



Novo Excipients Pvt. Ltd.

A-374, TTC Industrial Area, Mahape, Navi Mumbai-400710, Tel: +91-22-27788401/02
Email: info@novoexcipients.com Website: www.novomix.in Regd. Office : 5/C, Shree Laxmi Industrial Estate, New Link Road, Andheri(W), Mumbai-400053

RAW MATERIAL SPECIFICATION

Department	: Quality Control		
Material Name	: Hydroxypropyl Methyl cellulose 15 cps		
Specification No	: RM/SPEC/001-02	Material Code	: RM001
Review Before	: 2023-12-12		
Retest Period	: 24 Months 0 Days	Supersedes No	: NA
Storage Condition	: .		

Sr.	Test	Specification	Reference
1.	Description	A White or yellowish white, fibrous or granular powder; almost odourless, hygroscopic after drying.	IP
2.	Description	A White to slightly off white, fibrous or granular powder	USP
3.	Description	White, yellowish-white or greyish-white powder or granules, hygroscopic after drying	BP
4.	Solubility	Practically insoluble in hot water, in acetone, in ethanol, in ether and in toluene. It swells in w	IP
5.	Solubility	Insoluble in dehydrate alcohol, in ether and in chloroform. Swells in water and produces a clear to	USP
6.	Solubility	Practically insoluble in hot water, in acetone, in anhydrous ethanol and in toluene. It dissolves in	BP
7.	Identification Test	The solution should become cloudy or a flocculent precipitate should be formed. On cooling, the solu	IP
8.	Identification Test	The mixture should remain stable	IP
9.	Identification Test	A yellowish white flocculent precipitate should be produced which should be dissolved in 6M ammonia	IP
10.	Identification Test	A pink colour should be produced immediately which should become violet within 100 minutes.	IP
11.	Identification Test	A thin film should be produced.	IP
12.	Identification Test	The Powder Material aggregates on the surface	USP
13.	Identification Test	A clear or slightly turbid solution with thickness dependent on the viscosity grade	BP
14.	Identification Test	A red color develops first that changes to purple within 100 min.	USP
15.	Identification Test	A coherent clear film forms on the glass slide.	BP



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Sr.	Test	Specification	Reference
16.	Identification Test	The flocculation temperature is higher than 50°C	USP
17.	pH (Solution A)		IP
18.	Appearance of solution	Solution should not be more opalescent than opalescence standard OS3/III and not more intensely col	IP
19.	Apparent viscosity (2% aq. solution at 20°C)		IP
20.	Apparent viscosity (2% aq. solution at 20°C)		USP
21.	Heavy Metals		IP
22.	Chlorides		IP
23.	Sulphated Ash		IP
24.	Sulphated Ash		BP
25.	Sulphated Ash		USP
26.	Loss On Drying		IP
27.	Loss On Drying		USP
28.	Assay (On dried basis) Substitution Type 2910		USP
29.	Assay (On dried basis) Substitution Type 2910		BP

REVISION HISTORY

Specification No.	Revision No.	Change Made	Reasons for change	Effective Date
RM/SPEC/001-02	1		New Document	2019-02-26
RM/SPEC/001-02	2	CC/QC/21/003	Raw material Specification is revised for inclusion as per BP	2021-01-23

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	master		
Sign/Date	03-03-2023		
Designation			
Department	Store		Store