

## Trafa Pharmaceutical Inc.

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## **Specification Sheet**

Product Name MANNITOL		
ITEM	STANDARD	TESTING GROUNDS
Identification	Be consistent with the refer	USP41
Clarity & Colour	Clear and Colorless	USP41
Loss on Drying, %	≤ 0.5	USP41
Nickel, ppm	≤ 1.0	USP41
Sorbitol, %	≤ 2.0	USP41
Maltitol and Isomalt, %	≤ 2.0	USP41
Unspecified impurities, %	≤ 0.1	USP41
Total impurities, %	≤ 2.0	USP41
Assay, %	97.0 - 102.0	USP41
Melting Point, °C	165.0 – 170.0	USP41
Reducing sugar, %	≤ 0.1	USP41
Conductivity, μ S/cm	≤ 20	USP41
Total aerobic bacteria, CFU/g	≤ 1000	USP41
Mold and Yeast, CFU/g	≤ 100	USP41
Escherichia coli	Negative	USP41

Note: The above information is based on the specification sheet received from the manufacturer of this product and not intended as a substitute for strict quality control analysis by the purchaser of this product.

Reviewed by:

Abdullah Malik (QA)