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NOVO EXCIPIENTS PVT. LTD.	RAW MATERIAL SPECIFICATION Quality Control Department		Page No.	1 of 3
Name of Raw Material	Diethyl Phthalate			
Specification No.	RM/SPEC/HM/011-01	Supersedes No.	RM/SPEC/011-02	
Reference	IP/USP	Effective Date	24/04/2025	
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 HDPE container

Approved vendor : Please refer current approved vendor list.

Handling hazards : Refer Material Safety Data Sheet

Quantity to be sampled :

Analysis Sample	Control sample
90 g	180 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	24/04/25	24/04/25	24/04/2025
Designation	Sr. Executive	Asst. Manager	Manager
Department	Quality Control	Quality Control	Quality Assurance

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Name of Raw Material	Diethyl Phthalate		
Specification No.	RM/SPEC/HM/011-01		

Sr. No.	TEST	SPECIFICATIONS	REFERENCE
01.	Description #	A clear, oily liquid, colourless or very slightly yellow.	IP
		Colorless, practically odorless, oily liquid.	USP
02.	Solubility	Insoluble in water, Miscible with ethanol (95%) and in ether.	IP
		Insoluble in water. Miscible with alcohol, with ether, and with other usual organic solvents.	USP
03.	Identification: Test A may be omitted if test B, C and D are carried out. Tests B, C and D may be omitted if test A is carried out.		
	Test A: By IR	Compare the spectrum with that obtained with diethyl phthalate RS	IP/USP
	Test B : By Relative Density	1.117 to 1.121	IP
	Test C : By Thin layer chromatography	The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution.	IP
	Test D :	The solution should become yellow or brownish – yellow and shows green fluorescence.	IP
04.	Appearance of solution	The substance under examination should be clear and should not be more intensely coloured than reference solution YS6.	IP
05.	Specific Gravity	1.118 - 1.122 at 20°C	USP
06.	Acidity #	Not more than 0.1 ml of 0.1 M sodium hydroxide should be required to change the colour of the indicator to pink.	IP
		NMT 0.50 ml should be required for neutralization.	USP
07.	Related substances	The ratio of the sum of the areas of all peaks, other than the principal peak and the peaks due to the internal standard and the solvent, to the area of the peak due to the internal standard; should not greater than R (1.0%)	IP
08.	Sulphated ash	NMT 0.1%	IP

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	24104125	24/04/25	24/04/2025

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NOVO EXCIPIENTS PVT. LTD.	Quality Control Department		
Name of Raw Material	Diethyl Phthalate		
Specification No.	RM/SPEC/HM/011-01		

Sr. No.	TEST	SPECIFICATIONS	REFERENCE
09.	Residue on Ignition	NMT 0.02 %	USP
10.	Refractive index	1.500 - 1.505 at 20° c	USP
11.	Water #	NMT 0.2%	IP/USP
12.	Assay#	99.0% -101.0%	IP
	(on anhydrous basis)	98.0% -102.0%	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	24/04/2025

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