



METAPHARMACEUTICAL

N DE LOTE:

0141023

18/10/2023

MENADIONA

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CERTIFICATE OF ANALYSIS

CA.EP.3099/005/21

| | | | |
|----------------------|--|----------------|--------------|
| Product name: | GABAPENTIN | CAS Number: | [60142-96-3] |
| Chemical name: | 1-(Aminomethyl)cyclohexanecarboxylic acid | | |
| Molec. Formula: | C ₉ H ₁₇ NO ₂ | Molec. Weight: | 171.24 |
| Batch N°: | 3099/31473 | | |
| Date of Manufacture: | FEB-2023 | Retest Date: | JAN-2028 |

| TESTS | SPECIFICATIONS | RESULTS |
|------------|--|----------|
| Appearance | White or almost white, crystalline powder. | Complies |
| Solubility | Sparingly soluble in water, slightly soluble in ethanol (96 per cent), practically insoluble in methylene chloride. | Complies |

Identification

| | | |
|---------------------|---|----------|
| Infrared Absorption | Matches with the <i>Gabapentin</i> CRS. | Complies |
|---------------------|---|----------|

Appearance of solution

| | | |
|-----------------------|---------------------------------------|----------|
| Degree of opalescence | Not more than reference suspension I. | Complies |
|-----------------------|---------------------------------------|----------|

| | | |
|----------------------|---|----------|
| Degree of coloration | Not more than reference solution B ₉ . | Complies |
|----------------------|---|----------|

| | | |
|----|------------|-----|
| pH | 6.5 to 7.5 | 7.2 |
|----|------------|-----|

| | | |
|-----------|-----------------------|--------|
| Chlorides | Not more than 100 ppm | 21 ppm |
|-----------|-----------------------|--------|

| | | |
|-------|--------------------|-------|
| Water | Not more than 0.3% | 0.06% |
|-------|--------------------|-------|

| | | |
|---------------|--------------------|-------|
| Sulphated ash | Not more than 0.1% | 0.01% |
|---------------|--------------------|-------|

| | | |
|----------------|--------------------|-------|
| Loss on drying | Not more than 0.5% | 0.01% |
|----------------|--------------------|-------|

| | | |
|---------------|------------------------------------|----------|
| Particle size | More than 90% passes through 400µm | Complies |
|---------------|------------------------------------|----------|

Related substances

Test A (HPLC)

| | | |
|------------|---------------------|--------|
| Impurity A | Not more than 0.05% | <0.05% |
|------------|---------------------|--------|

| | | |
|---------------------------------|---------------------|-------|
| Individual unspecified impurity | Not more than 0.10% | 0.05% |
|---------------------------------|---------------------|-------|

Related substances

Test B (HPLC)

| | | |
|---------------------------------|---------------------|--------|
| Individual unspecified impurity | Not more than 0.05% | <0.03% |
|---------------------------------|---------------------|--------|

| | | |
|-----------------------------------|--------------------|-------|
| Total impurities (Test A+ Test B) | Not more than 0.3% | 0.05% |
|-----------------------------------|--------------------|-------|

| | | |
|--------------|---|-------|
| Assay (HPLC) | Between 98.0% and 102.0% (anhydrous substance). | 99.6% |
|--------------|---|-------|

nd: Not detected

20 ppm: DL for chlorides

0.05%: DL for related substances Test A

0.03%: DL for related substances Test B

NOTE: The product meets the requirements of current European Pharmacopoeia monograph for Gabapentin.

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| Q. Laboratory Manager APPROVED A. AMELLER 24/02/2023 | Quality Director APPROVED P. VERGE 24/02/2023 |
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