

Le Vet BV
Wilgenweg 7
3421 TV Oudewater
Nederland

Manufacturer's batch certificate

Sample-code(s). 2020110587 Raamsdonksveer, 26-11-2020

Description of the product **Meloxoral 0.5 mg/ml**

Pack size **PE bottle of 25 ml**

Product N° PP / client **P4846 871797356937**

Registration number **EU/2/10/111/004**

Recipe/filling number **R0962 / 43 U0547**

Order number **PO008888**

Batch number **20 K 021**

Batch size **281 pcs**

Manufacturing/output date **11-2020 / 11-2020**

Expiry date **10-2023**

Method	Description	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
<u>LAF001A</u>	<u>Parameter</u>							
	<u>pH value</u>	4.5			4.2	4.6		
<u>LAF002B</u>	<u>Absolute density</u>	1.079	g/ml	1.077	1.05	1.11		
<u>LAF005D</u>	<u>Uniformity of dosage (ml)</u>							
	<u>Measured dosages</u>	20		informative value				
	<u>≥ 18 doses</u>	conform		conform				
	<u>≤ 2 doses</u>	conform		conform				
<u>LAF006B</u>	<u>Viscosity (RotoVisco)</u>	237	mPa.s	240	180	336		
<u>LAF007A</u>	<u>Resuspendability</u>	resuspendability <60sec.		resuspendability <60sec.				
<u>LAF008A</u>	<u>Appearance</u>	suspension		suspension				
<u>LAF011A</u>	<u>Colour</u>	yellow-green		yellow-green				
<u>LAF014A</u>	<u>Particle size (volume)</u>							
	<u>10%</u>	18.1	µm	informative value				
	<u>20%</u>	27.2	µm	informative value				
	<u>50%</u>	55.4	µm	informative value				
	<u>80%</u>	107.6	µm	informative value				
	<u>90%</u>	151	µm	informative value				
	<u>100%</u>	586.2	µm	informative value				
<u>LAF015B</u>	<u>Sedimentation (Turbiscan)</u>							
	<u>sedimentation 1 hour</u>	0	° v			2.5		
<u>LAF025A</u>	<u>Homogeneity</u>	homogeneous		homogeneous				
<u>LAF026A</u>	<u>Dissolution</u>							
	<u>Method used for ...</u>	LAV168J		informative value				
	<u>Dissolution percentage</u>	93.9	%		80			
	<u>Dissolution time</u>	45	min.	45				
<u>LAF029A</u>	<u>Odour</u>	anise odour		anise odour				
<u>LAV168B</u>	<u>Meloxicam - impurities</u>							
	<u>Impurity A</u>	< 0.05	%			0.5		
	<u>Impurity B</u>	< 0.05	%			0.5		
	<u>Impurity C</u>	< 0.05	%			0.5		
	<u>Impurity individual unknown</u>	< 0.05	%			0.3		
	<u>Impurities total</u>	< 0.05	%			2.0		
<u>LAV168C</u>	<u>Meloxicam - Sodium benzoate</u>							
	<u>Meloxicam</u>	0.495	mg/ml	0.5	0.475	0.525		
	<u>Identification Meloxicam (RRT/UV scan to standard)</u>	positive		positive				
	<u>Sodiumbenzoate</u>	1.744	mg/ml	1.75	1.575	1.925		
	<u>Identification Sodiumbenzoate (RRT/UV scan to standard)</u>	positive		positive				

Initials qualified persons: AB / [Signature]

Continuation on following page Page 1 of 2

 AH_48094_2011261308

Le Vet BV
Wilgenweg 7
3421 TV Oudewater
Nederland

Manufacturer's batch certificate

Sample-code(s), 2020110587 Raamsdonksveer, 26-11-2020

Description of the product	Meloxoral 0.5 mg/ml	Registration number	EU/2/10/111/004
Pack size	PE bottle of 25 ml	Order number	PO008888
Product N° PP / client	P4846 871797356937	Batch size	281 pcs
Recipe/filling number	R0962 / 43 U0547	Expiry date	10-2023
Batch number	20 K 021		
Manufacturing/output date	11-2020 / 11-2020		

Continuation of previous page

Method	Description	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
<u>LAV168J</u>	<u>Parameter</u>							
	<u>Meloxicam dissolution USP <711></u>	0.5	mg/ml	0.5	0.4			
<u>LAF004C</u>	<u>Volume (ml, calculated)</u>	25.31	ml		25.0	26.4		
<u>LAV510C</u>	<u>Microbial quality</u>							
	<u>Total viable aerobic microbial count</u>	10	CFU/ml			1000	0	
	<u>Total combined yeast mould count</u>	<10	CFU/ml			100	0	
	<u>E. coli</u>	absent		absent				

All mentioned limits are equal to or stricter than the limits mentioned in the available documentation. Additional items may be specified without actual impact on the product specifications. Zeros in decimal values after the last reported digit (other than zero) are suppressed in the reporting system. Such a reported value conforms to the specification limit.

Produlab Pharma retains samples till 1 year after the expiry date. Records of the analysis are retained for 7 years and are available on request.

We hereby certify that the above information is authentic and accurate. This batch of product has been manufactured including packaging and quality control, at the below mentioned site in full compliance with the EU GMP requirements and with the specifications as agreed with the marketing authorization holder / contract giver of the importing country. The batch processing, packaging, and analysis records were reviewed and found to be in compliance with GMP.

No deviations with a direct impact on the product quality are applicable for this product batch; other applicable major deviations are mentioned below.
The batch is released into the market.

Produlab Pharma bv, Forellenweg 16, NL-4941 SJ Raamsdonksveer **Manufacturing licence** 1401-FIGL

J. van der Ploeg
J. van der Ploeg
QC Delegate

☐ N.D.M.J. van Zon- Jacobs, MSc ☒ H.J. Nootboom
QP Senior QP