

Product Specifications

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

Pag. 1 di 1

Product name:	Sugar spheres size 35-45
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Reference:	USP – NF monograph sugar spheres, current Ed. PH EUR Current Ed.
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Chemical properties	
Composition:	Sucrose EP grade 62,5 – 91,5% Maize starch EP grade 8,5 – 37,5%
Loss on drying:	Not More Than 4%
Heavy metals:	< 5ppm
Friability:	Not more than 5%
Specific Rotation:	Not Less Than +41° and Not More Than +61°
Residual of Ignition:	Not More Than 0,25% w/w

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 #30 (600µm) Not Less Than 90% passes through #35 (500µm) Not More Than 10% passes through #45 (355µm)
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
Salmonella:	Absent
Escherichia coli:	Absent
Staphylococcus aureus:	Absent
Pseudomonas aeruginosa:	Absent

prepared by: (Fabrizio Castelli)

Signature _____

Date _____

for acceptance:

Signature and Company Stamp

Date _____