

ANALYTICAL REPORT N°013/25-30

To: CLIENT

Order Number PO1010101		Net Weight 1500 Kg	
PRODUCT: Sugar Spheres		Batch Number: 18FE17	
SIZE: 25/30 (600-710)		Raw materials batch: S437;A324	
Characteristics	Acceptance Criteria	Results	Test Reference
Appearance	white, inert and odourless spherical particle	Conforms	USP-EP
Identification A	The insoluble portion of a slurry gives a reddish-violet to deep blue color with iodine	Conforms	NF
Identification B	+41° - +61°	+56°	USP
Identification A, B, C	Conforms	Conforms	EP
Assay	62,5% - 91,5%	85,90%	USP-EP
Heavy Metals	NMT 5µg/g	< 5µg/g	USP-EP
Loss on drying	NMT 4.0 %	1,20%	USP-EP
Friability	NMT 5%	2,58%	USP-EP
Residue on ignition	NMT 0.2 %	< 0.2 %	USP-EP
Fineness	NLT 90% between #25 (710µm) and #30 (600µm)	95,00%	EP
Particle Size	100% passes through #20 (850µm)	100,00%	USP
	NLT 90% passes through #25 (710µm)	97,60%	USP
	NMT 10% passes through #30 (600µm)	2,60%	USP
MICROBIAL LIMITS:	llab		
TAMC	10 ² CFU/g	< 200 CFU/g	USP-EP
TYMC	10 ² CFU/g	< 200 CFU/g	USP-EP
Escherichia coli	Absent in 1g	Absent	USP-EP
Pseudomonas aeruginosa	Absent in 1g	Absent	USP-EP
Salmonella species	Absent in 10g	Absent	USP-EP
Staphylococcus aureus	Absent in 1g	Absent	USP-EP
REMARKS: USP40NF35; Ph. Eur. Current ed. DMF n. 28032		Manufacturing date: 02/02/2018	
		Expiry date: 01/02/2021	
Date of delivery: 15/02/2018		QC Marco Serra	

QMS certificated UNI EN ISO 9001:2008 by Bureau Veritas Italia spa N° IT243949
QMS certificated IPEC PQG GMP 2006 by Bureau Veritas Italia spa N° IT260943

All claims must be filed within 20 days after receipt of the goods.

The expiry date refers to the material stored in its original packaging and conditions: store in well closed container and protect from direct heat and light.