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Significance of electromagnetic sieve shaker for particle size distribution analysis of Celphere[®] grades

Sieve analysis is an important test for pharma excipients due to the need of high degree of efficiency, accuracy and repeatability. **Archana Pokkalath**, Research Associate, Electrolab India; **Aditya Marfatia**, Director and Co-founder, Electrolab India and **Dr Heeshma Shah**, Director ... Technical Services, Signet Excipients, explain more

Sieve analysis of sample has application in separation and size determination of granular and fine particles. It is an important test for pharma excipients due to the need of high degree of efficiency, accuracy and repeatability. There are three main types of sieve shakers:

Mechanical sieve shakers: Mechanical sieve shakers employ motor-driven system to agitate and reorient particles with orbital, circular, rotational or tapping motions for particle size distribution analysis.

Electromagnetic/vibratory sieve shakers: Vibratory sieve shakers use quiet electromagnetic energy to agitate particles. A proper vibration setting creates a tri-dimensional sifting motion allowing maximum particles to pass through the sieve openings.

Sonic sieve shakers: Sonic sifters are machines that use sonic energy pulses per minute creating an oscillating air column that provides continuous agitation for lifting the particles and reorienting them to the mesh surfaces.

Significance of electromagnetic/vibratory sieve shakers

The particle distribution analysis from the mechanical sieve shakers (e.g. RO-TAP RX-29/RX-30) is an approved method for particle size analysis of variety of powders including the Celphere grades. However, there are certain limitations to the RO-TAP mechanical sieve shakers like the higher operating noise levels of approximately 85 dB generated during test, especially due to the tapping motion. With the sound enclosure cabinets, the noise



Archana Pokkalath



Aditya Marfatia



Heeshma Shah

Grade	CP-102	CP-203	CP-305	CP-507	CP-708
Sieve openings					
Top	212 µm	300 µm	500 µm	710 µm	850 µm
Middle	-	150 µm	300 µm	500 µm	710 µm
Bottom	106 µm	106 µm	106 µm	106 µm	106 µm

levels can be reduced to 78 dB, but this can lead to increase in the footprint of the entire unit.

As an alternative to the conventional mechanical sieve shakers, the analyst can opt for other types of sieve shakers like the vibratory and sonic sieve shakers. One of the benefits of these sieve shakers is that they are not as loud as the mechanical units. The vibratory sieve shakers use a vibrating motion to shake particles down through the stack of test sieves instead of the tapping and gears on the mechanical units. The vibratory sieve shaker - EMS-08 instrument operate at the noise level of less than 71 dB with sieves and material at maximum amplitude. Additionally, in the vibrational and the sonic sieve shakers, the user can vary the amplitude and frequency



Fig 1: RO-TAP (RX-29)



Fig 2: EMS-08

The particle size distribution analysis from the vibratory sieve shakers can be an effective alternative to mechanical sieve shakers with the added advantage of reduced noise levels during process that complies with the GLP requirements

/intensity adjustments making it useful for materials that may not readily be separated from other sieve shakers. Due to less moving parts, the vibratory sieve shakers require less maintenance than the mechanical units. In this study, we have performed sieve analysis of various grades of Celphere® using the vibratory sieve shaker- EMS-08.

Materials and method:

a. Materials:

Samples: Celphere® CP-102, Celphere® CP-203, Celphere® CP-305, Celphere® CP-507, Celphere® CP-708, Signet Excipients

Instrument: EMS-08, Electrolab

b. Method:

Celphere® sphere size test

1. Assemble the sieves in accordance with the below table. Set a well-fitting collecting pan on the bottom and a lid on top of the sieves.

