

#### Dana Pharmaceuticals Ltd., Shiroro Dam Road, Maitumbi, Minna. Formulations Unit

#### RAW MATERIAL SPECIFICIATIONS -DEXTROSE MONOHYDRATE

Spec. No: DPL/SPEC/RMA/ 011 Supercedes Specs. No: NIL Pharmacopoeia Reference: BP Review: FEB. 2014

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#### Desirable Pack:

To be packed in double polythene lined fiber bag/ drum properly identified with label having Name of the Material, Name of the Manufacturer/Supplier, Quantity, Manufacturer's Batch Number, Manufacturing Date & Expiry Date.

Sampling Instructions: As per the current approved Sampling Standard Operating Procedure

Storage conditions: To be stored in a well closed container

Approved Supplier/Manufacturer: As per the Approved Vendor's List

Retesting Period: 6 months from the date of approval.

Quantity of Sample for Analysis: 50 g

Sr. No.	Test	Specification	
1.	Description	A white, crystalline powder with a sweet taste, freely soluble in water, sparingly soluble in alcohol.	
2	Identification	Red precipitate formed	
30	Acidity or Alkalinity	NMT 0.15ml of 0.1M NaoH is required to change the colou of indicator to pink.	
4.	Specific optical rotation	+ 52.5 to + 53.3° calculated with reference to anhydrous substance.	
5.	Limit test for Chlorides	≤ 125 ppm	
6.	Limit test for Sulphates	≤ 200 ppm	
7.	Limit test for Barium	Not more intense than reference solution	
8.	Limit test for Arsenic	≤ 1 ppm	
9.	Limit test for Calcium	≤ 200 ppm	
10.	Limit test for Lead	≤ 0.5 ppm	
III.	L.O.D	7,0% - 9.5%	
12.	Sulphated Ash	NMT 0.1%	
13.	Microbiological Test	NMT1000 CFU	
14.	Pyrogen Test	Shall comply	

PREPARED BY	APPROVED BY	AUTHORISED BY
QUALITY CONTROL	QUALITY CONTROL	SUPERINTENDENT
CHEMIST	MANAGER	PHARMACIST

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