



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241523

| | |
|--------------------|------------------|
| Product: | GABAPENTIN |
| Lot: | 241523 |
| Expiry date: | 28/02/2027 |
| Reference: | Cumple PhEur11.5 |
| Synonyms: | |
| Formule: | C9H17NO2 |
| Poids moléculaire: | 171,24 g/mol |

| Assay | Result | Specification | |
|-----------------------------------|------------|---------------|---|
| pH | 7,2 | 6,5 - 7,5 | |
| Water | 0,02 % | <= 0,3% | |
| Organoleptic properties | Conform | PhEur | |
| Residual solvent: Ethanol | < 5000 ppm | <=5000 ppm | # |
| Appearance of solution | Conform | Test PhEur | |
| Nitrosamine impurities | Conform | Test PhEur | # |
| Unspecified impurities (test B) | < 0,05 % | <= 0,05 % | |
| Identification | Conform | Test PhEur | |
| Total impurities (sum test A + B) | 0,01 % | <= 0,5 % | |
| Impurity A | 0,01 % | <= 0,15 % | |
| Unspecified impurities (test A) | < 0,05 % | <= 0,10 % | |
| Assay (HPLC) | 100,3 % | 97,5-102,0% | |
| Sulphated ashes | 0,00 % | <= 0,1% | |
| Chlorides | 20 ppm | <= 100 ppm | |
| Elemental impurities | Conform | Test PhEur | # |
| Related substances (HPLC) | Conform | Test PhEur | |

Organoleptic characteristics: White or almost white, crystalline powder. sparingly soluble in water, slightly soluble in ethanol (96 per cent), practically insoluble in methylene chloride. It dissolves in dil. aci. and dil solutions of alkali hydrox.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 02/08/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00446 ZHEJIANG CHIRAL MEDICINE CHEMICALS, Co., Ltd.

Manufacturer batch: GAA-2403025

Produit

Nom

Capacité

Lot

| | | | |
|---------|-------------------|-------|------------|
| 1115246 | GABAPENTINA | 10 g | 241523-F-1 |
| 1115246 | GABAPENTINA | 10 g | 241523-F-2 |
| 1115246 | GABAPENTINA | 10 g | 241523-F-3 |
| 1115248 | GABAPENTINA | 50 g | 241523-I-1 |
| 1115248 | GABAPENTINA | 50 g | 241523-I-3 |
| 1115248 | GABAPENTINA | 50 g | 241523-I-4 |
| 1115250 | GABAPENTINA | 250 g | 241523-N-1 |
| 1115250 | GABAPENTINA | 250 g | 241523-N-2 |
| 1115250 | GABAPENTINA | 250 g | 241523-N-3 |
| 1115252 | GABAPENTINA | 1 kg | 241523-P-1 |
| 1115252 | GABAPENTINA | 1 kg | 241523-P-3 |
| 1115253 | GABAPENTINA | 5 kg | 241523-Q-1 |
| 1115253 | GABAPENTINA | 5 kg | 241523-Q-3 |
| 1115253 | GABAPENTINA | 5 kg | 241523-Q-4 |
| 1370173 | GABAPENTINA (FLB) | 1 kg | 241523-P-2 |
| 1370216 | GABAPENTINA (FLB) | 5 kg | 241523-Q-2 |
| 1370240 | GABAPENTINA (FLB) | 50 g | 241523-I-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

ACOFARMA DISTRIBUCIÓN, S.A.
C/ Llobregat, 20 - 08223 Terrassa (Barcelona)
Tel./ 93-736.00.88
www.acofarma.com

Date d'édición: 05/04/2025

