

Productname: PENSTREP-JECT 100 ML
 Lotno: 18J24-02C1
 Production date: 10-2018
 Expiry date: 04-2021
 Storage conditions: 2-8 °C

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

TEST	RESULT	UNIT	SPEC
CHARACTERS			
Appearance	CONFORM	-	CONFORM
RESUSPENDABILITY			
Resuspendability	CONFORM	-	CONFORM
PH			
pH	6.2	-	>=5 <=8
RELATIVE DENSITY			
Relative density	1.1478	-	>=1.134 <=1.149
VISCOSITY			
Viscosity	93.13	mPa.s	>=50 <=150
PARTICLE SIZE			
Particles <=10µm	90	%	>=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			
Benzylpenicillin	108.29	mg/ml	>=107.7 <=119
Benzylpenicillin	192749.97	IU/ml	
Dihydrostreptomycin	157.66	mg/ml	>=152 <=168
Dihydrostreptomycin sulphate	197.66	mg/ml	
Procaine	95.09	mg/ml	>=87.8 <=107.4
ASSAY-LC			
Methyl parahydroxybenzoate	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	101	ml	>=100 <=106

Release Date:	30-NOV-2018
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 manufacturing authorisation no. 0429-FIGL; GMP+:GMP010348.