

	RAW MATERIAL SPECIFICATION		Page No.	1 of 3
	Quality Control Department			
Name of Raw Material	Dextrin			
Specification No.	RM/SPEC/HM/108-01	Supersedes No.:	NA	
Reference	IP/USP	Effective Date	04/04/2025	
Ref. Annexure No.	A/SOP/QC/030/02	Review Month	Mar'2030	

GENERAL INFORMATION

Pharmacopeial reference : IP/USP

Special requirement of pack : Material should be packed in food grade fiber bags.

Approved vendor : Please refer current approved vendor list.

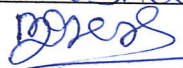
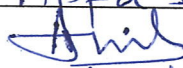
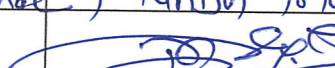
Handling hazards : Refer Material Safety Data Sheet

Quantity to be sampled

Analysis Sample	Control sample
120 g	240 g

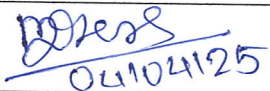
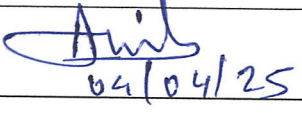
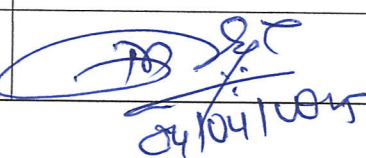
Retest Period : 12 Months

Storage : Store protected from moisture and preserve in well-closed container.

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Manisha Dhere	Appa S. Shinde	Manish Mahajan
Sign/Date	 04/04/25	 04/04/25	 04/04/25
Designation	S.O. Executive	Asst. Manager	Manager
Department	Quality Control	Quality Control	Quality Assurance

	RAW MATERIAL SPECIFICATION		Page No.	2 of 3
	Quality Control Department			
Name of Raw Material	Dextrin			
Specification No.	RM/SPEC/HM/108-01			

Sr. No.	TEST	SPECIFICATIONS	REFERENCE
01.	Description #	A white or pale yellow powder	IP
		Free flowing, white, yellow, or brown powder.	USP
02.	Solubility	Very soluble in boiling water forming a mucilaginous solution, slowly soluble in cold water, practically insoluble in ethanol (95%) and in ether.	IP
		Its solubility in water varies; it is usually very soluble, but often contains an insoluble portion.	USP
03.	Identification		
	Test A	The hilum may be bicleft and some of the granules may be distorted.	IP
	Test B	A purple color should be produced.	IP
	Test C	A red precipitate should be produced.	IP
	Test D	A blue to reddish-brown color results.	USP
	Test E	Forming a mucilaginous solution	USP
04.	Acidity	Not more than 1 ml of 0.1 M sodium hydroxide should be required to the change the color of the solution	IP
		NMT 3.0 ml	USP
05.	Ethanol-soluble substances	NMT 1.0 %	IP
06.	Chloride	NMT 0.2 %	IP
07.	Chloride and Sulfate	Any turbidity produced should not more than that of the control, corresponding to not more than 0.2 % of chloride	USP
08.	Heavy Metals	NMT 40 ppm	IP
09.	Protein	NMT 0.5 %	IP
10.	Limit of Protein	NMT 1.0 %	USP
11.	Reducing substances	NMT 10.0 %	IP
12.	Ash	NMT 1.0 %	IP

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 04/04/25	 04/04/25	 04/04/25

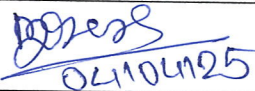
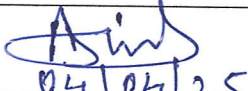
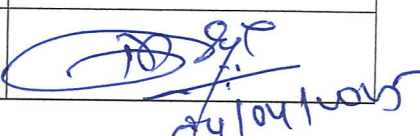
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Name of Raw Material	Dextrin			
Specification No.	RM/SPEC/HM/108-01			

Sr. No.	TEST	SPECIFICATIONS	REFERENCE
13.	Residue on ignition	NMT 0.5 %	USP
14.	Loss on Drying [#]	NMT 12.0 %	IP
		NMT 13.0 %	USP
15.	Botanic characteristics	The hilum is frequently bicleft and small proportion of the granules are distorted.	USP
16.	Assay [#] Reducing sugars (Dextrose equivalent)	NMT 10 %	USP

#: Re-evaluation tests

REVISION HISTORY FOR SPECIFICATION:

Revision No.	Revision Description	Effective Date
01	Specification prepared as per Approved Change control CC/PD/25/004	04/04/2025

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 04/04/25	 04/04/25	 04/04/2025