

**ACETIL CISTEINA (EUR. PH.)**

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|------------------------------------|--------------------------------|---------------------|
| PRODUCT CODE: 151358 | CAS Nº: 616-91-1 | ANALYSIS Nº: 190/23 |
| MANUFACTURER BATCH: C103-202207113 | CERTIFICATE ID: 38.871 | |
| SUPPLIER BATCH: 221014 836 | MANUFACTURING DATE: 29/07/2022 | |
| METAPH BATCH: 0320623 | RETEST DATE: 22/07/2025 | |

| ATTRIBUTES | SHOULD BE | IS |
|---------------------------|--|------------------------------|
| Appearance | White or almost white crystalline powder or colorless crystals | White crystalline powder (*) |
| Solubility | Freely soluble in water and in ethanol (96 %), practically insoluble in methylene chloride | Complies |
| Identification A | Complies | Complies (*) |
| Identification C | Complies | Complies (*) |
| Appearance of solution | Clear and colourless | Clear and colourless |
| pH | 2.0 - 2.8 | Complies |
| Specific optical rotation | +21.0° / +27.0° | + 23.7 (*) |
| Related substances | | |
| Impurity C | =< 0.3 % | < 0.3 % |
| Impurity B | =< 0.2 % | < 0.2 % |
| Impurity D | =< 0.15 % | < 0.15 % |
| Unspecified impurities | =< 0.10 % | < 0.10 % |
| Total impurities | =< 0.5 % | < 0.5 % |
| Zinc | =< 10 ppm | < 1 ppm |
| Loss on drying | =< 1.0 % | 0.2 % |
| Sulfated ash | =< 0.2 % | 0.1 % |
| Assay | 98.5 - 101.0 % | 98.6 % |

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

(*) Data controlled by Metapharmaceutical Industrial SL.

Acetylcysteine is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

The product is not of animal origin and no animal product is used in its production, so it is risk-free BSE/TSE.

The product is not derived from GMO. No genetically modified organism is used in its production and no GMO product comes in contact with the product during any stage of production.

STORAGE

Keep tightly closed and in a dry, cool and well-ventilated place.

Analysis date: 11/07/2023

Signature: Cristina Borrell Olea (QA/QP)

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000685

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