



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240976

| | |
|-------------------|------------------|
| Product: | GABAPENTIN |
| Lot: | 240976 |
| Expiry date: | 28/02/2027 |
| Reference: | Cumple PhEur11.4 |
| Synonyms: | |
| Formula: | C9H17NO2 |
| Molecular weight: | 171,24 g/mol |

| Assay | Result | Specification | |
|-----------------------------------|------------|---------------|---|
| Identification | Conform | Test PhEur | |
| Organoleptic properties | Conform | PhEur | |
| Appearance of solution | Conform | Test PhEur | |
| pH | 7,1 | 6,5 - 7,5 | |
| Water | 0,02 % | <= 0,3% | |
| Elemental impurities | Conform | Test PhEur | # |
| Related substances (HPLC) | Conform | Test PhEur | |
| Sulphated ashes | 0,01 % | <= 0,1% | |
| Chlorides | 20 ppm | <= 100 ppm | |
| Assay (HPLC) | 100,2 % | 97,5-102,0% | |
| Impurity A | 0,01 % | <= 0,15 % | |
| Unspecified impurities (test A) | < 0,05 % | <= 0,10 % | |
| Unspecified impurities (test B) | 0,03 % | <= 0,05 % | |
| Total impurities (sum test A + B) | 0,04 % | <= 0,5 % | |
| Residual solvent: Ethanol | < 5000 ppm | <=5000 ppm | # |
| Nitrosamine impurities | 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: 30/05/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00446

Manufacturer batch: GAA-2403009

| Product | Name | Capacity | Batch |
|---------|------|----------|-------|
|---------|------|----------|-------|

| | | | |
|---------|-------------|-------|------------|
| 1115248 | GABAPENTINA | 50 g | 240976-I-1 |
| 1115250 | GABAPENTINA | 250 g | 240976-N-1 |
| 1115252 | GABAPENTINA | 1 kg | 240976-P-1 |
| 1115253 | GABAPENTINA | 5 kg | 240976-Q-1 |

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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