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NOVO EXCIPIENTS PVT. LTD.	RAW MATERIAL SPECIFICATION Quality Control Department		Page No.	1 of 3
Name of Raw Material	Stearic Acid 95 Powder			
Specification No.	RM/SPEC/ HM /106-01	Supersedes No.:	NA	
Reference	IP/USP	Effective Date	05/05/25	
Ref. Annexure No.	A/SOP/QC/030/02	Review Month	Apr'2030	

GENERAL INFORMATION

Pharmacopeial reference : IP/USP

Special requirement of pack : Material should be packed in food grade fiber bags.

Approved vendor : Please refer current approved vendor list.

Handling hazards : Refer Material Safety Data Sheet

Quantity to be sampled

Analysis Sample	Control sample
50 g	100 g

Retest Period : 12 Months

Storage : Store protected from moisture and preserve in well-closed containers.

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Manisha Dhere	Appa S. Shinde	Manish Malviya
Sign/Date	05/05/25	05/05/25	
Designation	Sr. Executive	Asst. Manager	Manager
Department	Quality Control	Quality Control	Quality Assurance

Name of Raw Material	Stearic Acid 95 Powder
Specification No.	RM/SPEC/HM/106-01

Sr. No.	TEST	SPECIFICATIONS	REFERENCE
01.	Description #	A white powder or white, greasy, flaky crystals or hard masses showing signs of crystallization.	IP
		Hard, white or faintly yellowish, somewhat glossy and crystalline solid, or white or yellowish-white powder. Its odor and taste are slight, suggesting tallow	USP
02.	Solubility	Soluble in chloroform, in ethanol and in ether, practically insoluble in water.	IP
		Freely soluble in chloroform and in ether; soluble in alcohol; practically insoluble in water.	USP
03.	Identification		IP/USP
	Test A: By Assay #	The chromatogram should be obtained with the test solution shows two principal peaks which correspond to the two principal peaks in the chromatogram should be obtained with the reference solution.	
	Test B: Freezing Point	64 - 69	USP
	Test C: Acid Value	194 - 212	USP
04.	Fats and Fixed oils (Iodine value)	NMT 1.5	USP
05.	Congealing Temperature	NLT 54°	IP
06.	Colour of solution	The resulting liquid should not more intensely colored than Standard solution Y or Standard solution BY.	USP

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	05/05/25	05/05/25	05/05/25

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Name of Raw Material	Stearic Acid 95 Powder		
Specification No.	RM/SPEC/HM/106-01		

Sr. No.	TEST	SPECIFICATIONS	REFERENCE
07.	Acidity	No red color should be develops.	USP
08.	Freezing Point	64 - 69	USP
09.	Acid Value	200 to 212	IP
10.	Iodine Value	NMT 4.0	IP
11.	Mineral Acid	No red colour should be produced.	IP
12.	Heavy Metals	NMT 20 ppm.	IP
13.	Sulphated Ash /Residue on Ignition	NMT 4 mg (0.1 %)	IP/USP
14.	Assay #		
	Stearic Acid :	NLT 40.0 %	IP
	Sum of Stearic acid and Palmitic acid :	NLT 90.0 %	
15.	Assay #		
	Stearic (Octadecanoic) Acid :	NLT 90.0 %	USP
	Sum of Stearic acid and Palmitic acid :	NLT 96.0 %	
#: Re-evaluation tests			

REVISION HISTORY FOR SPECIFICATION:

Revision No.	Revision Description	Effective Date
01	1) 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	05/05/25

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	05/05/25	05/05/25	05/05/2025