



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 242137

| | |
|--------------------|------------------------------|
| Product: | ACETYL CYSTEINE |
| Lot: | 242137 |
| Expiry date: | 29/04/2027 |
| Reference: | Cumple PhEur11.5 |
| Synonyms: | N-Acetil-3-mercaptopalanina. |
| Formule: | C5H9NO3S |
| Poids moléculaire: | 163,2 g/mol |

| Assay | Result | Specification | |
|---------------------------|---------------|-------------------|---|
| Identification | Conform (A,C) | | |
| Organoleptic properties | Conform | | |
| Appearance of solution S | Conform | | |
| Specific rotation | (+23,3) | (+21,0) - (+27,0) | |
| Related substances (HPLC) | Conform | | |
| Zinc | < 10 ppm | <= 10 ppm | |
| Loss on drying | 0,02 % | <= 1,0 % | |
| Sulphated ashes | 0,02 % | <= 0,2 % | |
| Assay | 99,9 % | 98,5 - 101,0 % | |
| Elemental impurities | Conform | Test PhEur | # |
| Impurity B | < 0,05 % | <= 0,2 % | |
| Impurity C | 0,06 % | <= 0,3 % | |
| Impurity D | < 0,05 % | <= 0,15 % | |
| Any other impurity | < 0,05 % | <= 0,10 % | |
| Total impurities | 0,06 % | <= 0,5 % | |
| Organic solvents residues | Conform | Test PhEur | # |
| Nitrosamine impurities | Conform | | # |

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 13/12/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00312 WUHAN GRAND HOYO CO., LTD

Manufacturer batch: C103-202404644F

| | | | |
|---------|----------------|----------|------------|
| Produit | Nom | Capacité | Lot |
| 1100954 | ACETILCISTEINA | 25 g | 242137-G-1 |

| | | | |
|---------|----------------|-------|------------|
| 1100954 | ACETILCISTEINA | 25 g | 242137-G-2 |
| 1100955 | ACETILCISTEINA | 100 g | 242137-J-1 |
| 1100955 | ACETILCISTEINA | 100 g | 242137-J-2 |
| 1100958 | ACETILCISTEINA | 1 kg | 242137-P-1 |
| 1100958 | ACETILCISTEINA | 1 kg | 242137-P-2 |

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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