

## Product Specifications

Mod. P09 REV 3 aggiornato al 20/11/2014

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<b>Product name:</b>	Sugar spheres <b>size 35-40</b>
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<b>Reference:</b>	USP – NF monograph sugar spheres, current Ed. PH EUR Current Ed.
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Chemical properties	
<b>Composition:</b>	Sucrose EP grade            62,5 – 91,5% Maize starch EP grade    8,5 – 37,5%
<b>Loss on drying:</b>	Not More Than 4%
<b>Heavy metals:</b>	< 5ppm
<b>Friability:</b>	Not more than 5%
<b>Specific Rotation:</b>	Not Less Than +41° and Not More Than +61°
<b>Residual of Ignition:</b>	Not More Than 0,25% w/w

Physical properties	
<b>Solubility in water:</b>	Varies according to the sugar- to - maize starch ratio
<b>Shape:</b>	Uniform, spherical seeds
<b>Color:</b>	White / Off white
<b>Odour:</b>	Neutral
<b>Particle size range:</b>	Not Less Than 100% passes through #30 (600µm) Not Less Than 90% passes through #35 (500µm) Not More Than 10% passes through #40 (425µm)
<b>Shelf life:</b>	36 months (with correct preservation)
<b>Description:</b>	Hard, brittle, free-flowing, spherical masses. Usually white, but may be coloured.

Microbiological properties	
<b>Total aerobic microbial count:</b>	Not More Than 10 <sup>2</sup> cfu: maximum acceptable count = 200
<b>Salmonella:</b>	Absent
<b>Escherichia coli:</b>	Absent
<b>Staphylococcus aureus:</b>	Absent
<b>Pseudomonas aeruginosa:</b>	Absent

prepared by: (Fabrizio Castelli)

Signature \_\_\_\_\_

Date \_\_\_\_\_

for acceptance:

Signature and Company Stamp

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Date \_\_\_\_\_