

Product Data Sheet

Citric Acid Anhydrous

Version: PDS Citric Acid Anhydrous Version 06	Issue date: 01/02/2019	Supersedes versions: 1/10/2015
Reason for issue: 3-yearly update		--> PDS 04 82951 Version 05 Citric Acid Anhydrous Med Gran 1200 PDS 04 83087 Version 05 Citric Acid Anhydrous Fine Gran 700 PDS 04 32938 Version 05 Citric Acid Anhydrous Fine Gran 51N PDS 04 32962 Version 05 Citric Acid Anhydrous Fine Gran 16/40 PDS 04 32717 Version 05 Citric Acid Anhydrous Powder

Appearance

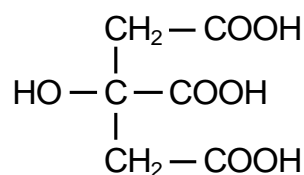
Citric Acid Anhydrous consists of colourless crystals or a white, granular to fine powder, practically odourless, with a strong acid taste.

Product identification

Chemical name: 2-hydroxy-1,2,3-propanetricarboxylic acid

Synonyms: citric acid

CAS No.:	77-92-9
EINECS No.:	201-069-1
E No:	E 330
INCI name:	Citric Acid
Empirical formula:	C ₆ H ₈ O ₇
Molecular mass:	192.12 g/mol



Specifications

Odour	odourless	Barium	< 1 ppm
Identification	meets requirements	Copper	< 1 ppm
Water (K. Fischer)	0.000 – 0.200 %	Zinc	< 1 ppm
Extraneous matter	passes test	Iron	< 1 ppm
Colour (500 g/L, T at 405 nm, 1 cm)	98.00 – 100.00 %	Calcium	< 10 ppm
Appearance of solution	meets EP requirements (visual test)	Magnesium	< 1 ppm
Clarity of solution	meets USP requirements (colour:%T)	Aluminium	< 0.2 ppm
Colour of solution	meets USP requirements (colour:%T)	Chlorides	< 5 ppm
Readily carbonizable substances RCS	meets requirements	Sulphates	< 30 ppm
Heavy metals (sum: Cd, Cr, Cu, Pb, Hg, Zn, Ni)	< 1 ppm	Oxalates / oxalic acid	< 10 ppm
Arsenic	< 1 ppm	Sulphated ash / Residue on ignition	meets FCC requirements (NMT 0.05% on 4g)
Lead	< 0.5 ppm	Assay	99.80 – 100.20 % (on anhydrous substance)
Mercury	< 1 ppm	Tridodecylamine	not applicable for Citrique Belge, only for solvent extracted citric acid

Fineness (ISO standard sieves) / MESH		Product Code
Medium Granular 1200		04 82951
On No. 16 (1180 µm) max. 5%	Through No. 35 (500 µm) max. 10%	
Fine Granular 700		04 83087
On No. 25 (710 µm) max. 5%	Through No. 50 (300 µm) max. 5%	
Fine Granular 51N		04 32938
On No. 30 (600 µm) max. 5%	Through No. 100 (150 µm) max. 5%	
Fine Granular 16/40		04 32962
On No. 40 (425 µm) max. 5%	Through No. 100 (150 µm) max. 5%	
Powder		04 32717
On No. 60 (250 µm) max. 5%	Through No. 200 (75 µm) min. 65%	

Solubility

Citric Acid Anhydrous is very soluble in water, freely soluble in ethanol and sparingly soluble in ether.

Stability and storage

Citric Acid Anhydrous may be stored for 36 months from the date of manufacture in the unopened original packaging (bags and big bags). A relative humidity of 50% and a temperature range of 10 – 30 °C are the most suitable conditions for storage.

Temperatures above 40 °C and a relative humidity above 70% should be avoided in order to prevent caking, especially the Fine Granular 51 N and 16/40 and Powder forms. The stacking of the Fine Granular 51 N and 16/40 and Powder forms for long periods is not recommended.

Stability tests have shown that citric acid anhydrous is chemically stable for at least five years in tightly closed packaging under proper storage conditions.

Uses

- As an acidulant, flavour enhancer and sequestering agent in food applications and beverages, and as a synergist in antioxidant mixtures.
- For cosmetics and personal care products.
- For pharmaceutical preparations, especially effervescent tablets.
- This product is not intended for use in the manufacture of sterile drug products. The purchaser assumes all responsibility for additional processing, testing, labelling and registration required for such use.

