



SPECIFICATION

MANNITOL SPHERES SANAQ[®] (USP/NF / Ph. EUR)

Type	MSS 75	MSS 150	MSS 180	MSS 250	MSS 425	MSS 600	Test Method
Appearance	Hard, brittle, free flowing, white colour spherical masses						MSS Standard
Odor	Odorless						MSS Standard
Physical Parameters							
Particle Size	75 – 150 µm	150 – 180 µm	180 – 250 µm	250 – 300 µm	425 – 600 µm	600 – 850 µm	MSS Standard ≥ 85 %
Loss on drying	NMT 0.5 %						USP/NF
Identification	shall complies infrared absorbance						USP/NF
Specific optical rotation	Between +137° and +145°						USP/NF
Acidity	Not more than 0.30 ml of 0.020 N sodium hydroxide is required for neutralization						USP/NF
Chloride	NMT 0.07 %						USP/NF
Sulfate	NMT 0.01 %						USP/NF
Arsenic	NMT 1 ppm						USP/NF
Reducing Sugar	NMT 0.1 %						USP/NF
Heavy Metals	Maximum 5 ppm						USP/NF
Assay	Between 96% and 101%						USP/NF
Microbiological Parameters							
Total aerobic microbial count	NMT 100cfu/gm						Ph. EUR / USP/NF
Salmonella	Absent						Ph. EUR / USP/NF
Escherichia coli	Absent						Ph. EUR / USP/NF
Staphylococcus aureus	Absent						Ph. EUR / USP/NF
Pseudomonas aeruginosa	Absent						Ph. EUR / USP/NF

Contact

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