

Le Vet BV
Wilgenweg 7
3421 TV Oudewater
Nederland

Manufacturer's batch certificate

Sample-code(s), 2020090830 Raamsdonksveer, 25-09-2020

Description of the product **Meloxoral 1.5 mg/ml**
Pack size **PE bottle of 50 ml**
Product N° PP / client **P4847 871797356940**
Recipe/filling number **R0897 / 43 U0546**
Batch number **20 I 036**
Manufacturing/output date **09-2020 / 09-2020**

Registration number **EU/2/10/111/002**
Order number **PO008888**
Batch size **250 pcs**
Expiry date **08-2023**

Method	Description	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
<u>LAF001A</u>	<u>pH value</u>	4.43			4.2	4.6		
<u>LAF002B</u>	<u>Absolute density</u>	1.079	g/ml	1.08	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 (Roto Visco)</u>	239	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>	13	µm	informative value				
	<u>20%</u>	24.4	µm	informative value				
	<u>50%</u>	59.5	µm	informative value				
	<u>80%</u>	128.6	µm	informative value				
	<u>90%</u>	187.6	µm	informative value				
	<u>100%</u>	587.1	µm	informative value				
<u>LAF015B</u>	<u>Sedimentation (Turbiscan)</u>							
	<u>sedimentation 1 hour</u>	0.6	% 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>	96.1	%		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>	1.491	mg/ml	1.5	1.425	1.575		
	<u>Identification Meloxicam (RRT/UV scan to standard)</u>	positive		positive				
	<u>Sodiumbenzoate</u>	1.737	mg/ml	1.75	1.575	1.925		
	<u>Identification Sodiumbenzoate (RRT/UV scan to standard)</u>	positive		positive				

Initials qualified persons:

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Produlab Pharma b.v.

Wilgenweg 7
NL-4741 SJ Raamsdonksveer
The Netherlands

Phone: +31 (0)1127 7 800
info@produlabpharma.nl
www.produlabpharma.nl

Kibichink
B.G./SWIFT RABO NL01
IBAN: NL443904250201426031
VAT: NL804250242B01

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transactions

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Product N° PP / client	P4847 871797356940	Batch size	250 pcs
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<u>LAV168J</u>	<u>Parameter</u>							
	<u>Meloxicam dissolution USP <711></u>	1.4	mg/ml	1.5	1.2			
<u>LAF004C</u>	<u>Volume (ml, calculated)</u>	51.4	ml		50.0	52.7		
<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				

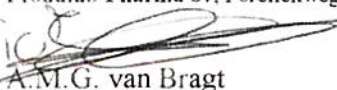
All mentioned limits are equal to or stricter than the limits mentioned in the available documentation. Additional items may be specified without actual impact on the product specifications. Zeros in decimal values after the last reported digit (other than zero) are suppressed in the reporting system.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


A.M.G. van Bragt
QC Delegate

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