Compendial compliance

Citric Acid Anhydrous meets all requirements of the USP, FCC, Ph. Eur., JP, JECFA and the Commission regulation (EC) No 231/2012 when tested according to the latest versions of these compendia.

Citric Acid Anhydrous is classified as a GRAS (Generally Recognized As Safe) substance following the US Food and Drug Administration (FDA).

Safety

This product is safe for the intended use. Avoid inhalation of dust, contact with eyes and prolonged contact with skin by applying suitable protective measures and personal hygiene.

For full safety information and necessary precautions, please refer to the respective Material Safety Data Sheet.

Legal notice

The information given in this publication is based on our current knowledge and experience, and may be used at your discretion and risk. It does not relieve you from carrying out your own precautions and tests. We do not assume any liability in connection with your product or its use. You must comply with all applicable laws and regulations, and observe all third party rights.

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Specifications and Tests

Citric Acid Anhydrous

Version: Citric Acid Anhydrous Version 03	Issue date: 01/10/2015	Supersedes versions: 2009-05-05
Reason for issue: Adaptation to update of the latest pharmacopoeia and regulations		PC 04 82951 Version 02 Citric Acid Anhydrous Med Gran 1200 PC 04 83087 Version 02 Citric Acid Anhydrous Fine Gran 700 PC 04 32938 Version 02 Citric Acid Anhydrous Fine Gran 51N PC 04 32962 Version 02 Citric Acid Anhydrous Fine Gran 16/40 PC 04 32717 Version 02 Citric Acid Anhydrous Powder

Parameter	Specification	Test Method
Appearance	Colourless crystals or white, granular to fine powder	visual test
Odour	Odourless	Odour test
Identification	Meets requirements	First Identification : B , E Second Identification : A , C , D , E Proceed according to the Identification Tests A (dissolve), E (water) and B (IR spectrum 1/year by an external lab) described in the monograph "Citric Acid Anhydrous" of Ph. Eur. Identification C : not applicable in CB – colour reaction Identification D : not applicable in CB – precipitation reaction
Water	Max. 0.2%	Karl Fischer titration: Proceed according to the test described in the monograph "Anhydrous Citric Acid" of Ph. Eur.
Extraneous matter	Passes CB test	Dissolve about 250 g Citric Acid in 600 ml pure demineralized water. Filter on a 0.8 µm membrane filter. The surface of the filter has to remain practically white without obnoxious particles or detrimental particles and has essentially no physical matter.

Note: CB = Citrique Belge

Parameter	Specification	Test Method
Heavy metals	< 1 ppm (sum of Cd, Cr, Cu, Pb, Hg, Zn, Ni)	Inductively Coupled Plasma (ICP) 1. Reagents a) Standard Solutions: Titrisol Merck (1.0 g/l) b) Citric Acid, free of cations, sulphate and other acids c) Intermediate Solution 1 Pipet 1.0 ml each of the following standard solutions: Al, As, Ba, Ca, Cd, Cr, Cu, Fe, Mg, Mn, Ni, Pb, Si, and Zn and dilute to 100 ml with twice deionized water d) Intermediate Solution 2 Pipet 1 ml of the Hg standard solution and dilute to 100.0 ml with twice deionized water 2. Procedure a) Sample preparation Dissolve 10 g of Citric Acid in 100 ml twice deionized water b) Standard preparation To 10 g of Citric Acid (2.b) add 5 ml Intermediate Solution 1, 0.1 ml standard solution of K, 0.3 ml standard solution of SO ₄ , 0.5 ml Intermediate Solution 2 and dilute to 100 ml with twice deionized water. c) Blank Dissolve 10 g of Citric Acid (2.b) in 100 ml of twice deionized water.
Arsenic	< 1 ppm	Proceed as described under Heavy metals
Lead	< 0.5 ppm	Proceed as described under Heavy metals
Mercury	< 1 ppm	Proceed as described under Heavy metals
Copper	< 1 ppm	Proceed as described under Heavy metals
Zinc	< 1 ppm	Proceed as described under Heavy metals
Iron	< 1 ppm	Proceed as described under Heavy metals
Barium	< 1 ppm	Proceed as described under Heavy metals
Calcium	< 10 ppm	Proceed as described under Heavy metals

