

FICHA TÉCNICA

ÁCIDO CÍTRICO ANHIDRO

Product Specification

Citric Acid Anhydrous

Food & Pharmaceutical Grade (conforms to Ph. Eur. / USP / FCC / EU)

Product name	Citric acid anhydrous	C ₆ H ₈ O ₇
EC No.	201-069-1	
CAS No.	77-92-9	
E-No.	E 330	
Characteristics	Colourless crystals or a white, crystalline powder; very soluble in water, freely soluble in ethanol (96%), sparingly soluble in ether	
Odour	typical, practically odourless	
Identification	conforms	
Appearance of solution	clear and colourless	
Clarity of solution	conforms	
Colour of solution	conforms	
Readily carbonisable substances	conforms	
Oxalic acid / oxalate	max. 100 mg/kg	
Sulphate	max. 100 mg/kg	
Heavy metals	max. 5 mg/kg	
Arsenic	max. 1 mg/kg	
Lead	max. 0.5 mg/kg	
Mercury	max. 0.5 mg/kg	
Calcium	max. 30 mg/kg	
Iron	max. 3 mg/kg	
Chloride	max. 5 mg/kg	
Residue on ignition	max. 0.05 %	
Sulphated ash	max. 0.05 %	
Water	max. 0.50 %	
Assay	99.7 - 100.3 %	

We herewith confirm that this product meets the requirements of the latest edition of the European Pharmacopoeia (Ph. Eur.), the United States Pharmacopeia (USP), the Food Chemicals Codex (FCC) and of Commission Regulation (EU) No 231/2012. All analytical methods are in accordance with the latest requirements of the Ph. Eur., the USP, the FCC or are equivalent. Test methods are available on request.



Microbiological Data

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Total Aerobic Microbial Count (TAMC)	max. 10 ³ CFU /g
Total Combined Yeasts / Moulds Count (TYMC)	max. 10 ² CFU / g
Staphylococcus Aureus	negative / 1 g
Escherichia Coli	negative / 5 g
Salmonella	negative / 10 g
Bile-Tolerant Gram-Negative Bacteria	negative / 5 g

Jungbunzlauer has voluntarily set a microbiological specification for citric acid anhydrous in order to comply with the Ph. Eur. Requirements on the Microbiological Quality of Non-Sterile Pharmaceutical Preparations and Substances for Pharmaceutical use. Jungbunzlauer guarantees to meet the limits of the corresponding Ph. Eur. Monograph 5.1.4. The test methods have been adopted and validated for our products according to Ph. Eur. 7.0:2011. The microbiological testing is performed once per quarter by an external accredited laboratory. However, these parameters are not release criteria and they do not appear on the Certificate of Analysis of our standard materials.



Nutritional Data

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Nutrition declaration according Regulation (EU) No. 1169/2011		
Typical values based on 100 g of Citric Acid Anhydrous		
Energy:		1300 kJ / 300 kcal
Fat:		- g
of which		
- saturates		- g
- mono-unsaturates		- g
- polyunsaturates		- g
Carbohydrate:		- g
of which		
- sugars		- g
- polyols		- g
- starch		- g
Fibre:		- g
Protein:		- g
Salt:		
- sodium		< 0.2 mg
Organic acid:		~ 99.9 g
Moisture content:		~ 0.1 g
Vitamins:		none
Minerals:		
- Potassium		< 0.1 mg
- Chloride		< 0.5 mg
- Calcium		< 0.1 mg
- Phosphorus		< 0.3 mg
- Magnesium		< 0.1 mg
- Iron		< 0.1 mg
- Zinc		< 0.1 mg
- Copper		< 0.05 mg
- Manganese		< 0.05 mg
- Fluoride		< 5 mg
- Selenium		< 0.1 mg
- Chromium		< 0.05 mg
- Molybdenum		< 0.1 mg
- Iodine		- µg



Granulation Specification

Citric Acid Anhydrous

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Standard Granulations manufactured in Pernhofen, Austria

N1560	> 1.25 mm	corresponds to	max. 5%
	< 0.40 mm		max. 10%
	on 14 mesh		max. 5%
	through 45 mesh		max. 10%
N1500	> 1.25 mm	corresponds to	max. 5%
	< 0.20 mm		max. 10%
	on 14 mesh		max. 5%
	through 100 mesh		max. 10%
F6000	> 0.63 mm	corresponds to	max. 10%
	< 0.20 mm		max. 10%
	on 25 mesh		max. 10%
	through 100 mesh		max. 10%

These specifications refer to our standardized sieving procedure. Only the mm-values are valid. The mesh-values are calculated and are meant for information. The detailed method is available on request.



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Special Granulations manufactured in Pernhofen, Austria

G3015	> 2.8 mm		max. 10%
	< 0.8 mm		max. 10%
	on 7 mesh	corresponds to	max. 10%
	through 25 mesh		max. 10%
F7040	> 0.71 mm		max. 5%
	< 0.40 mm		max. 5%
	on 25 mesh	corresponds to	max. 5%
	through 45 mesh		max. 5%
F6040	> 0.60 mm		max. 5%
	< 0.20 mm		max. 5%
	on 30 mesh	corresponds to	max. 5%
	through 100 mesh		max. 5%
F5020	> 0.50 mm		max. 5%
	< 0.20 mm		max. 5%
	on 35 mesh	corresponds to	max. 5%
	through 100 mesh		max. 5%
F4020	> 0.40 mm		max. 5%
	< 0.20 mm		max. 15%
	on 40 mesh	corresponds to	max. 5%
	through 100 mesh		max. 15%

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F3500	> 0.355 mm		max. 5%
	< 0.075 mm		max. 5%
	on 45 mesh	corresponds to	max. 5%
	through 200 mesh		max. 5%
F2500	> 0.250 mm		max. 20%
	< 0.125 mm		max. 20%
	on 60 mesh	corresponds to	max. 20%
	through 120 mesh		max. 20%
F0000	> 0.18 mm		max. 20%
	on 80 mesh	corresponds to	max. 20%
F0001	> 0.40 mm		0%
	> 0.18 mm		max. 7%
	on 40 mesh	corresponds to	0%
	on 80 mesh		max. 7%

These specifications refer to our standardized sieving procedure. Only the mm-values are valid. The mesh-values are calculated and are meant for information. The detailed method is available on request.



Shelf Life and Storage Conditions

Citric Acid, Trisodium Citrate

This information refers to following Jungbunzlauer products:

- Citric acid anhydrous
- Citric acid monohydrate
- Trisodium citrate anhydrous
- Trisodium citrate dihydrate

Storage Conditions

Citric acid and trisodium citrate should be stored in original packaging or tight containers in a cool and dry place.

Recommended temperature: max. 30°C

Recommended relative humidity: max. 70 %

Prolonged storage at higher temperatures and/or higher humidity should be avoided in order to prevent caking.

Shelf Life

A shelf life of 3 years (till end of the month) from the date of manufacturing has been defined for above mentioned products. This shelf life is guaranteed if the product is stored in the originally closed bag or tight containers under the above described storage conditions.

In the calculation of the shelf life, short-term excursions during transport of the product have been taken into consideration. The shelf-life is conditional upon compliance at all times by the customer with the above mentioned storage conditions.

Physical properties may change on prolonged storage, thus a retest is recommended after the mentioned shelf life period.

Expiry Date

The expiry date is consequently 3 years (till end of the month) after the date of production.

On the packaging of citric acid anhydrous, citric acid monohydrate, trisodium citrate dihydrate and trisodium citrate anhydrous the production and expiry date are mentioned as follows:

- Production date (YY/MM/DD)
- Expiry date (YY/MM)

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