

## Suglets® 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 Specification	Limits	Historical Avg (n=145 lots)	Standard Deviation
Sucrose (%)	62.5 – 91.5	84.5	1.9
LOD (%)	< 4	1.6	0.3
#20 Mesh (% retained)	0 – 10	3.8	1.3
#25 Mesh (% retained)	90 – 100	94.0	1.4
#25 Mesh (Max.% thru)	0 – 10	2.2	1.2

More Than Monograph
<b>Median Particle Size</b>
<b>Sphericity</b>
<b>Friability</b>

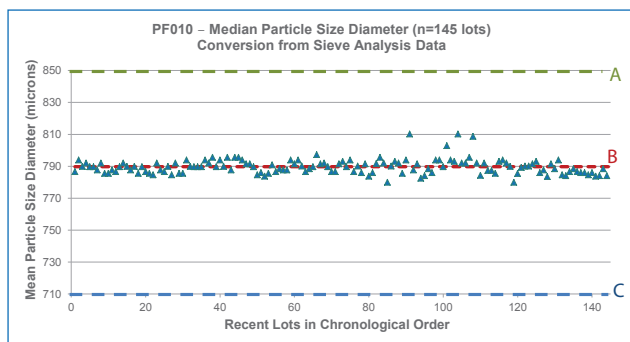
Monograph data for sugar sphere, size 710-850 µm and historic average results for Colorcon Suglet, size 710-850 µm. Standard deviation demonstrates tight control over our process capabilities.

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.

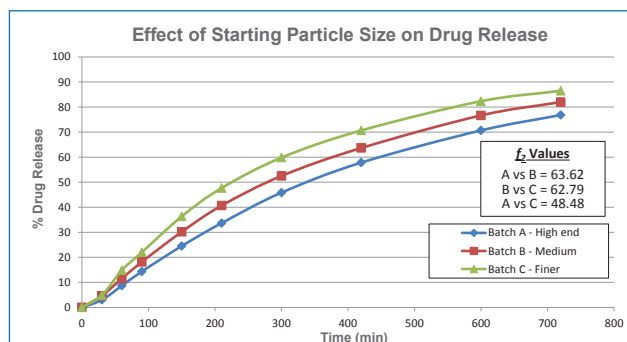
### More Than Monograph: *Impact of Median Particle Size*

Using Camsizer for more advanced particle analysis - shape and size

#### Consistency of Particle Size (710-850 µm)



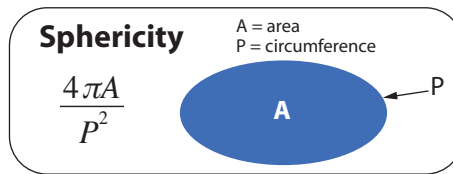
#### Impact on Drug Delivery



Shift in particle size can create an undesirable drug release profile.

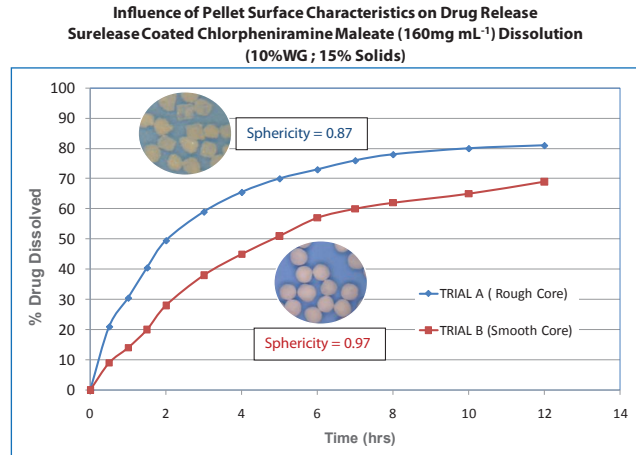
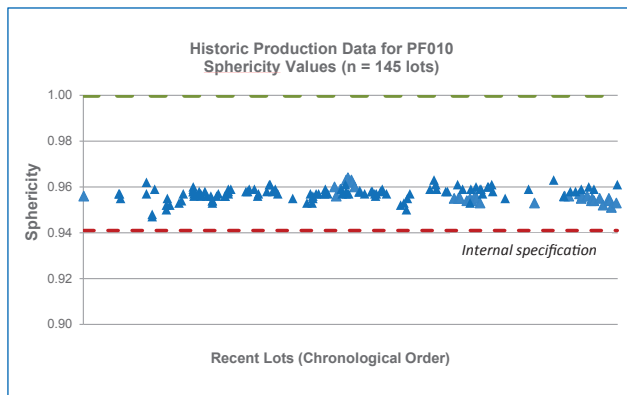
## More Than Monograph: *Impact of Sphericity*

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.

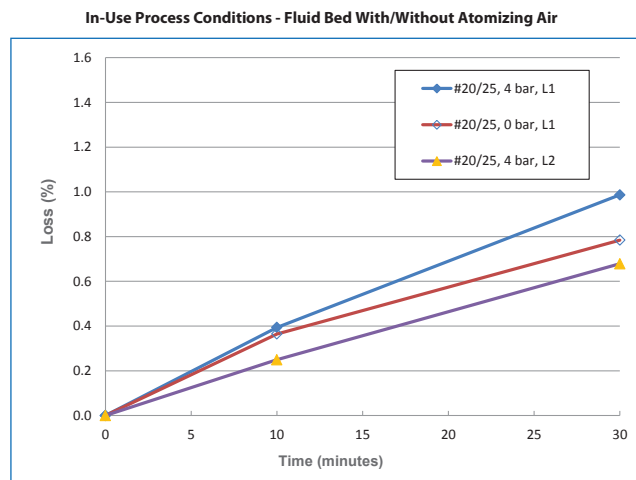
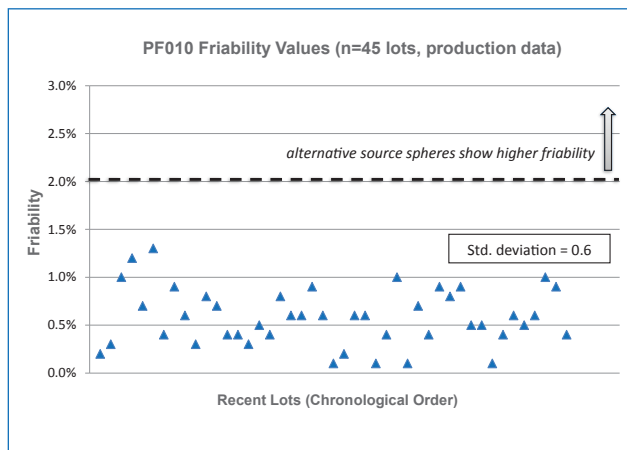
Sphericity of Suglet PF 010 is maintained at an internal production target of > 0.94, indicating an extremely high degree of sphericity.



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

## More Than Monograph: *Impact of Friability*

Demonstrates robustness and rigidity of spheres under production conditions.



**SUGLETS®**

For more information, contact your Colorcon representative or call:

North America +1-215-699-7733 Europe/Middle East/Africa +44-(0)-1322-293000 Asia Pacific +65-6438-0318 Latin America +54-11-5556-7700

You can also visit our website at [www.colorcon.com](http://www.colorcon.com)

**Colorcon®**

©BPSI Holdings LLC, 2013. The information contained in this document is proprietary to Colorcon and may not be used or disseminated inappropriately.

All trademarks, except where noted, are property of BPSI Holdings LLC.

TB\_Suglets\_V2\_1113