2. Place exactly 10 g of Celphere samples, microcrystalline cellulose spheres, on the top sieve, and replace the lid.

3. Agitate the sieves for

RESULTS:

◆ Celphere® CP-102:

Sr. No	Sieve Size (μ)	Sphere size (%)	Limits (%)
1.	106 μ on 212 μ pass	97.7	NLT 87.5
2.	212 μ on	2	NMT 7.5

◆ Celphere® CP-203

Sr. No	Sieve Size (μ)	Sphere size (%)	Limits (%)
1.	150 μ on 300 μ pass	98.40	NLT 88.0
2.	300 μ on	1.40	NMT 8.5
3.	150 μ pass	0.20	NMT 3.5

◆ Celphere® CP-305

Sr. No	Sieve Size (μ)	Sphere size (%)	Limits (%)
1.	300 μ on 500 μ pass	98.90	NLT 88.0
2.	500 μ on	0.50	NMT 7
3.	300 μ pass	0.60	NMT 5

◆ Celphere® CP-507

Sr. No	Sieve Size (μ)	Sphere size (%)	Limits (%)
1.	500 μ on 710 μ pass	95.10	NLT 75
2.	710 μ on	1.70	NMT 10
3.	500 μ pass	3.20	NMT 15

◆ Celphere® CP-708

Sr. No	Sieve Size (μ)	Sphere size (%)	Limits (%)
1.	710 μ on 850 μ pass	90.51	NLT 75
2.	850 μ on	3.40	NMT 5
3.	710 μ pass	6.09	NMT 20
4.	500 μ pass	0.00	NMT 1

five minutes (at 20 mm amplitude and 67 taps per minute)

4. Then remove the material on each sieve without loss and weigh

5. Calculate the sphere size (wt. %) by the formula:

◆ (Middle sieve opening) on (top sieve opening) pass = 100 - [(top sieve opening) on (wt. %) + (middle sieve opening) pass (wt. %)]

◆ (Top sieve opening) on = on

the top sieve (g) × 10

◆ (Middle sieve opening) pass = [on the bottom sieve (g) + on the collecting pan (g)] × 10

◆ (Bottom sieve opening) pass = on the collecting pan (g) × 10

Conclusions:

The results obtained from the vibratory sieve shaker (EMS-08) for Celphere grades were within the limits of the exist-

ing RO-TAP criteria for Celphere grades. This suggests that electromagnetic/vibratory sieve shakers can be used as an alternative to RO-TAP mechanical sieve shakers with added advantage of effective performance in reduced noise levels that complies with the GLP requirements.

References:

◆ Backus, Ben, An Expert

Guide to Selecting a Sieve Shaker, <https://www.globalgilson.com/blog/an-expert-guide-to-selecting-a-sieve-shake>

◆ Clyde, Weslee, *What Is a RO-TAP® Sieve Shaker? (Definition, Types, and Calibration + Video)*, April 17th, 2019, <https://blog.wstyler.com/particle-analysis/what-is-a-ro-tap-sieve-shaker>

Balancing profitability with sustainability

Sunil Roy Wadhwa, Head, API Manufacturing ... API Unit 9, Viatriis, spoke on a very pertinent topic, 'Balancing profitability with sustainability.' As a senior pharma professional and leader with proven success driving start-ups, transformation, and turnaround initiatives, he drew from his immense experience and expertise to share insights on development of cutting-edge business practices and manufacturing processes to deliver innovative pharma products across multiple disease areas. He was emphatic that today, profitability is not enough. A business operation must be sustainably



Sunil Roy Wadhwa, Head, API Manufacturing ... API Unit 9, Viatriis

profitable to provide some assurance that the profits will continue to accrue tomorrow. He also explained that sustainable profitability means profits are reasonably expected to be maintained at the same or higher level in the future.

Pointing out that governments at local and national level are supporting environmentally friendly businesses with incentives, he outlined key functional areas which needed more focus, to balance profitability with sustainability such as:


- ◆ Aiming at RFT (Quality and Quantity)
- ◆ Cost reduction (Recycling,

Overheads, etc.,)

- ◆ Backward integration (Availability and Dependency)
- ◆ Two-way communication (Supply Chain Management and Logistics)
- ◆ Welfare (Employee and Environment)

He urged the industry to adopt a more strategic and holistic approach for sustainability supported through measures like digitalisation, cost optimisation and collaboration.

A vital message from his address was, "Don't see healthcare as it is, but as it should be. Act courageously, uniquely and target to be a source of stability."



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