

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 analyzer
- 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

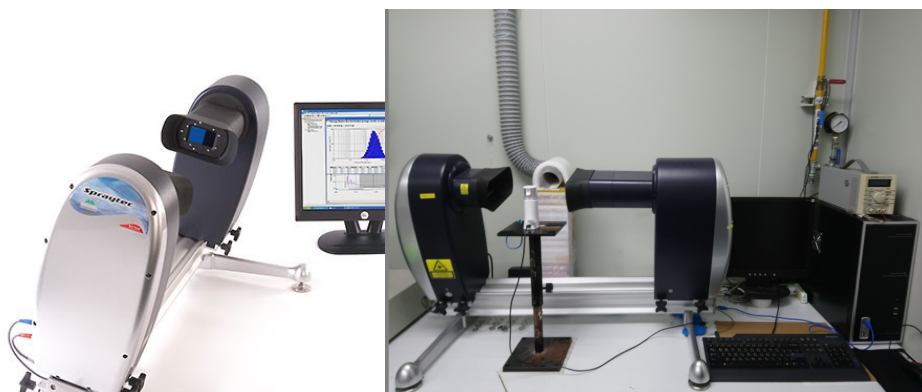


Fig 1. Malvern Spraytec and Testing site

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 cascade 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.

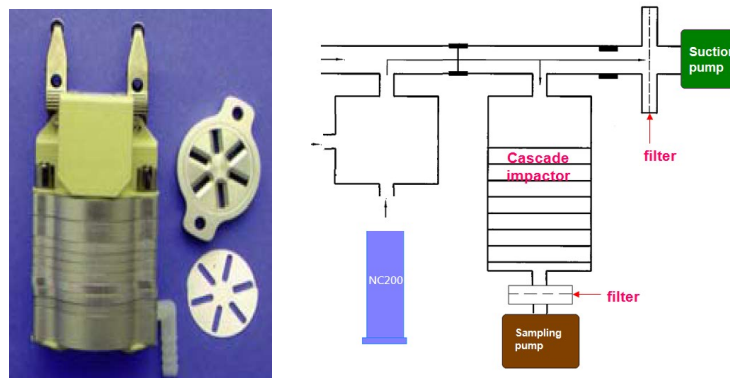


Fig 2. Cascade Impactor and Testing setup

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

5.0 Testing Results

5.1 Aerosol Particle Size Distribution Testing(By Malvern Spraytec)

| 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 | |
| Sample 2 | 1 | 2.469 | 5.402 | 11.000 | 4.494 | |
| | 2 | 2.155 | 5.324 | 11.440 | 4.174 | Fig 4 |
| | 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 | |

Average Particle Size Distribution

(average size distribution, weighted)

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Sample : NC200

Start+7 (s) :: +2:59 (s)

Standard Values:

Trans = 58.4 (%)

Cv = 19.54 (PPM)

SSA = 1.576 (m²/cc)

Dv(10) = 2.091 (μm)

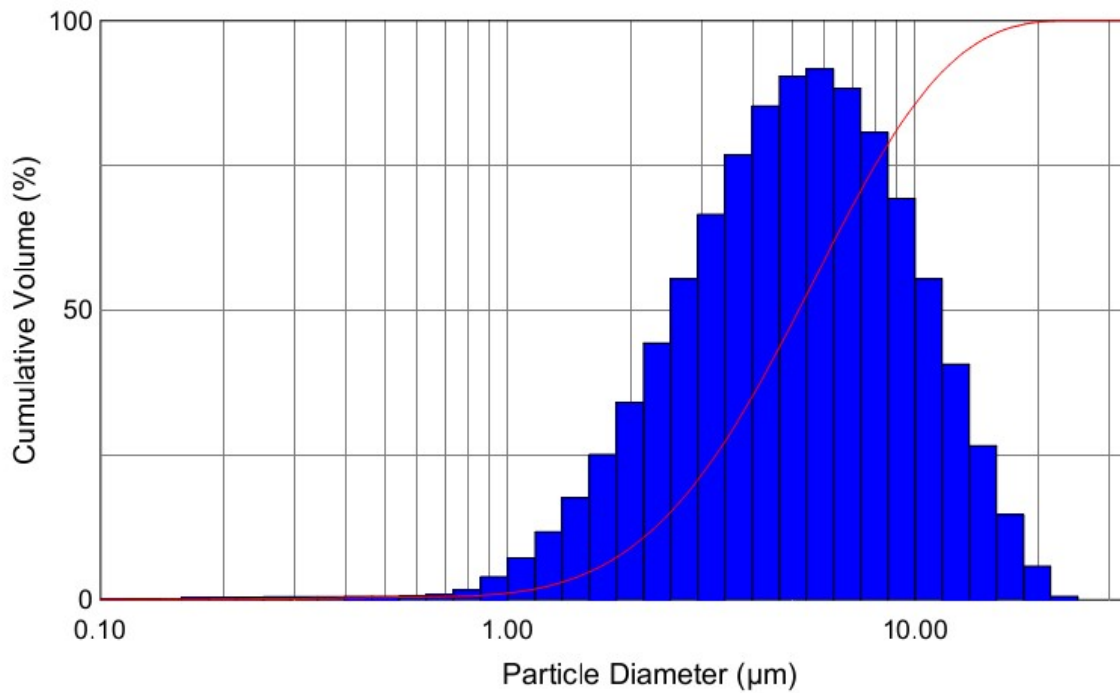
Dv(50) = 5.179 (μm)

