

BATCH CERTIFICATE / CERTIFICATE OF ANALYSIS  
RF-781.5

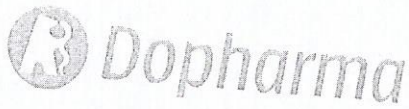
Dopharma Holding B.V.  
Zalmweg 24  
4941 VX Raamsdonksveer  
The Netherlands  
Tel: + 31 (0) 162 58 20 00

Productname: DEXA-JECT 2MG/ML INJ 100ML  
Lotno: 18F26-04C8  
Production date: 06-2018  
Expiry date: 06-2021  
Storage conditions: 15-25 °C

Reg.number(incl. country): HU:3191/2/12 NEBIH ATI RO:170200  
Ordernumber: 13995

Remark: PACKING SLIP 922181 / CUSTOMER NO. I0182

TEST	RESULT	UNIT	SPEC
PH			
pH correction	NO		
CHARACTERS			YES
Appearance	CONFORM		NO
APPEARANCE OF SOLUTION			CONFORM
Clarity and opalescence	CONFORM		
Colour	CONFORM		CONFORM
PH			CONFORM
pH	7.5		
ASSAY-LC			>=6.9
Benzylalcohol	14.7		<=7.9
RSD Benzylalcohol		mg/ml	>=13.5
Dexamethasone sodium phosphate	.0	%	<=16.5
RSD Dexamethasone sodium phosphate	2.69	mg/ml	>=2.49
	.1	%	<=2.77
RELATED SUBSTANCES-LC			<=4
Impurity A	0.181	%	
Impurity B	0.036	%	<= 5
Impurity C	0	%	<= 5
Impurity D	0	%	<= 2
Impurity E	0	%	<= 2
Impurity F	0	%	<= 2
Any other impurity	0.159	%	<= 2
Total impurities	0.543	%	<= 2
Unknown RRT 0.55	0	%	<=1
BACTERIAL ENDOTOXINS			<= .02
Bacterial endotoxins	.05		
MICROBIAL CONTAMINATION		IU/ml	<=1.67
TAMC	0		
STERILITY		CFU/ml	<= .1
Sterility	CONFORM	Microbial growth	CONFORM



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Release Date: 14-AUG-2018  
Disposition Code: FULL RELEASE  
Released By: J. Rijnen  
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.