

Product Specifications

Mod. P09 REV 3 aggiornato al 20/06/2016

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Product name:	Sugar spheres size 45-60
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Reference:	USP – NF monograph sugar spheres, current ed. EP current ed.
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Chemical properties	
Composition:	Sucrose EP grade 62,5 – 91,5% (USP) Maize starch EP grade 8,5 – 37,5% (USP)
Loss on drying:	Not More Than 4% (USP)
Heavy metals:	< 5ppm (EP)
Friability:	Not more than 5%
Specific Rotation:	Not Less Than +41° and Not More Than +61° (USP)
Residual of Ignition:	Not More Than 0,20% w/w (Emilio Castelli limit)

Physical properties	
Solubility in water:	Varies according to the sugar-to-maize starch ratio
Shape:	Uniform, spherical seeds
Color:	White / Off white
Odour:	Neutral
Particle size range:	Not Less Than 100% passes through #40 (425µm)
<input type="checkbox"/> ASTM	Not Less Than 90% passes through #45 (355µm)
<input type="checkbox"/> ISO	Not More Than 10% passes through #60 (250µm)
Shelf life:	36 months (with correct preservation)
Description:	Hard, brittle, free-flowing, spherical masses. Usually white, but may be coloured.

Microbiological properties	
Total aerobic microbial count:	Not More Than 10 ² cfu: maximum acceptable count = 200 (USP)
Total yeast and moulds count:	Not More Than 10 ¹ cfu: maximum acceptable count = 20 (USP)
Salmonella:	Absent 10/g (USP – EP)
Escherichia coli:	Absent 1/g (USP – EP)
Staphylococcus aureus:	Absent 1/g (USP – EP)
Pseudomonas aeruginosa:	Absent 1/g (USP – EP)

Specs updated on: 08/07/2016

prepared by: QC
Signature _____

Date _____

for acceptance:
Signature and Company Stamp

Date _____