Dv(90) = 11.25 (μm)

Span = 1.768

D[3][2] = 3.806 (μm)

D[4][3] = 6.035 (μm)



| Size (μm) | % V < | % V | Size (μm) | % V < | % V | Size (μm) | % V < |
|-----------|-------|------|-----------|-------|------|-----------|--------|
| 0.117 | 0.01 | 0.01 | 2.51 | 15.17 | 4.44 | 54.12 | 100.00 |
| 0.136 | 0.03 | 0.02 | 2.93 | 20.71 | 5.54 | 63.10 | 100.00 |
| 0.158 | 0.05 | 0.03 | 3.41 | 27.37 | 6.65 | 73.56 | 100.00 |
| 0.185 | 0.09 | 0.03 | 3.98 | 35.06 | 7.69 | 85.77 | 100.00 |
| 0.215 | 0.12 | 0.04 | 4.64 | 43.58 | 8.52 | 100.00 | 100.00 |
| 0.251 | 0.17 | 0.04 | 5.41 | 52.62 | 9.04 | 116.59 | 100.00 |
| 0.293 | 0.22 | 0.05 | 6.31 | 61.79 | 9.16 | 135.94 | 100.00 |
| 0.341 | 0.27 | 0.05 | 7.36 | 70.63 | 8.84 | 158.49 | 100.00 |
| 0.398 | 0.32 | 0.05 | 8.58 | 78.69 | 8.07 | 184.79 | 100.00 |

Fig 3. Sample 1 testing result

Average Particle Size Distribution

(average size distribution, weighted)

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Sample : NC200_2

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

Standard Values:

Trans = 58.9 (%)

Cv = 19.87 (PPM)

SSA = 1.438 (m²/cc)

Dv(10) = 2.155 (μm)

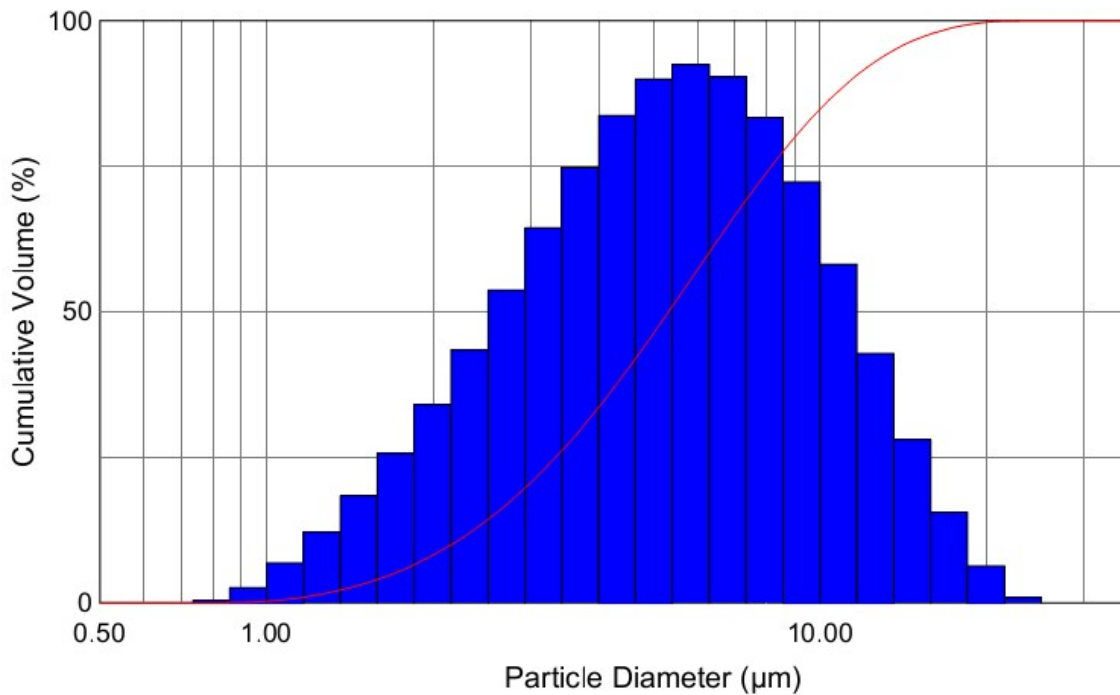
Dv(50) = 5.324 (μm)

