



BATCH CERTIFICATE / CERTIFICATE OF ANALYSIS
RF-781.4

Dopharma Holding B.V.
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The Netherlands
Tel: + 31 (0) 162 58 20 00

Productname: PENSTREP-JECT 100 ML
Lotno: 18D11-01C1
Production date: 04-2016
Expiry date: 10-2018
Storage conditions: 2-8 °C

Reg.number(incl. country): ROMANIA 080050
Ordernumber: 10718

Remark: PACKING SLIP 880081 / CUSTOMER NO. 10182

TEST	RESULT	UNIT	SPEC
CHARACTERS			
Appearance	CONFORM	-	CONFORM
IDENTIFICATION SULPHATES			
Identification	CONFORM	-	CONFORM
RESUSPENDABILITY			
Resuspendability	CONFORM	-	CONFORM
VISCOSITY			
Viscosity	91.39	mPa.s	≥ 50 ≤ 150
PARTICLE SIZE			
Particles $\leq 10\mu\text{m}$	100	%	≥ 80
Particles $> 50\mu\text{m}$	0	%	≤ 0
ASSAY-LC			
Benzyloxy penicillin	112.93	mg/ml	≥ 107.7 ≤ 119
Benzyloxy penicillin	201013.04	IU/ml	
Dihydrostreptomycin	182.07	mg/ml	≥ 152 ≤ 188
Dihydrostreptomycin sulphate	202.95	mg/ml	
Procaine	98.76	mg/ml	≥ 87.8 ≤ 107.4
ASSAY-LC			
Methyl parahydroxy benzoate	1.47	mg/ml	≥ 1.35 ≤ 1.65
BIOBURDEN			
Total viable bacteria	.0	CFU/ml	≤ 1
STERILITY			
Sterility	CONFORM	Microbial growth	CONFORM
SURFACE PLATE MONITORING			
C-106C_1 penicillin	22	CFU/plate.	≤ 38 NOT APPLICABLE
C-106C_2 penicillin	19	CFU/plate.	NOT APPLICABLE ≤ 38