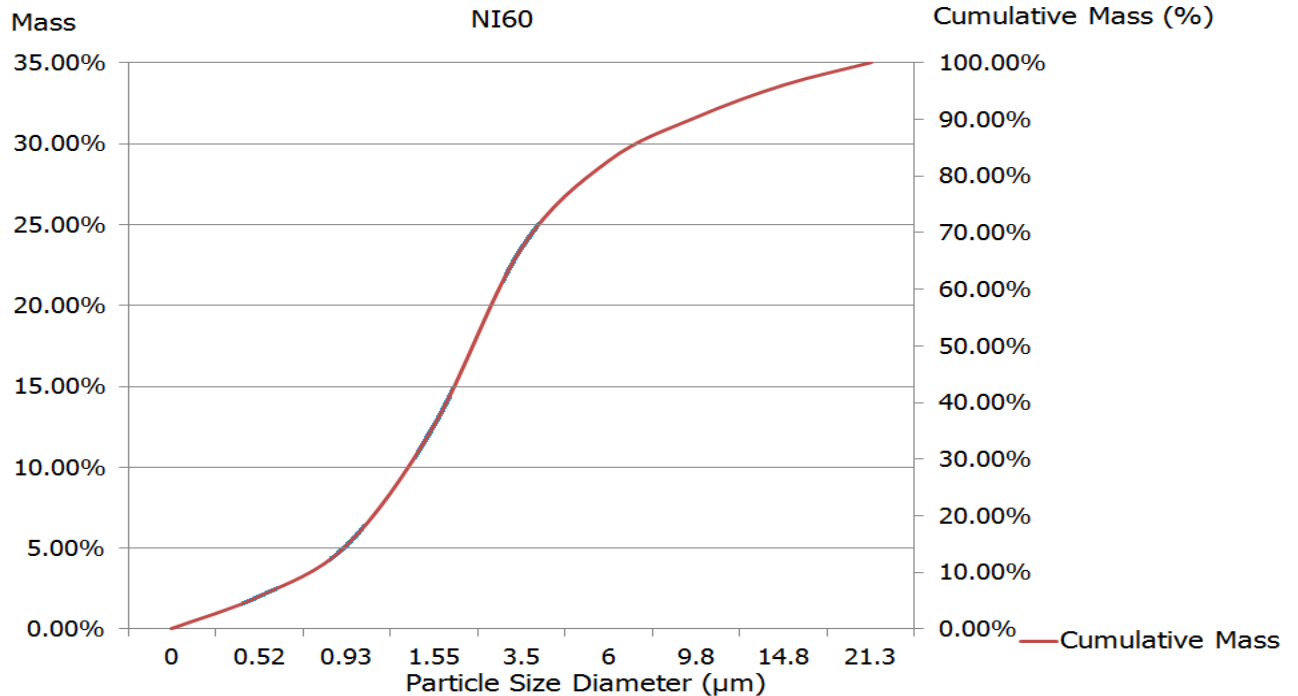


Fig 7. Aerodynamic particle size distribution

5.3 Nebulization Rate Testing(Including Drug Testings)

NI60	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, μ m	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	0.65	0.64	0.65

5.5 Reliability Test

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

