Dopharma

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	Reg.number(incl. country):	HU:5191/2/12 NEBIH ATI RO:120271
Lotno:	17C31-12C6	Ordernumber:	
Production date:	03-2017		
Expiry date:	03-2020		
Storage conditions:	15-25 °C		

TEST	RESULT	UNIT	SPEC
CHARACTERS			
Appearance	CONFORM	-	CONFORM
APPEARANCE OF SOLUTION			
Clarity and opalescence	CONFORM	-	CONFORM
Colour	CONFORM	-	CONFORM
PH			
pH	7.5	-	>=6.9
			<=7.9
ASSAY-LC			
Benzylalcohol	14.7	mg/ml	>=13.5
			<=16.5
RSD Benzylalcohol	.5	%	<=6
Dexamethasone sodium phosphate	2.62	mg/ml	>=2.49
			<=2.77
RSD Dexamethasone sodium phosphate	.5	%	<=4
RELATED SUBSTANCES-LC			
Impurity A	0.006	%	<=.5
Impurity B	0.000	%	<=.5
Impurity C	0.0	%	<=.2
Impurity D	0.001	%	<=.2
Impurity E	0	%	<=.2
Impurity F	0.0	%	<=.2
Any other impurity	0.003	%	<=.2
Total impurities	0.010	%	<=1
Unknown RRT 0.55	0.0	%	<=.02
BACTERIAL ENDOTOXINS			
Bacterial endotoxins	.50	IU/ml	<=1.67
MICROBIAL CONTAMINATION			
TAMC	0.01	CFU/ml	<=.1
STERILITY			
Sterility	CONFORM	Microbial growth	CONFORM

Release Date:	25-JUL-2017
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.