



Citric acid monohydrate

Meets USP-NF, EP, BP, JP and IP Testing Specifications

Product Code: TC454M

Product Description:

Molecular weight: 210.14 Molecular formula: C₆H₈O₇.H₂O

CAS No.: 5949-29-1

Quality Control:

Appearance (USP)

Colorless, translucent crystals, or white granular to fine crystalline powder.

Appearance (JP)

Colorless crystals, white granules or crystalline powder.

Appearance (EP, BP)

White or almost white, crystalline powder, colourless crystals or granules.

Appearance (IP)

Colourless crystals or a white crystalline powder, slightly efflorescent in warm, dry air

Solubility (USP)

Very soluble in water, freely soluble in alcohol, very slightly soluble in ether

Solubility (JP)

Very soluble in water, and freely soluble in ethanol (99.5%)

Solubility (EP, BP)

Very soluble in water, freely soluble in ethanol (96%)

Solubility (IP)

Very soluble in water; freely soluble in ethanol (95%); sparingly soluble in ether

Identification: FTIR (JP)

Matches with the standard pattern (dry the substance at 105°C for 2h)

Identification A (EP, BP)

10% solution in water is strongly acidic

Identification A: FTIR (USP, IP)

Matches with the standard pattern (dry the substance at 105°C for 2 h)

Identification B: FTIR (EP, BP)

Matches with the standard pattern (dry the substance at 105 \pm 2°C for 2h)

Identification B (IP)

Reaction (A) for citrates

Identification C (EP, BP)

A red colour develops

Identification C (**IP**)

10% solution in water is strongly acidic

Identification D (EP, BP)

A white precipitate is formed.

Identification E : Water (EP, BP)

7.50 - 9.00%

Appearance of solution (EP, BP)

The solution is clear and colourless or not more intensely coloured than reference solution Y7, BY7 or GY7

Appearance of solution (IP)

20% w/v solution in water is clear and not more intensely coloured than reference solution YS7, BYS7 or GYS7

Clarity of solution (USP)

The sample solution shows the same clarity as that of water or its opalescence is not more pronounced than standard suspension A

Colour of solution (USP)

The sample solution is not more intensely coloured than standard solution A, B and C

Clarity and color of solution (JP)

The solution is clear and colorless or has no more color than the control solutions (1), (2) or (3).

Readily carbonisable substances (EP, BP)

The solution is not more intensely coloured than a mixture of 1 mL of red primary solution and 9 mL of yellow primary solution

Readily carbonisable substances (USP)

The colour of the acid is nor darker than that of a similar volume of matching fluid K



Readily carbonisable substances (JP)

The solution is not more colored than the matching fluid.

Readily carbonisable substances (IP)

Any colour produced is not more intense than that of a mixture of 1.0 ml of CCS and 9.0 ml of FCS

Oxalic acid (IP)

Any pink colour produced is not more intense than that produced by carrying out the test using 0.2 mg of oxalic acid dissolved in 4 ml of water

Oxalic acid (EP, BP, USP, JP)

<= 0.036%

Sulfates (JP, BP, EP, USP, IP)

<= 0.015%

Iron (IP)

<= 0.005%

Chloride (IP)

<= 0.005%

Barium (IP)

Any opalescence produced is not more intense than that of a mixture of 5 ml of solution A and 5 ml of distilled water

Arsenic (IP)

<= 0.0001%

Calcium (IP)

<= 0.02%

Aluminium (EP, BP, USP)

<= 0.00002%

Heavy metals (JP, IP)

<= 0.0010%

Water (EP, BP, USP, JP, IP)

7.50 - 9.00%

Sulfated ash (EP, BP, IP)

<= 0.10%

Residue on ignition (JP, USP)

 $\leq 0.10\%$

Assay (NaOH Titration, on anhydrous basis): (USP,

EP, BP, JP)

99.50 - 100.50%

Assay (NaOH Titration, on anhydrous basis): IP

99.00 - 101.00%

Bacterial endotoxins test (USP)

Complies

Bacterial endotoxins (EP, BP)

<= 0.50 IU/mg

Storage and Shelf Life:

Store below 30°C.

Shelf life is 48 months.

Use before expiry date given on the product label.

Disclaimer: Revision: 04/2023

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