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NOVO EXCIPIENTS	RAW MATERIAL SPECIFICATION		Page No.	1 of 3
NOVO PVT. LTD.	Quality Control Department			
Name of Raw Material	Carnauba Wax			
Specification No.	RM/SPEC/HM/074-01 Supersedes No.		RM/SPEC/	074-01
Reference	IP/USP	Effective Date	22/04/21	025
Ref. Annexure No.	A/SOP/QC/030/02		Mar'20:	

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
40 g 80 g

Retest Period

: 12 Months

Storage

: Store protected from light and moisture and preserve in well-

closed containers.

Name Manisha Dhese Appa S-Shindo Manish Mahajan Sign/Date Sign/Date Designation Designation So. Executive Asst-Manager Department Quality Control Buality Control Buality Control Quality Asst-Manager		PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date Sign/Date Designation Department Department Department Sign/Date Sign/D	Name	Manisha Dhene	Anna Calla lado	Maile Maleice
Designation St. Executive Asst-Manager Manager	Sign/Date	100res	Ain	70 8pt
Department Control on 1	Designation	STIFXQUILLING		
	Department	Quality Condrol	Quality Control	Quality Assurance



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Sr. No.	TEST	SPECIFICATIONS	REFERENCE
01.	Description #	A Pale yellow to light brown coarse powder,	
		flakes or lumps of hard brittle wax; odour,	IP
		characteristic and free from rancidity.	
		Light brown to pale yellow, moderately coarse	
		powder or flakes, possessing a characteristic	USP
		bland odor, and free from rancidity.	
02.	Solubility	Soluble on warming in chloroform, in ethyl	
		acetate and in xylene; Practically insoluble in	IP
2		water and in ethanol (95 percent)	
		Freely soluble in warm benzene, soluble in	
		warm chloroform and in warm toluene, slightly	USP
		soluble in boiling alcohol, insoluble in water.	
03.	Identification		
	Test A: By thin layer	To comply	
	chromatography		IP
	Test B: By IR	The IR-Spectrum of test sample should be	USP
		concordant with that of standard spectrum.	
04.	Melting Point #	78° - 88°	IP
		80° - 86°	USP
05.	Acid Value #	NMT 12.0	IP
		2 -7	USP
06.	Fats and Fixed oils /	Between 78 - 95	
	Saponification value #		IP/USP
07.	Heavy metals	NMT 40 ppm	IP
08.	Sulphated ash	NMT 0.25%	IP
09.	Residue on Ignition	NMT 0.25%	USP
#: Re-e	evaluation tests		

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	22104125	22/04/25	700 4 9

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NOVO EXCIPIENTS PVT. LTD.	Quality Control Department		
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REVISION HISTORY FOR SPECIFICATION:

Revision No.	Revision Description	Effective Date
	1) New pharmacopoeial grade document prepared as per	
01	approved Change control No. CC/QC/23/002	¥
	2) SPEC and ATR prepared as per approved change control No. CC/QC/25/008	21/04/2025

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	22104125	Aus 04/25	ADST.