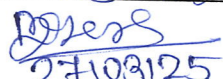
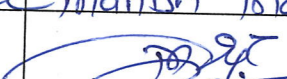


	RAW MATERIAL SPECIFICATION		Page No.	1 of 3
	Quality Control Department			
Name of Raw Material	Polyvinyl Alcohol (5 Cps)			
Specification No.	RM/SPEC/HM/016-01	Supersedes No.	RM/SPEC/016-02	
Reference	IP/BP/USP	Effective Date	27/03/2025	
Ref. Annexure No.	A/SOP/QC/030/02	Review Month	Feb'2030	

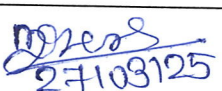
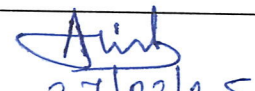
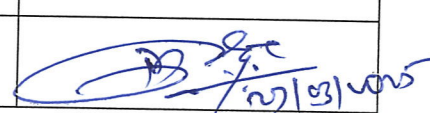
GENERAL INFORMATION

Pharmacopeial reference	: IP/BP/USP				
Special requirement of pack	: Material should be packed in paper bag.				
Approved vendor	: Please refer current approved vendor list.				
Handling hazards	: Refer Material Safety Data Sheet.				
Quantity to be sampled	: <table border="1"> <tr> <td>Analysis Sample</td><td>Control sample</td></tr> <tr> <td>145 g</td><td>290 g</td></tr> </table>	Analysis Sample	Control sample	145 g	290 g
Analysis Sample	Control sample				
145 g	290 g				
Retest Period	: 12 Months				
Storage	: Store protected from moisture, at a temperature not exceeding 30° C and preserve in well-closed containers, and store at room temperature in a dry place.				

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Manisha Dhese	Appa S. Shinde	Manish Mahajan
Sign/Date	 27/03/25	 27/03/25	 27/03/2025
Designation	SD-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	Polyvinyl Alcohol (5 Cps)			
Specification No.	RM/SPEC/HM/016-01			

Sr. No.	TEST	SPECIFICATIONS	REFERENCE
01.	Description [#]	A White to cream coloured granular powder.	IP
		Yellowish-white powder or translucent granules.	BP
		White to cream- coloured granules, or white to cream- colored powder. Odorless.	USP
02.	Solubility	Soluble in water, slightly soluble in ethanol (95%), insoluble in organic solvents.	IP
		Soluble in water, slightly soluble in anhydrous ethanol (95%), practically insoluble in acetone.	BP
		Freely soluble in water at room temperature.	USP
03.	Identification		
	Test A: By IR	Compare the spectrum with that obtained with Polyvinyl Alcohol RS or with the reference spectrum of Polyvinyl Alcohol	IP/BP/USP
	Test B	i) A dark red to blue colour should be produced. ii) A white, turbid or flocculent precipitate should be formed.	IP/USP
	Test C: By Viscosity	4.25 cps – 5.75 cps	BP/USP
04.	pH [#]	5.0 to 8.0	IP/USP
		4.5 to 6.5	BP
05.	Appearance of solution	Solution should be clear and should not more intensely colored than reference solution Y ₇	BP
06.	Viscosity [#]	4.25 cps – 5.75 cps	IP/BP/USP
07.	Acid Value	NMT 3.0	IP/BP/USP
08.	Ester value [#]	90.0 % to 110.0 % (Value 140)	IP/BP
09.	Heavy Metals	NMT 10 ppm	IP

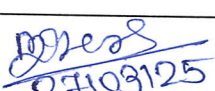
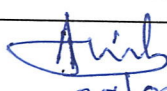
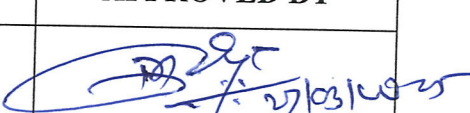
	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 27/03/25	 27/03/25	 27/03/25

	RAW MATERIAL SPECIFICATION	Page No.	3 of 3
	Quality Control Department		
Name of Raw Material	Polyvinyl Alcohol (5 Cps)		
Specification No.	RM/SPEC/HM/016-01		

Sr. No.	TEST	SPECIFICATIONS	REFERENCE
10.	Sulphated ash	NMT 1.0 %	IP/BP
11.	Residue on Ignition	NMT 1.0%	USP
12.	Water Insoluble Substances	NMT 6.4 mg of water -insoluble substances are found (corresponding to NMT 0.1 %)	USP
13.	Limit of Methanol (Methyl alcohol) and Methyl Acetate	Methanol (Methyl Alcohol) : NMT 1.0 % Methyl Acetate: NMT 1.0 %	USP
14.	Loss on drying #	NMT 5.0 %	IP/BP/USP
15.	Degree Of Hydrolysis	85 % - 89 %	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	27/03/2025

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 27/03/25	 27/03/25	 27/03/25