

Société
NEWCO PHARM HUNGARIA KFT
RÁKÓCZI U. 142- 146
7100 SZEKSZÁRD
HUNGARY

Hoogstraten,06.04.2016

Material:

PO94101-006994-01- NEOGENT 5%- 100ml

Pharmaceutical form:

Sterile solution

Batch: 23123.20

Manufacturing date: 07/2015

Expiry date: 07/2019

Inspection lot 40000005549 from 03.2016

Batch release Certificate:

We declare that this batch has been manufactured and packed according to current GMP rules and has been released according to the relevant Marketing Authorization.

Formula:

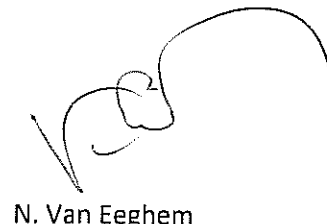
Gentamycinesulfate equivalent with 50mg base- excipients q.s. ad 1ml

Testparameters	Specification	results
Aspect	Clear, almost colourless solution	Complies
Average volume	98.00- 102.00%	100.63%
pH	4.00-6.00	5.72
Relative density	1.030-1.050	1.045
Id: Gentamycin	Complies	Complies
Id: Methyl p-hydroxybenzoate	Complies	Complies
Id: Propyl p-hydroxybenzoate	Complies	Complies
Assay: Gentamycin	90.00-110.00%	103.00%
Assay: Methyl p-hydroxybenzoate	90.00-110.00%	97.37%
Assay: Propyl p-hydroxybenzoate	90.00-110.00%	98.59%
Sterility	Passes sterility test	Complies

Conclusion:

Quality test complied

Qualified person:



N. Van Eeghem