### 1.0 Object

1.1 To test the performance of Rossmax NC200 mesh nebulizer

### 2.0 Equipment List

- 2.1 Rossmax NC200 mesh nebulizer\*2
- 2.2 Malvern Spraytec particle size analyer
- 2.3 Marple 298 Cascade Impactor
- 2.4 Chroma 61602 Programmable AC Source
- 2.5 Shimadzu AUW120D microbalance
- 2.6 A.P. Buck, Inc. Libra Plus LP-5 sampling pump
- 2.7 Humidity/Temperature Meter
- 2.8 2.5% NaF solution
- 2.9 Taiwan Biotech Co., Ltd 0.9% Saline solution
- 2.10 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
- 3.4 Residual Volume Testing

### 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 nebulizer cup,
- 4.1.3 Connect nebulizer cup with NC200 and put at the testing site, nebulizer cup's outlet must be kept at 3.0 cm from laser beam.
- 4.1.4 Start recording Spraytec for more than 15 secs, then start NC200 for testing.
- 4.1.5 After 3.0 minutes have been reached, stop NC200 and then 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 nebulizer cup, measure its weight before and after testing.

- 4.2.3 Connect suction and sampling pumps to cascade impactor testing module as see in the Fig 2.
- 4.2.4 Put nebulizer cup into NC200 and connect its 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 NC200.(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, NC200 is switched off, followed a few seconds later by sampling pump and then suction pump.
- 4.2.8 Dismount cascaade impactor from testing module
- 4.2.9 Dismantle impactor and determine the amount of NaF solution on individual stage of the impactor, the input connection and the outlet filter.



Fig 2. Cascade Impactor and Testing setup

#### 4.3 Nebulization Rate Testing

- 4.3.1 Each sample should be tested with 3.0 ml 2.5% NaF solution for 3 minutes.
- 4.3.2 Add 3.0 ml 2.5% NaF solution into nebulizer cup, measure its weight before and after the testing.
- 4.3.3 Connect nebulizer cup with NC200 and then start NC200 for testing.
- 4.3.4 After 3.0 minutes have been reached, stop NC200
- 4.3.5 Calculates how many weights of the solution 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 nebulizer cup is empty.
- 4.4.2 Add 2.0ml 0.9% saline solution into nebulizer cup, measure its weight before and after testing.
- 4.4.3 Connect nebulizer cup with NC200 and then start NC200 for testing.
- 4.4.4 Shakes nebulizer one or two times during nebulizing if there has large droplet stick on the wall inside nebulizer cup.
- 4.4.5 After nebulizer cup is empty, stop NC200 and measure its mass of tested nebulizer cup
- 4.4.6 Calculates the Residual Volume

μ m	Testing times	Dv10	Dv50	Dv90	SMD	
Sample 1	1	2.106	5.365	11.700	3.796	
	2	2.091	5.179	11.250	3.806	Fig 3
	3	2.050	5.255	11.520	3.544	
	Mean	2.082	5.266	11.490	3.715	
	Std Dev	0.029	0.094	0.226	0.148	
	1	2.469	5.402	11.000	4.494	
	2	2.155	5.324	11.440	4.174	Fig 4
Sample 2	3	2.167	5.517	11.960	4.257	
	Mean	2.264	5.414	11.467	4.308	
	Std Dev	0.178	0.097	0.481	0.166	

5.0 Testing Results 5.1 Aerosol Particle Size Distribution Testing(By Malvern Spraytec)

### Average Particle Size Distribution

(average size distribution, weighted) 20210712.smea\Exp 001 - 2021 Jul 13\Averages\NC200 1 1.psd Sample : NC200 Start+7 (s) :: +2:59 (s)

#### Standard Values:



% V <	% V	Size (µm)	% V <	% V	Size (µm)	% V <	
0.01	0.01	2.51	15.17	4.44	54.12	100.00	ан. С
0.03	0.02	2.93	20.71	5.54	63.10	100.00	
0.05	0.03	3.41	27.37	6.65	73.56	100.00	
0.09	0.03	3.98	35.06	7.69	85.77	100.00	
0.12	0.04	4.64	43.58	8.52	100.00	100.00	
0.17	0.04	5.41	52.62	9.04	116.59	100.00	
0.22	0.05	6.31	61.79	9.16	135.94	100.00	
0.27	0.05	7.36	70.63	8.84	158.49	100.00	
0.32	0.05	8 58	78 69	8 07	184 79	100 00	
	% V    0.01 0.03   0.05 0.09   0.12 0.17   0.22 0.27   0.32 0.32	% V < % V   0.01 0.01   0.03 0.02   0.05 0.03   0.09 0.03   0.12 0.04   0.22 0.05   0.22 0.05   0.22 0.05   0.27 0.05   0.32 0.05	% V  % V Size (µm)   0.01 0.01 2.51   0.03 0.02 2.93   0.05 0.03 3.41   0.09 0.03 3.98   0.12 0.04 4.64   0.17 0.04 5.41   0.22 0.05 6.31   0.27 0.05 7.36   0.32 0.05 8.58	% V % V Size (µm) % V <   0.01 0.01 2.51 15.17   0.03 0.02 2.93 20.71   0.05 0.03 3.41 27.37   0.09 0.03 3.98 35.06   0.12 0.04 4.64 43.58   0.17 0.04 5.41 52.62   0.22 0.05 6.31 61.79   0.27 0.05 7.36 70.63   0.32 0.05 8.58 78.69   Fig 3 Sample 1 tecting	% V $%$ V Size (µm) $%$ V $%$ V   0.01 0.01 2.51 15.17 4.44   0.03 0.02 2.93 20.71 5.54   0.05 0.03 3.41 27.37 6.65   0.09 0.03 3.98 35.06 7.69   0.12 0.04 4.64 43.58 8.52   0.17 0.04 5.41 52.62 9.04   0.22 0.05 6.31 61.79 9.16   0.27 0.05 7.36 70.63 8.84   0.32 0.05 8.58 7.869 8.07   Fig 3 Sample 1 testing result	% V $%$ V Size (µm) $%$ V $%$ V Size (µm)   0.01 0.01 2.51 15.17 4.44 54.12   0.03 0.02 2.93 20.71 5.54 63.10   0.05 0.03 3.41 27.37 6.65 73.56   0.09 0.03 3.98 35.06 7.69 85.77   0.12 0.04 4.64 43.58 8.52 100.00   0.17 0.04 5.41 52.62 9.04 116.59   0.22 0.05 6.31 61.79 9.16 135.94   0.27 0.05 7.36 70.63 8.84 158.49   0.32 0.05 8.58 7.869 8.07 184.79	% V  % V Size (µm) % V  Size (µm) % V    0.01 0.01 2.51 15.17 4.44 54.12 100.00   0.03 0.02 2.93 20.71 5.54 63.10 100.00   0.05 0.03 3.41 27.37 6.65 73.56 100.00   0.09 0.03 3.98 35.06 7.69 85.77 100.00   0.12 0.04 4.64 43.58 8.52 100.00 100.00   0.17 0.04 5.41 52.62 9.04 116.59 100.00   0.22 0.05 6.31 61.79 9.16 135.94 100.00   0.27 0.05 7.36 70.63 8.84 158.49 100.00   0.32 0.05 8.58 7.869 8.07 184.79 100.00

