

CERTIFICATE OF QUALITY

Name of product: **NEOGENT 200 mg/g por belsőleges oldathoz A.U.V.**
Batch number: **118284**
Expiry date: **09.2021.**
Manufacturer: **Pernix Pharma Gyógyszergyártó Kft.**
Manufacturing date: **24.09.2018.**
Examination number: **T18/575**
Quantity: **99 pcs × 1 kg**
Quality: **KME-173-3**
Certificate number: **MB-18/766**

| Examination parameters: | Quality requirements: | Results: |
|--|--|---|
| 3. Control of bulk product | | |
| 3.1.1. Properties | White or almost white powder. | conforms |
| 3.1.2. pH | pH of 1% aqueous solution: 3.5 – 5.5 | 4.42 |
| 3.1.3. Loss on drying | maximum 8.5% | 3.22 % |
| 3.1.4. Solubility | The aqueous solution must be clear without any sediments. | conforms |
| 3.2.1. Identity | Based on HPLC-MS test must be identical | identical |
| 3.2.2. Assay | 128,200 IU/g ± 10% (115,400 IU/g – 141,000 IU/g) | 136,473 IU/g |
| 3.2.3. Composition of gentamicin sulfate | C1: 25.0 – 45.0 % C1a: 10.0 – 30.0 % C2: 35.0 – 55.0 % | 27.27 % 27.17 % 45.55 % |
| 4. Control of packaging | | |
| 4.1. Testing packaging materials | The tested packaging materials must comply with the Packaging Material Quality Specification and the packaging material master piece. Must be free from damage, crease, contamination. | conforms |
| 4.2. Sealing | Material spillage must not be observed. | conforms |
| 4.3. Deliverable filling mass | minimum 1000 g (1000 - 1050 g) | 1003.8 g |
| 4.4. Markings | Batch number and expiry date are indicated readably, according to the batch manufacturing record of the finished product. | Gy.sz.: 118284 Felh. :2021.09. conforms |

The product has been manufactured and packed in full compliance with GMP requirements. The product of batch number **118284** fulfills the requirements stated in the Quality Specification no. KME-173-3, there was no deviance during the manufacturing and packaging.

The above product is released for sale.

1 ... számú másolati példány
Csak a piros szín hiteles!
Pernix Pharma Kft.
Minőségbiztosítás

Zalaegerszeg, 25.10.2018.

PERNIX
P H A R M A
Pernix Pharma Gyógyszergyártó Kft.
Minőségbiztosítás
Róbert Németh
Qualified Person