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| EXCIPIENTS PVT. LTD. | RAW MATERIAL SPECIFICATION<br>Quality Control Department | | Page No. | 1 of 3 |
|---|---|---|---|---|
| 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** | 19104125 | 19/04/25 | 19/04/2025 |
| **Designation** | Sr. Executive | Asst. Manager | Manager |
| **Department** | Quality Control | Quality Control | Quality Assurance |

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| NOVO EXCIPIENTS PVT. LTD. | RAW MATERIAL SPECIFICATION<br>Quality Control Department | Page No. | 2 of 3 |
|---|---|---|---|
| Name of Raw Material | Triethyl Citrate | | |
| Specification No. | RM/SPEC/HM/031-01 | | |

| SR. NO. | TEST | SPECIFICATIONS | REFERENCE |
|---|---|---|---|
| 01. | Description # | A Clear, Viscous, colourless or almost colourless, hygroscopic liquid. | IP |
| | | Practically colorless, oily liquid. | USP |
| 02. | Solubility | Miscible with ethanol (95%), Soluble in water; slightly soluble in fatty oils. | IP |
| | | Soluble in water. Miscible with alcohol and with ether. | USP |
| 03. | Identification:<br>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.<br>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 | IP |
| | | NMT 1.0 ml of 0.10 N sodium hydroxide should be required. | USP |
| 06. | Refractive index | 1.440 to 1.446 | IP |

| | PREPARED BY | REVIEWED BY | APPROVED BY |
|---|---|---|---|
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| | RAW MATERIAL SPECIFICATION | Page No. | 3 of 3 |
|---|---|---|---|
| novo EXCIPIENTS PVT. LTD. | Quality Control Department | | |
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| Specification No. | RM/SPEC/HM/031-01 | | |

| 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 SPECIFICATION:**

| Revision No. | Revision Description | Effective Date |
|---|---|---|
| 01 | 1) New pharmacopoeial grade document prepared as per approved Change control No. CC/QC/23/002<br>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 |