

Productname: PENSTREP-JECT 100 ML
Lotno: 16I14-09C1
Production date: 09-2016
Expiry date: 03-2019
Storage conditions: 2-8 °C

Reg.number(incl. country): RO:150515

Ordernumber: 11147

Remark: CUSTOMER NO: I0182 / PACKING SLIP: 871570

TEST	RESULT	UNIT	SPEC
CHARACTERS			
Appearance	CONFORM	-	CONFORM
RESUSPENDABILITY			
Resuspendability	CONFORM	-	CONFORM
PH			
pH	6.0	-	>=5 <=8
RELATIVE DENSITY			
Relative density	1.1488	-	>=1.134 <=1.149
VISCOSITY			
Viscosity	114.22	mPa.s	>=50 <=150
PARTICLE SIZE			
Particles <=10µm	92	%	>=80
Particles >50µm	0	%	<=0
IDENTIFICATION SULPHATES			
Identification	CONFORM	-	CONFORM
IDENTIFICATION OF PROC BENZYL PEN			
Identification of proc.benz.pen. by LC	CONFORM	-	CONFORM
IDENTIFICATION OF DHS			
Identification of DHS by LC	CONFORM	-	CONFORM
IDENTIFICATION OF MOB			
Identification of MOB by LC	CONFORM	-	CONFORM
ASSAY-LC			
Benzy lpenicillin	114.21	mg/ml	>=107.7 <=119
Benzy lpenicillin	203297.36	IU/ml	
Dihy drostreptomycin	154.96	mg/ml	>=152 <=168
Dihy drostreptomycin sulphate	194.05	mg/ml	
Procaine	98.46	mg/ml	>=87.8 <=107.4
ASSAY-LC			
Methyl parahydroxy benzoate	1.45	mg/ml	>=1.35 <=1.65
BIOBURDEN			
Total viable bacteria	.0	CFU/ml	<= 1
STERILITY			
Sterility	CONFORM	Microbial growth	CONFORM
FILLING VOLUME			
Filling volume	100	ml	>=100 <=105

TEST	RESULT	UNIT	SPEC
SURFACE PLATE MONITORING			
C-106C_1 penicillin	0	CFU/plate.	≤ 27 NOT APPLICABLE
C-106C_2 penicillin	1	CFU/plate.	NOT APPLICABLE ≤ 27

Release Date: 17-OCT-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.