

CERTIFICATE OF QUALITY


Name of product:	NEOGENT 20% por belsőleges oldathoz
Batch number:	115186
Expiry date:	06.2018.
Manufacturer:	Pernix Pharma Gyógyszergyártó Kft.
Manufacturing date:	08.06.2015.
Examination number:	T15/438
Quantity:	99 pcs × 1 kg
Quality:	KME-173-2
Certificate number:	MB-15/478


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	4.63
3.1.3. Loss on drying	maximum 8.5%	2.26 %
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)	131,456 IU/g
3.2.3. Composition of gentamicin sulfate	C1: 25.0 – 45.0 % C1a: 10.0 – 30.0 % C2: 35.0 – 55.0 %	29.36 % 24.78 % 45.86 %
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)	1006.5 g
4.4. Markings	Batch number and expiry date are indicated readably, according to the batch manufacturing record of the finished product.	Gy.sz.: 115186 Felh. :2018.06. conforms

The product has been manufactured and packed in full compliance with GMP requirements. The product of batch number **115186** fulfills the requirements stated in the Quality Specification no. KME-173-2, there was no deviance during the manufacturing and packaging.

The above product is released for sale.

Zalaegerszeg, 17.06.2015.




PERNIX
 P H A R M A
 Pernix Pharma Gyógyszergyártó Kft.

Róbert Németh
 Qualified Person