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NOVO EXCIPIENTS PVT. LTD.	RAW MATERIAL SPECIFICATION Quality Control Department		Page No.	1 of 3
Name of Raw Material	Hydroxypropyl Methyl Cellulose 5 cps (Hypromellose)			
Specification No.	RM/SPEC/HM/061-01	Supersedes No.:	RM/SPEC/061-02	
Reference	IP/BP/USP	Effective Date	31/03/2025	
Ref. Annexure No.	A/SOP/QC/030/02	Review Month	Feb'2030	

GENERAL INFORMATION

Pharmacopeial reference : IP/BP/USP

Special requirement of pack : Material should be packed in LDPE bag in HDPE/ Fiber drum.

Approved vendor : Please refer current approved vendor list.

Handling hazards : Refer Material Safety Data Sheet

Quantity to be sampled

Analysis Sample	Control sample
80 g	160 g

Retest Period : 12 Months

Storage : Store well closed container, Store protected from moisture and Preserve in well-closed containers. No storage requirements are specified.

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Manisha Dhere	Appa S. Shinde	Manish Thakiyan
Sign/Date	28/03/25	28/03/25	28/03/2025
Designation	Sr. Executive	Asst. Manager	Manager
Department	Quality Control	Quality Control	Quality Assurance

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	Quality Control Department		
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Specification No.	RM/SPEC/HM/061-01		

SR. NO.	TEST	SPECIFICATIONS	REFERENCE
01.	Description #	A White, yellowish white or Greyish-white, powder or granules; hygroscopic after drying.	IP/BP
		A White to slightly off white, fibrous or granular powder	USP
02.	Solubility	It dissolves in cold water giving a colloidal solution. Practically insoluble in hot water, in acetone, in ethanol and in toluene.	IP
		Practically insoluble in hot water, in acetone, in anhydrous ethanol and in toluene. It dissolves in cold water giving a colloidal solution.	BP
		Insoluble in dehydrate alcohol, in ether and in chloroform. Swells in water and produces a clear to opalescent viscous, colloidal mixture.	USP
03.	Identification Test		
	Test A	The powdered material aggregates on the surface.	IP/BP/USP
	Test B	A clear or slightly turbid solution occurs with its thickness dependent on the viscosity grade.	IP/BP/USP
	Test C	A red color develops at first and changes to purple within 100 minutes.	IP/BP/USP
	Test D	A coherent, clear film forms on the glass slide.	IP/BP/USP
	Test E	The flocculation temperature is higher than 50° C.	IP/BP/USP
04.	Appearance of solution	The solution should not more opalescent than opalescence standard OS3 and should not more intensely coloured than reference solution YS6.	IP
		Solution should not be more opalescent than reference solution III and should not more intensely coloured than reference solution Y6.	BP
05.	pH#	5.0 to 8.0	IP/BP/USP
06.	Viscosity#	4 mPas – 6 mPas	IP/BP/USP
07.	Heavy Metals	NMT 20 ppm	IP

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Sign/Date	28/03/25	28/03/25	28/03/2025

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novo EXCIPIENTS PVT. LTD.	Quality Control Department		
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SR. NO.	TEST	SPECIFICATIONS	REFERENCE
08.	Sulphated Ash / Residue on Ignition	NMT 1.5 %	IP/BP/USP
09.	Loss On Drying#	NMT 5.0 %	IP/BP/USP
10.	Assay# (On dried basis) (Substitution Type- 2910)		IP/BP/USP
	Methoxy	28.0% - 30.0%	
	Hydroxypropoxy	7.0 % - 12.0 %	
# : Re-evaluation tests			

REVISION HISTORY FOR SPECIFICATION:

Revision No.	Revision Description	Effective Date
01	1) Individual Pharmacopoeial grade new document prepared as per Approved Change control No. CC/QC/23/002 2) Only SPEC and ATR prepared as per approved change control No. CC/QC/25/008	31/03/2025

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	28/03/25	28/03/25	28/03/2025