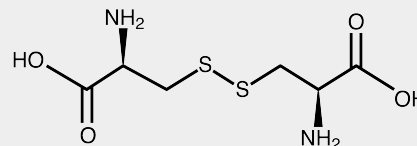


FERMOPURE[®] L-CYSTINE PHARMA Low Sulfate

Cystine products

Description: a white or almost white, crystalline powder, practically insoluble in water and alcohol. It dissolves in dilute solutions of alkali hydroxides. L-Cystine is the amino acid dimer formed when a pair of L-Cysteine molecules are joined by a disulfide bond through oxidation. L-Cysteine is one of the 20 natural amino acids and, besides methionine, the only one which contains sulfur. WACKER has developed a new production method for L-Cystine via fermentation from non-animal and non-human raw materials.



CAS No. 56-89-3 | Empirical formula C₆H₁₂N₂O₄S₂ | Molecular weight 240.30

Properties

Content min. 98.5 – 101.0%
Complies with current Eur.Ph. and FCC specifications
Non-GMO microorganisms
BSE/TSE-free
Natural according
Regulation
1334/2008/EC
Origin: vegetarian fermentation
Kosher certified
Halal certified

Technical data

Specification

Property	Condition	Value	Method
Ammonium	-	max. 0.02 %	PH. EUR. (2.2.56)
Appearance	-	positive	Visual Control
Appearance of solution	-	colorless, clear liquid	PH. EUR. (2.2.1)
Arsenic	-	max. 1 ppm	PH. EUR. (2.4.2/A)
Assay	-	98.5 - 101.0 %	PH. EUR. (2.2.20)
Chloride	-	max. 200 ppm	PH. EUR.
Heavy metals	-	max. 10 ppm	PH. EUR. (2.4.8/D)
Identification A,B	-	positive	PH. EUR.
Iron	-	max. 10 ppm	PH. EUR. (2.4.9)
Lead	-	max. 5 ppm	PH. EUR. (2.4.8/D)
Loss on drying	-	max. 0.2 %	PH. EUR. (2.2.32)
Ninhydrin-pos.-substances: for each imp.	-	max. 0.2 %	PH. EUR. (2.2.56)
Residue on ignition	-	max. 0.1 %	PH. EUR. (2.4.14)
Specific rotation [α] _{20/D}	-	-224 - -218 °	PH. EUR. (2.2.7)
Sulfate	-	max. 280 ppm	PH. EUR. (2.4.13)
any Ninhydrin-positive substances: total	-	max. 0.5 %	PH. EUR. (2.2.56)

General Characteristics

Property	Condition	Value	Method
Solubility in water	20 °C	0.122 g/l	EU-GL.A.6
pH-Value (0,04 g/l H ₂ O)	-	5 - 6.5	specific method

These figures are only intended as a guide and should not be used in preparing specifications.

All the information provided is in accordance with the present state of our knowledge. Nonetheless, we disclaim any warranty or liability whatsoever and reserve the right, at any time, to effect technical alterations. The information provided, as well as the product's fitness for an intended application, should be checked by the buyer in preliminary trials. Contractual terms and conditions always take precedence. This disclaimer of warranty and liability also applies particularly in foreign countries with respect to third parties' rights.

Compliance

Full compliance info plus certificates can be downloaded from the product website.

- ✓ FSSC 22000
- ✓ Kosher certified
- ✓ Halal
- ✓ Kosher Certificate

Applications

- Pharma
- Excipients & Auxiliaries

Application details

- Excipient for API synthesis, e.g. expectorants
- Essential ingredient in cell culture media

Packaging and storage

Packaging

Units of 25 kg

Storage

L-CYSTINE Low Sulfate has a shelf life of at least 36 months when stored in unbroken original packaging in dry storage areas.

The best use before date of each batch is shown on the product label. Storage beyond the date specified on the label does not necessarily mean that the product is no longer usable. In this case however, the properties required for the intended use must be checked for quality assurance reasons.

Safety notes

Comprehensive instructions are given in the corresponding Material Safety Data Sheets. They are available on request from WACKER subsidiaries or may be printed via WACKER web site <http://www.wacker.com>.

QR Code FERMOPURE® L-CYSTINE PHARMA Low Sulfate



For technical, quality or product safety questions, please contact:

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The data presented in this medium are in accordance with the present state of our knowledge but do not absolve the user from carefully checking all supplies immediately on receipt. We reserve the right to alter product constants within the scope of technical progress or new developments. The recommendations made in this medium should be checked by preliminary trials because of conditions during processing over which we have no control, especially where other companies' raw materials are also being used. The information provided by us does not absolve the user from the obligation of investigating the possibility of infringement of third parties' rights and, if necessary, clarifying the position. Recommendations for use do not constitute a warranty, either express or implied, of the fitness or suitability of the product for a particular purpose.