

Product Specification

Betacyclodextrin

Shelf life of the product: 3 Year from the date of manufacturing of the product.

TEST PARAMETERS	TEST METHOD
Chemical Analysis	
Appearance	White, practically odorless, fine crystalline powder having a slight sweet taste
Solubility	Sparingly soluble in water
Colour and clarity of solution	The solution is clear and colourless
Identification	
A Infra Red Absorption	The IR spectrum of sample dispersed in KBr should be concordant with the IR spectrum of Beta cyclodextrin WS
B By HPLC	The retention time of the major peak in the chromatogram of the assay preparation should correspond to that in the chromatogram of the Standard Preparation.
C. By Thin layer Chromatography	The R _f value of the principal spot obtained from the test solution should correspond to that obtain from the standard solution
D. Reaction with iodine solution	To comply with the test
Assay for Betadex on anhydrous basis	Between 98.0% to 102.0%
Water	Not more than 14.0%
Specific Rotation at 20°C	Between + 160° and + 164 °
pH	5.0 to 8.0
Light-absorbing impurities	Between 230 to 350nm : Abs. NMT 0.10 Between 350 to 750 nm: Abs. NMT 0.05
Residue on ignition	Not more than 0.1%
Heavy Metals	Not more than 5 ppm
Reducing Sugar	The Abs. of test solution NMT that of Std. solution (0.2%)
Microbial Contamination	
1) Total Plate Count	a) Not more than 1000 CFU/g
2) Total Yeast and Moulds	b) Fungi Not more than 100 CFU/g
3) Staphylococcus aureus	Absent
4) Pseudomonas aeruginosa	Absent
5) E. Coli Salmonella	Absent
Extraneous matter	it does not contain any black particles, fibres or any other extraneous matter

Packaging: 10 kg in double polyethylene bag (LDPE) inside with labeled HDPE drum as outer container.