



Productname: GENTA-JECT 10% 100 ML Reg.number(incl. country): RO: 150350
Lotno: 16C22-08C3 Ordernumber: 10689
Production date: 03-2016
Expiry date: 03-2018 Remark: PACKING SLIP 857924 / CUSTOMER NO. I0182
Storage conditions: 15-25 °C

TEST	RESULT	UNIT	SPEC
CHARACTERS			
Appearance	CONFORM	-	CONFORM
IDENTIFICATION GENTAMICINE			
Identification	CONFORM	-	CONFORM
ASSAY-LC			
Methyl parahydroxy benzoate	1.01	mg/ml	≥ 9 ≤ 1.1
ASSAY-ANTIBIOTICS			
Component	GENTAMICIN	-	GENTAMICIN
Content	97.80	mg/ml	≥ 90 ≤ 110
BIOBURDEN			
Total viable bacteria	0	CFU/ml	≤ 1
STERILITY			
Sterility	CONFORM	Microbial growth	CONFORM

Release Date: 21-APR-2016
Disposition Code: FULL RELEASE
Released By: E. van Kuppeveld
Job Title: Q.P.

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control in full compliance with the GMP requirements of the local Regulatory Authority and within the specifications in the Marketing Authorisation in the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP. The Batch certificate/certificate of analysis has been produced by a validated Laboratory Information Management System and therefore bears no handwritten signature. GMP Cert.no.: NL/V 14/0005; GMP+: GMP010348.