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	RAW MATERIAL SPECIFICATION		Page No.	1 of 3
novo EXCIPIENTS PVT. LTD.	Quality Control Department			
Name of Raw Material	Crospovidone			
Specification No.	RM/SPEC/HM/073-01	Supersedes No.	RM/SPEC/073-01	
Reference	IP/USP	Effective Date	22/04/2025	
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 paper bag.

Approved vendor : Please refer current approved vendor list.

Handling hazards : Refer Material Safety Data Sheet

Quantity to be sampled :

Analysis Sample	Control sample
160 g	220 g

Retest Period : 12 Months

Storage : Store protected from moisture and preserve in tight containers.

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Manisha Dhere	Appa S. Shinde	Manish Mahajan
Sign/Date	22104125	22/04/25	22/04/25
Designation	Sr. Executive	Asst. Manager	Manager
Department	Quality Control	Quality Control	Quality Assurance

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Name of Raw Material	Crospovidone		
Specification No.	RM/SPEC/HM/073-01		

Sr. No.	TEST	SPECIFICATIONS	REFERENCE
01.	Description #	A White to creamy white hygroscopic powder.	IP
		White to creamy-white, hygroscopic powder, having a faint odor.	USP
02.	Solubility	Insoluble in water and in ordinary organic solvents.	IP/USP
03.	Identification :		
	Test A : By IR	Compare the spectrum with that obtained with crospovidone RS or with the reference spectrum of crospovidone.	IP/USP
	Test B	No blue color should be developed	IP/USP
	Test C	A suspension should be formed; No clear solution should be obtained within 15 minutes.	IP/USP
	Test D: By Sieve method	Type A: If the sieving residue fraction through 63 µm sieve should be more than 15%	IP/USP
		Type B: If the sieving residue fraction through 63 µm sieve should be less than or equal to 15%	
04.	Peroxides	Type A: The absorbance should not more than 0.35 corresponding to NMT 0.04 % (400 ppm) expressed as hydrogen peroxide.	IP/USP
		Type B: The absorbance should not more than 0.35 corresponding to NMT 0.1% (1000 ppm) expressed as hydrogen peroxide.	
05.	Water-soluble substances	The weight of the residue should not exceed 75 mg (1.5%)	IP/USP

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	22/04/25	22/04/25	22/04/2025

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NOVO EXCIPIENTS PVT. LTD.	RAW MATERIAL SPECIFICATION Quality Control Department	Page No.	3 of 3
Name of Raw Material	Crospovidone		
Specification No.	RM/SPEC/HM/073-01		

Sr. No.	TEST	SPECIFICATIONS	REFERENCE
06.	Impurity A[#] Vinylpyrrolidinone	The area of the peak from the sample solution should be not more than the area of the principal peak in the chromatogram obtained with reference solution (a). (NMT 10 ppm)	IP/USP
07.	Heavy metals	NMT 10 ppm	IP
08.	Sulphated ash / Residue on Ignition	NMT 0.1 %	IP/USP
09.	Loss on Drying [#]	NMT 5.0 %	IP/USP
10.	Assay[#] Nitrogen (On dried basis)	NLT 11.0 % and NMT 12.8 %	IP/USP
#: Re-evaluation tests			

REVISION HISTORY FOR SPECIFICATION:

Revision No.	Revision Description	Effective Date
01	1) New individual pharmacopoeial grade document prepared as per approved Change control No. CC/QC/23/002 2) SPEC and ATR prepared as per approved change control No. CC/QC/25/008	22/04/2025

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	22/04/25	22/04/25	24/04/2025