## Suglets ${ }^{\circledR}$ PF010 Sugar Spheres

Best-in-class drug layering substrates. Suglets are available as multiple sizes; PF010 grade (particle size range of 710-850 microns or 20/25 mesh).

## Meeting Pharmacopoeia Specifications: More Than Monograph

Suglets meet all specifications listed in the Sugar Spheres USP-NF and Ph. Eur. monographs.

| NF <br> Specification | Limits | Historical Avg <br> (n=145 lots) | Standard <br> Deviation |
| :---: | :---: | :---: | :---: |
| Sucrose (\%) | $62.5-91.5$ | 84.5 | 1.9 |
| LOD (\%) | $<4$ | 1.6 | 0.3 |
| \#20 Mesh <br> (\% retained) | $0-10$ | 3.8 | 1.3 |
| \#25 Mesh <br> (\% retained) | $90-100$ | 94.0 | 1.4 |
| \#25 Mesh <br> Max.\% thru) | $0-10$ | 2.2 | 1.2 |

Monograph data for sugar sphere, size $710-850 \mu \mathrm{~m}$ and historic average results for Colorcon Suglet, size 710-850 $\mu \mathrm{m}$. Standard deviation demonstrates tight control over our process capabilities.

| More Than Monograph |
| :---: |
| Median Particle Size |
| Sphericity |
| Friability |

Three key attributes have been established as internal quality parameters by Colorcon for product produced at Stoughton, USA and Bazanville, FR facilities: Particle Size, Sphericity and Friability.

## More Than Monograph: Impact of Median Particle Size

Using Camsizer for more advanced particle analysis - shape and size


For a perfect sphere, the sphericity ratio of $4 \pi A / P^{2}=1.0$

$A=$ area and $P=$ perimeter of two-dimensional cross-section of an imaged sphere.
Sphericity of Suglet PF 010 is maintained at an internal production target of $>0.94$, indicating an extremely high degree of sphericity.


- Smooth, spherical
- Reproducible release profile
- Batch to batch consistency
- Reduced loss in production


## More Than Monograph: Impact of Friability

Demonstrates robustness and rigidity of spheres under production conditions.


## SUGLETS ${ }^{\circledR}$

For more information, contact your Colorcon representative or call:

| North America | Europe/Middle East/Africa | Asia Pacific | Latin America |
| :--- | :--- | :--- | :--- |
| $\mathbf{+ 1 - 2 1 5 - 6 9 9 - 7 7 3 3}$ | $\mathbf{+ 4 4 - ( 0 ) - 1 3 2 2 - 2 9 3 0 0 0}$ | $\mathbf{+ 6 5 - 6 4 3 8 - 0 3 1 8}$ | $\mathbf{+ 5 4 - 1 1 - 5 5 5 6 - 7 7 0 0}$ |

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