Fig 3. Sample 1 testing result

### Average Particle Size Distribution (average size distribution, weighted) 20210712.smea\Exp 001 - 2021 Jul 13\Averages\NC200\_2 1 1.psd Sample : NC200\_2

Start+7:46 (s) :: +9:55 (s)

### Standard Values: Trans = 58.9 (%) Dv(10) = 2.155 (µm) Span = 1.745 Cv = 19.87 (PPM) SSA = 1.438 (m<sup>2</sup>/cc) D[3][2] = 4.174 (μm) D[4][3] = 6.179 (μm) Dv(50) = 5.324 (µm) $Dv(90) = 11.44 (\mu m)$ 100 Cumulative Volume (%) 50 0 0.50 1.00 10.00 Particle Diameter (µm)

% V <	% V	Size (µm)	% V <	% V	Size (µm)	% V <
0.00	0.00	2.51	14.33	4.34	54.12	100.00
0.00	0.00	2.93	19.70	5.37	63.10	100.00
0.00	0.00	3.41	26.14	6.44	73.56	100.00
0.00	0.00	3.98	33.61	7.47	85.77	100.00
0.00	0.00	4.64	41.98	8.37	100.00	100.00
0.00	0.00	5.41	50.98	9.00	116.59	100.00
0.00	0.00	6.31	60.22	9.24	135.94	100.00
0.00	0.00	7.36	69.25	9.03	158.49	100.00
0.00	0.00	8.58	77.59	8.34	184.79	100.00
	% V < 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.	% V < % V   0.00 0.00   0.00 0.00   0.00 0.00   0.00 0.00   0.00 0.00   0.00 0.00   0.00 0.00   0.00 0.00   0.00 0.00   0.00 0.00   0.00 0.00   0.00 0.00   0.00 0.00	% V < % V Size (µm)   0.00 0.00 2.51   0.00 0.00 2.93   0.00 0.00 3.41   0.00 0.00 3.98   0.00 0.00 4.64   0.00 0.00 5.41   0.00 0.00 6.31   0.00 0.00 8.58	% V < % V Size (µm) % V <   0.00 0.00 2.51 14.33   0.00 0.00 2.93 19.70   0.00 0.00 3.41 26.14   0.00 0.00 3.98 33.61   0.00 0.00 4.64 41.98   0.00 0.00 5.41 50.98   0.00 0.00 6.31 60.22   0.00 0.00 7.36 69.25   0.00 0.00 8.58 77.59	% V < % V Size (µm) % V < % V   0.00 0.00 2.51 14.33 4.34   0.00 0.00 2.93 19.70 5.37   0.00 0.00 3.41 26.14 6.44   0.00 0.00 3.98 33.61 7.47   0.00 0.00 4.64 41.98 8.37   0.00 0.00 5.41 50.98 9.00   0.00 0.00 6.31 60.22 9.24   0.00 0.00 7.36 69.25 9.03   0.00 0.00 8.58 77.59 8.34	% V < % V Size (µm) % V < % V Size (µm)   0.00 0.00 2.51 14.33 4.34 54.12   0.00 0.00 2.93 19.70 5.37 63.10   0.00 0.00 3.41 26.14 6.44 73.56   0.00 0.00 3.98 33.61 7.47 85.77   0.00 0.00 4.64 41.98 8.37 100.00   0.00 0.00 5.41 50.98 9.00 116.59   0.00 0.00 6.31 60.22 9.24 135.94   0.00 0.00 7.36 69.25 9.03 158.49   0.00 0.00 8.58 77.59 8.34 184.79

Fig 4. Sample 1 testing result

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

Tested with 2.5% NaF solution MMAD= $3.051 \,\mu$  m FPD(Fine Particle Dose)=76.57%(particle size less than  $5.0 \,\mu$  m)



#### 5.3 Nebulization Rate Testing

2.5% NaF solution	Sample 1	Sample 2
ml/min	0.383	0.349

#### 5.4 Residual Volume Testing

0.9% Saline	Sample 1	Sample 2
Residual Volume (ml)	0.08	0.07