# Tricholine Citrate

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

**Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.**



## Document History and Schedule for the Adoption Process

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| Further follow-up action as required. | |

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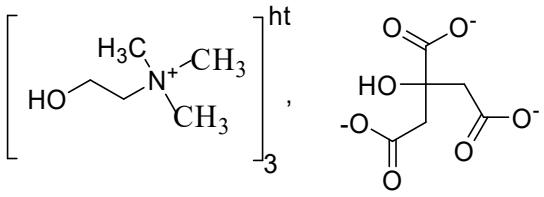

$C_{15}H_{42}N_3O_3$, $C_6H_5O_7$ Mol. Wt. 501.6

Tricholine Citrate is 2-(hydroxyethyl) trimethylammonium citrate.

Tricholine Citrate contains not less than 97.0 per cent and not more than 103.0 per cent of the stated amount of Tricholine citrate, $C_{15}H_{42}N_3O_3$,$C_6H_5O_7$.

**Category**. Hepatoprotectant.

**Description**. A colourless to pale yellow coloured viscous liquid.

## Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *tricholine citrate IPRS* or with the reference spectrum of tricholine citrate.

B. It gives reaction (A) of citrates (2.3.1).

## Tests

**Appearance of solution**. A 1.0 per cent w/v solution is clear (2.4.1), and not more intensely coloured than reference solution BS8 (2.4.1).

**pH** (2.4.24). 6.0 to 7.5, determined in a 10.0 per cent w/v solution.

**Chlorides** (2.3.12). Dissolve 0.36 g in 5 ml of *water*, add 10 ml of *dilute nitric acid*. The resulting solution complies with the limit test for chlorides (700 ppm).

**Specific gravity** (2.4.29). Not less than 1.125 and not more than 1.140 for 50 per cent, not less than 1.160 and not more than 1.180 for 65 per cent w/w and not less than 1.160 and not more than 1.190 for 70 per cent w/w, solution of tricholine citrate.

**Sulphates** (2.3.17). Dissolve 0.3 g in 15 ml of *water* with the addition of 0.15 ml of *5 M acetic acid*, filter. The filtrate complies with the limit test for sulphates (500 ppm).

**Sulphated ash** (2.3.18). Not more than 0.1 per cent.

**Assay**. Determine by liquid chromatography (2.4.14).

*Test solution*. Dissolve 1 g of the substance under examination in the mobile phase with the aid of ultrasound for 2 minutes and dilute to 100.0 ml with the mobile phase.

*Reference solution.* A 1.0 per cent w/v solution of *tricholine citrate IPRS* in the mobile phase.

Chromatographic system
– a stainless steel column 25 cm × 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm),

- mobile phase: a mixture of 88 volumes of a buffer solution prepared by dissolving 2.27 g of *potassium dihydrogen orthophosphate* and 5.8 g of *dipotassium hydrogen phosphate* in 1000 ml of *water*, adjusted to pH 5.7 with 10 per cent v/v solution of *orthophosphoric acid*, 10 volumes of *acetonitrile* and 2 volumes of *methanol,*
- flow rate: 1.1 ml per minute,
- spectrophotometer set at 210 nm,
- injection volume: 20 µl.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{15}H_{42}N_3O_3$,$C_6H_5O_7$.

**Storage**. Store protected from light.