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	Quality Control Department			
Name of Raw Material	Triethyl Citrate			
Specification No.	RM/SPEC/HM/031-01	Supersedes No.	RM/SPEC/031-02	
Reference	IP/USP	Effective Date	19/04/2025	
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

Approved vendor : Please refer current approved vendor list.

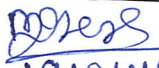
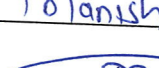
Handling hazards : Refer Material Safety Data Sheet

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.

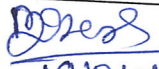
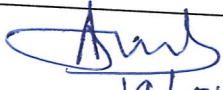
	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Manisha Dhere	Appa S. Shinde	Manish Mahajan
Sign/Date	 19/04/25	 19/04/25	 19/04/25
Designation	SO. Executive	Asst. Manager	Manager
Department	Quality Control	Quality Control	Quality Assurance

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SR

SR. NO.	TEST	SPECIFICATIONS	REFERENCE
01.	Description #	A Clear, Viscous, colourless or almost colourless, hygroscopic liquid. Practically colorless, oily liquid.	IP USP
02.	Solubility	Miscible with ethanol (95%), Soluble in water; slightly soluble in fatty oils. Soluble in water. Miscible with alcohol and with ether.	IP USP
03.	Identification: Test A may be omitted if tests B and C are carried out. Test B and C may be omitted if test A is carried out.		
	Test A: By IR	Compare the spectrum with that obtained with Triethyl Citrate RS or with the reference spectrum of triethyl citrate.	IP/USP
	Test B: Reaction of citrate	i) No precipitate should be produced. ii) A white precipitate soluble in 6 M acetic acid should be produced.	IP
	Test C: Reaction of ester	A bluish-red or red colour should be produced.	IP
	Test D: By Chromatogram	The retention time of the major peak of the sample solution corresponds to that the standard solution.	USP
04.	Appearance of solution	The solution should be clear and should not more intensely coloured than reference solution BYS6	IP
05.	Acidity	Not more than 0.3 ml of 0.1 M sodium hydroxide should be required to change the color of the indicator to blue NMT 1.0 ml of 0.10 N sodium hydroxide should be required.	IP USP
06.	Refractive index	1.440 to 1.446	IP

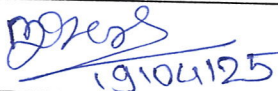
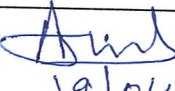
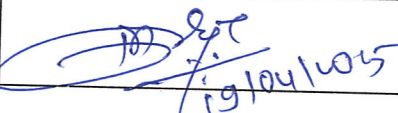
	PREPARED BY	REVIEWED BY	APPROVED BY
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SR. NO.	TEST	SPECIFICATIONS	REFERENCE
07.	Related substances	The area of any secondary peak is not more than 0.2 per cent the area of the principal peak in the chromatogram obtained with the reference solution. The sum of the areas of all the secondary peaks is not more than 0.5 per cent the area of the principal peak in the chromatogram obtained with the reference solution. Ignore any peak with an area less than 0.04 % the area of the principal peak in the chromatogram obtained with the reference solution.	IP
08.	Heavy metals	NMT 5 ppm.	IP
09.	Organic impurities #		USP
	Triethyl aconitrate	NMT 0.2%	
	Individual Impurity	NMT 0.2%	
	Total Impurities	NMT 0.5%	
10.	Sulphated ash	NMT 0.1 %	IP
11.	Water #	NMT 0.25 %	IP/USP
12.	Assay # (On anhydrous basis)	98.5 % - 101.0 %	IP
		97.0 % to 102.0 %	USP
# : Re-evaluation tests			
REVISION HISTORY FOR SPECIFICATIONS			

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	19/04/2025

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 19/04/25	 19/04/25	 19/04/25