Calcium Orotate

Published on: 08.10.2024 **Last date for comments:** 22.11.2024

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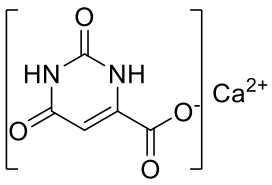
Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls 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

Description	Details
Document version	1.0
Monograph proposed for inclusion	IP 2026
Tentative effective date of monograph	July, 2026
First draft published on IPC website for public comments	08.10.2024
Draft revision published on IPC website for public comments	-
Further follow-up action as required.	

Calcium Orotate



$(C_5H_3N_2O_4)_2.Ca$ Mol. Wt. 350.3

Calcium Orotate is Calcium 2,6-dioxo-1,2,3,6-tetrahydropyrimidine-4-carboxylate.

Calcium orotate contains not less than 98.0 per cent and not more than 102.0 per cent of $2C_5H_3N_2O_4.Ca$, calculated on the dried basis.

Category. Calcium replenisher.

Description. A white to almost white crystalline powder.

Identification

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

B. It gives reaction (B) of calcium (2.3.1).

Tests

pH (2.4.24). 7.0 to 8.5, determined in a 5.0 per cent w/v solution.

Calcium content. Not less than 9.5 per cent and not more than 11.5 per cent, calculated on the dried basis.

Weigh and transfer 0.1 g to a 500-ml conical flask, add 150 ml of *water*, heat to boiling until dissolution is complete. Cool to room temperature, add 1 ml of *0.05M magnesium sulphate* and 15 ml of *ammonia-ammonium chloride buffer*. Titrate with *0.05 M ethylene diamine tetra acetic acid* using *eriochrome black T* as indicator until a clear blue colour is obtained. Carry out a blank titration.

1 ml of 0.05 M ethylene diamine tetra acetic acid is equivalent to 0.0020 g of $(C_5H_3N_2O_4)_2.Ca$.

Orotic acid content. Not less than 88.5 per cent and not more than 90.5 per cent, calculated on the dried basis.

Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 20 mg of substance under examination in 70 ml of *water*, heat on a water bath at 80° for 45 minutes and dilute to 100.0 ml with *water*. Dilute 1.0 ml of the solution to 10.0 ml with *water*.

Reference solution. Dissolve 20 mg of *oratic acid IPRS* in 70 ml of *water*, heat on a water bath at 80° for 45 minutes and dilute to 100.0 ml with *water*. Dilute 1.0 ml of the solution to 10.0 ml with *water*.

Chromatographic system
- a stainless steel column 25 cm × 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a buffer solution prepared by dissolving 27.2 g of *monobasic potassium phosphate* in1000 ml of *water*, adjusted to pH 2.4 with *orthophosphoric acid*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 214 nm,
- injection volume: 20 µl.

Inject the reference solution. The test is not valid unless 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 orotic acid.

Particle size distribution estimation (2.5.7). Not less than 95 per cent passes through sieve 60 mesh, determined on 10 g.

Sulphates (2.3.17). Dissolve 0.75 g in 20 ml of *water*, add 2 ml of *3M hydrochloric acid* and filter, the filtrate complies with the limit test for sulphates (0.02 per cent).

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

Loss on drying (2.4.19). Not more than 1.0 per cent, determined on 1.0 g at 105° for 3 hours.

Assay. Weigh 0.1 g in a 500-ml conical flask, add 150 ml of *water* and sonicate for 15 minutes. Further add 150 ml of *water* and heat to boiling until complete dissolution. Cool to room temperature, add 1 ml of *0.05 M magnesium sulphate* and 15 ml of *ammonia-ammonium chloride buffer*. Titrate with *0.05 disodium edetate* using *eriochrome black T* as indicator until a wine red to clear blue colour is obtained. Carry out a blank titration.

1 ml of 0.05 M disodium edetate is equivalent to 0.019315 g of $(C_5H_3N_2O_4)_2.Ca$.

Storage. Store protected from moisture, at a temperature not exceeding 30°.

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Solubility: Practically insoluble in *water*, in *ethanol (95 per cent)* and in *ether*.