



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251970

| | |
|-------------------|------------------|
| Product: | TRANEXAMIC ACID |
| Lot: | 251970 |
| Expiry date: | 19/07/2030 |
| Reference: | Cumple PhEur11.8 |
| Synonyms: | |
| Formula: | C8H15NO2 |
| Molecular weight: | 157.2 g/mol |

| Assay | Result | Specification | |
|--------------------------------|------------|----------------|---|
| Identification | Conform | | |
| Organoleptic properties | Conform | PhEur | |
| pH | 7,5 | 7,0 - 8,0 | |
| Related substances (HPLC) | Conform | Test PhEur | |
| Loss on drying | 0,05 % | <= 0,5 % | |
| Sulphated ashes | 0,01 % | <= 0,1 % | |
| Halides expressed as chlorides | <= 140 ppm | <= 140 ppm | |
| Elemental impurities | Conform | Test PhEur | # |
| Assay | 99,8 % | 99,0 - 101,0 % | |
| Impurity B | < 0,03 % | <= 0,15 % | |
| Impurity C | < 0,01 % | <= 0,05 % | |
| Impurity D | < 0,03 % | <= 0,05 % | |
| Impurity E | < 0,01 % | <= 0,05 % | |
| Impurity F | < 0,01 % | <= 0,05 % | |
| Unspecified Impurities | < 0,03 % | <= 0,05 % | |
| Total impurities | < 0,03 % | <= 0,2 % | |
| Residual solvents | Conform | Test PhEur | # |
| Nitrosamine impurities | Conform | Test PhEur | # |

Organoleptic characteristics: White or almost white, crystalline powder. Freely soluble in water and in glacial acetic acid, practically insoluble in acetone and in ethanol (96 per cent).

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 31/10/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00419 HUNAN DONGTING PHARMACEUTICAL Co., Ltd.

Manufacturer batch: X2508304M

| Product | Name | Capacity | Batch |
|---------|-------------------------|----------|------------|
| 1130600 | ACIDO TRANEXAMICO | 10 g | 251970-F-1 |
| 1130600 | ACIDO TRANEXAMICO | 10 g | 251970-F-2 |
| 1130601 | ACIDO TRANEXAMICO | 25 g | 251970-G-1 |
| 1130601 | ACIDO TRANEXAMICO | 25 g | 251970-G-3 |
| 1130602 | ACIDO TRANEXAMICO | 100 g | 251970-J-1 |
| 1130602 | ACIDO TRANEXAMICO | 100 g | 251970-J-2 |
| 1130603 | ACIDO TRANEXAMICO | 250 g | 251970-N-1 |
| 1130603 | ACIDO TRANEXAMICO | 250 g | 251970-N-2 |
| 1130604 | ACIDO TRANEXAMICO | 1 kg | 251970-P-1 |
| 1130604 | ACIDO TRANEXAMICO | 1 kg | 251970-P-2 |
| 1370254 | ACIDO TRANEXAMICO (FLB) | 25 g | 251970-G-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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