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NOVO EXCIPIENTS PVT. LTD.	RAW MATERIAL SPECIFICATION Quality Control Department		Page No.	1 of 3
Name of Raw Material	Lecithin			
Specification No.	RM/SPEC/HM /029-01	Supersedes No.	RM/SPEC/029-02	
Reference	IP/USP	Effective Date	21/04/2025	
Ref. Annexure No.	A/SOP/QC/030/02	Review Month	Mar' 2030	

GENERAL INFORMATION

Pharmacopoeial reference : IP/USP

Special requirement of pack : Material should be packed in HDPE container / 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
120 g	240 g

Retest Period : 12 Months

Storage : Store protected from moisture at temperature not exceeding 30° C and preserve in well-closed, light-resistant containers. Store at the temperature indicated on the label. Protect from excess heat and moisture.

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Manisha Dhere	Appa S. Shinde	Manish Malajan
Sign/Date	21/04/25	21/04/25	21/04/2025
Designation	Sr. Executive	Asst. Manager	Manager
Department	Quality Control	Quality Control	Quality Assurance

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Specification No.	RM/SPEC/HM/029-01		

SR. NO.	TEST	SPECIFICATIONS	REFERENCE
01.	Description#	Cream to Brown coloured powder / liquid	In House
		Light yellow to Brown color, depending on the source, on crop variation, and on whether it is bleached or unbleached. It is odorless or has a characteristic, slight nut like odor and bland taste.	USP
02.	Solubility	Sparingly soluble in ethanol (95%), slightly soluble in water	IP
		Practically insoluble in water, Soluble in fatty acids, Practically insoluble in fixed oils, Sparingly soluble in alcohol and Practically insoluble in acetone.	USP
03.	Identification		
	A) By chemical Test	A yellow precipitate should be produced.	IP
	B) By paper chromatography	The principal spot in the chromatogram obtained with the test solution corresponds to the principal spot in the chromatogram obtained with the reference solution.	
	C) Phospholipids By Thin-Layer chromatography	The R_f values of the spots for phosphatidylcholine, phosphatidylethanolamine, phosphatidic acid and lysophosphatidylcholine from the sample solution corresponds to those from standard solution A and standard solution B.	USP
04.	Acid value	NMT 36 mg of potassium hydroxide	IP
05.	Peroxide value	NMT 10	IP/USP
06.	Water#	NMT 1.5%	IP
		NMT 2.0 %	USP
07.	Hexane-insoluble matter	NMT 0.3 %	IP/USP
		For Sunflower Lecithin: NMT 1.0%	USP

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	21/04/25	21/04/25	21/04/2025

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Name of Raw Material	Lecithin		
Specification No.	RM/SPEC/HM/029-01		

SR. NO.	TEST	SPECIFICATIONS	REFERENCE
08.	Lead	NMT 0.001 %	IP
		NMT 10 ppm	USP
09.	Heavy metals	NMT 20 ppm	IP
10.	Acetone-insoluble matter#	NLT 50 %	IP/USP
11.	Fats and fixed oils / Acid value	NMT 36	USP
12. *	Assay # (content of phospholipids)		USP
	Pohsphatidylcholine	18-22	
	Phosphatidylethanolamine	16-18	
	Phosphatidylinositol	17-19	
	Phosphatidic acid	3-5	
13.	Microbial Enumeration Test #		USP
	Total Aerobic Microbial Count	NMT 10^3 cfu/g	
	Total combined molds and Yeast count	NMT 10^2 cfu/g	
	Test for specified microorganisms#		USP
	Salmonella	Absent/10g	
	Escherichia coli	Absent/1g	

: Re-evaluation tests

* : Value to be reported from vendor COA

REVISION HISTORY FOR SPECIFICATION:

Revision No.	Revision Description	Effective Date
01	1) New 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	21/04/2025

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	21/04/25	21/04/25	21/04/2025