



SPECIFICATION

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

| Type | MSS 300 | MSS 425 | Test Method |
|-----------------------------------|--|--------------|------------------|
| Appearance | | | MSS Standard |
| Physical Parameters | | | |
| Particle Size | | | |
| | 300 – 425 µm | 425 – 600 µm | MSS Standard |
| | ≥ 85 % | | |
| Loss on drying | NMT 2.0 % | | USP/NF |
| Identification | By IR the Infra-red absorbance spectrum obtained from the sample should be concordant with the spectrum obtained with reference spectrum of mannitol | | USP/NF |
| Buld Density | NLT 0.5 gm/ml | | |
| Loss on drying | NMT 2.0 % | | USP/NF |
| Nickel | NMT 1 µg/g | | USP/NF |
| Melting Range | 165 to 170° | | USP/NF |
| Assay | Between 76.5% and 93.5% | | 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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