Dv(90) = 11.44 (μm)

Span = 1.745

D[3][2] = 4.174 (μm)

D[4][3] = 6.179 (μm)



| Size (μm) | % V < | % V | Size (μm) | % V < | % V | Size (μm) | % V < |
|-----------|-------|------|-----------|-------|------|-----------|--------|
| 0.117 | 0.00 | 0.00 | 2.51 | 14.33 | 4.34 | 54.12 | 100.00 |
| 0.136 | 0.00 | 0.00 | 2.93 | 19.70 | 5.37 | 63.10 | 100.00 |
| 0.158 | 0.00 | 0.00 | 3.41 | 26.14 | 6.44 | 73.56 | 100.00 |
| 0.185 | 0.00 | 0.00 | 3.98 | 33.61 | 7.47 | 85.77 | 100.00 |
| 0.215 | 0.00 | 0.00 | 4.64 | 41.98 | 8.37 | 100.00 | 100.00 |
| 0.251 | 0.00 | 0.00 | 5.41 | 50.98 | 9.00 | 116.59 | 100.00 |
| 0.293 | 0.00 | 0.00 | 6.31 | 60.22 | 9.24 | 135.94 | 100.00 |
| 0.341 | 0.00 | 0.00 | 7.36 | 69.25 | 9.03 | 158.49 | 100.00 |
| 0.398 | 0.00 | 0.00 | 8.58 | 77.59 | 8.34 | 184.79 | 100.00 |

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 μ m

FPD(Fine Particle Dose)=76.57%(particle size less than 5.0 μ m)

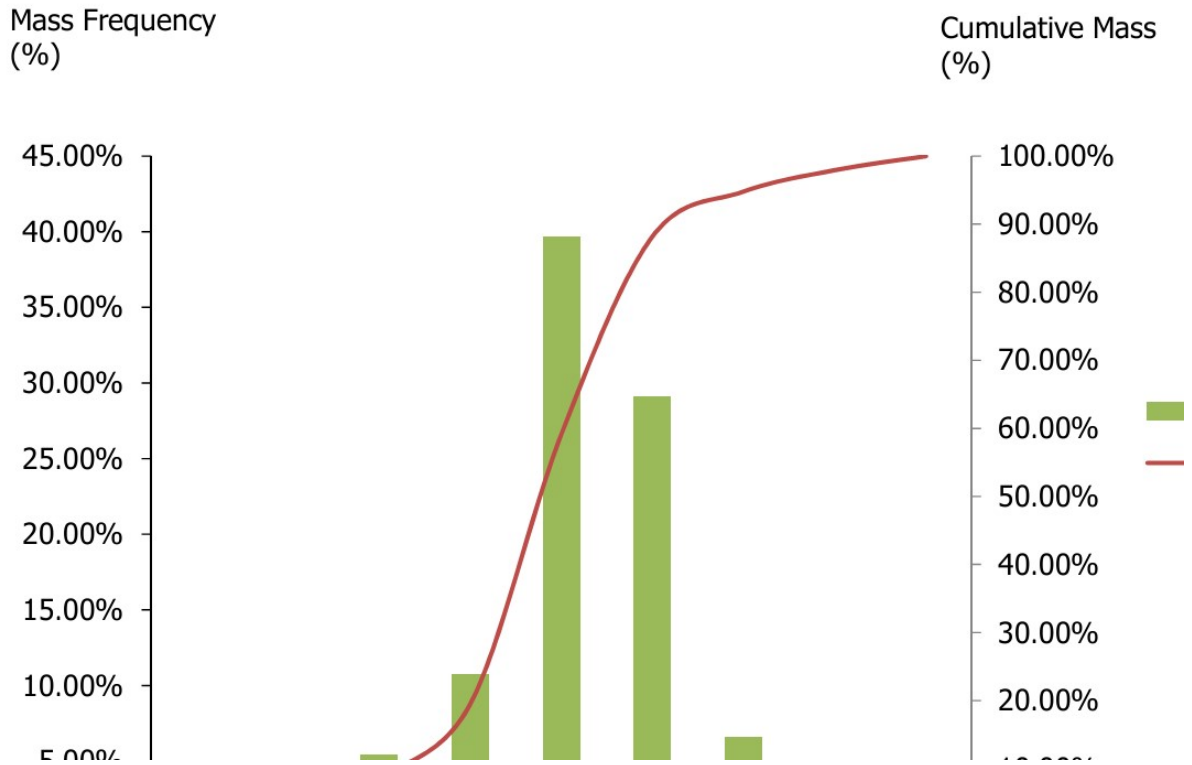


Fig 5. Aerodynamic particle size distribution

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 |