Parameter	Specification	Test Method																
Magnesium	< 1 ppm	Proceed as described under Heavy metals																
Aluminium	< 0,2 ppm	Proceed as described under Heavy metals																
Chlorides	< 5 ppm	By nephelometry																
Sulphates	< 30 ppm	Proceed as described under Heavy metals																
Oxalates	< 10 ppm	<p>High Performance Liquid Chromatography (HPLC)</p> <p>a) Apparatus</p> <table> <tr> <td>Pump</td> <td>Dionex ICS-5000 EG</td> </tr> <tr> <td>Injection system</td> <td>AS-AP</td> </tr> <tr> <td>Column</td> <td>Ion Pac AS17-C (DIONEX) 250 x 2.0 mm i.d.</td> </tr> <tr> <td>Detector</td> <td>conductivity detector(DIONEX)</td> </tr> </table> <p>b) Working conditions</p> <table> <tr> <td>Mobile phase 1</td> <td>twice deionized water</td> </tr> <tr> <td>Mobile phase 2</td> <td>KOH EG</td> </tr> <tr> <td>Flow rate</td> <td>0.3 ml / min</td> </tr> <tr> <td>Injected volume</td> <td>6 µl</td> </tr> </table> <p>c) Standards</p> <p>Gradient from 15 % to 80 % of eluent 2 in 40 min.</p> <p>Oxalic acid standard: dissolve 140 mg of oxalic acid in 1000 ml of twice deionized water.</p> <p>Citric Acid standard: dissolve 10 g of Citric Acid free of cations, sulphates and other acids in 100 ml of twice deionized water.</p> <p>Mix oxalic acid standard with Citric Acid standard to obtain concentrations of 0, 5, 10, 20 and 50 mg of oxalic acid per kg of citric acid.</p> <p>d) Sample Solution</p> <p>Dilute 10 g of sample in 100 ml of twice deionized water</p>	Pump	Dionex ICS-5000 EG	Injection system	AS-AP	Column	Ion Pac AS17-C (DIONEX) 250 x 2.0 mm i.d.	Detector	conductivity detector(DIONEX)	Mobile phase 1	twice deionized water	Mobile phase 2	KOH EG	Flow rate	0.3 ml / min	Injected volume	6 µl
Pump	Dionex ICS-5000 EG																	
Injection system	AS-AP																	
Column	Ion Pac AS17-C (DIONEX) 250 x 2.0 mm i.d.																	
Detector	conductivity detector(DIONEX)																	
Mobile phase 1	twice deionized water																	
Mobile phase 2	KOH EG																	
Flow rate	0.3 ml / min																	
Injected volume	6 µl																	
Readily Carbonizable Substances RCS	meets requirements	Proceed according to the test described in the monograph "Citric Acid Anhydrous" of Ph. Eur. (followed by colorimetry)																

Parameter	Specification	Test Method
Sulphated Ash	meets requirements	Proceed according to the test "Residue on Ignition" described in the monograph "Citric Acid" of FCC (weight = 4 g – 0.05% sulphated ash).
Tridodecylamine:	Not tested method	Not applicable for Citrique Belge : only for solvent extracted citric acid
Colour	min 98 %	(500 g/ l, T at 405 nm in a 1 cm cell) Clarity of solution : meets USP requirements (colour: %T) Colour of solution : meets USP requirements (colour: %T)
Appearance of solution	Meets requirements	Visual test: Proceed according to the test described in the monograph "Citric Acid Anhydrous" of Ph. Eur.: The solution is clear and colourless or not more intensely coloured than reference solution Y ₇ , BY ₇ or GY ₇
Assay	99.8 - 100.2 % (on anhydrous substance)	Dissolve 0.550 g of Citric Acid in 50 ml of water. Using 0.5 ml of phenolphthalein solution as indicator, titrate with 1N sodium hydroxide until a pink colour is obtained.--> potentiometric titration :1 g of sample, 0.5 N NaOH 1 ml of 1N (2 ml of 0.5N) sodium hydroxide is equivalent to 64.03 mg of Citric Acid.

Fineness (ISO standard sieves) / MESH

Medium Granular 1200	On 1180 µm Through 500 µm	max. 5% max.10%	Sieving with dish
Fine Granular 700	On 710 µm Through 300 µm	max. 5% max. 5%	Sieving with dish
Fine Granular 51N	On 600 µm Through 150 µm	max. 5% max. 5%	Sieving with dish
Fine Granular 16/40	On 425 µm Through 150 µm	max. 5% max. 5%	Sieving with dish
Powder	On 250 µm Through 75 µm	max. 5% min. 65%	Air-jet Sieving

Prodotto distribuito da:

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