



DOPHARMA
DOPHARMA HOLDING B.V.

CERTIFICATE OF ANALYSIS
RF-781

Dopharma Holding B.V.
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Productname: DEXA-JECT 2MG/ML INJ 100ML
Lotno: 15D24-20C2
Production date: 04-2015
Expiry date: 04-2018
Storage conditions: 15-25 °C

Reg.number(Incl. country): HU:3191/2/12 NEBIH ATI RO:120271
Ordernumber: 9873
Remark: CUSTOMER NO : I0182

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	14.9	mg/ml	>=13.5 <=16.5
RSD Benzylalcohol	.1	%	<=6
Dexamethasone sodium phosphate	2.61	mg/ml	>=2.49 <=2.77
RSD Dexamethasone sodium phosphate	.1	%	<=4
RELATED SUBSTANCES-LC			
Impurity A	0.28	%	<= 5
Impurity B	0.03	%	<= 5
Impurity C	0	%	<= 5
Impurity D	0	%	<= 5
Impurity E	0	%	<= 5
Impurity F	0	%	<= 5
Any other impurity	0.11	%	<= 2
Total impurities	0.49	%	<=1
BACTERIAL ENDOTOXINS			
Bacterial endotoxins	.05	IU/ml	<=1.67
MICROBIAL CONTAMINATION			
TAMC	0.005	CFU/ml	<= 1
STERILITY			
Sterility	CONFORM	Microbial growth	CONFORM

Release Date: 10-JUL-2015
Disposition Code: FULL RELEASE
Released By: R. Lakkerwa
Job Title: Q.P.

This lot number is produced in accordance with cGMP (EU) and if applicable lives up to the conditions which are mentioned in the marketing authorisation for the product. The certificate of analysis has been produced by a validated Laboratory Information Management System and therefore bears no handwritten signature.