



BATCH CERTIFICATE / CERTIFICATE OF ANALYSIS
RF-781.4

Dopharma Holding B.V.
Zalmweg 34
4841 VX Raamsdonksveer
The Netherlands
Tel: +31 (0) 182 88 20 00

Productname: MELOVEN 20 MG/ML INJ 100ML
Lotnr: 18818-01C3
Production date: 03-2016
Expiry date: 03-2018
Storage conditions: 15-25 °C

Reg.number(noi. country): EU/2108/008/003 HJ RO
Ordernumber: 10888
Remark: PACKING SLIP 861833 / CUSTOMER NO. 10182

TEST	RESULT	UNIT	SPEC
CHARACTERS			
Appearance	CONFORM	-	CONFORM
pH			
pH (Finished product)	8.87	-	>=6.3 <=9.3
APPEARANCE OF SOLUTION			
Clarity and opalescence	CONFORM	-	CONFORM
Colour	CONFORM	-	CONFORM
RELATED SUBSTANCES			
Impurity A at 350nm	0.000	%	<=1
Impurity B at 280nm	0.08573	%	<=5
Impurity C at 350nm	0.000	%	<=05
Impurity D at 350nm	0.000	%	<=05
Max unidentified impurity	0.04883	%	<=2
Total Impurities	0.15886	%	<=1
ASSAY-LE			
Meloxicam	19.80	mg/ml	>=19 <=21
MICROBIAL CONTAMINATION			
TAMC+TYMC	0	CFU/ml	<=1
ASSAY-SC			
Ethanol content	181.52	mg/ml	>=135 <=185
STERILITY			
Stability	CONFORM	Microbial growth	CONFORM
VISIBLE PARTICLES			
Overall performance	CONFORM	-	CONFORM

Release Date: 16-JUN-2016
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 Cert.no.: NL/V 14/0005; GMP+: GMP010348.