

Le Vet BV
Wilgenweg 7
3421 TV Oudewater
Nederland

Manufacturer's batch certificate

Sample-code(s), 2022122344 Raamsdonksveer, 13-01-2023

Description of the product **Meloxoral 0.5 mg/ml**
Pack size PE bottle of 25 ml
Product N° PP / client P4846 043853
Recipe/filling number R0962 / 48 U0547
Batch number **22L271**
Manufacturing/output date 12-2022 / 01-2023

Registration number EU/2/10/111/004
Order number 1009719
Batch size 495 pcs
Expiry date 11-2025

Method	Description Parameter	Result	Unit	Target	Lower limit	Upper limit	Lower warning	Upper warning
LAF001A	pH value	4.5			4.2	4.6		
LAF002B	Absolute density	1.078	g/ml	1.077	1.05	1.11		
LAF005D	Uniformity of dosage (ml)							
	Measured dosages	20		informative value				
	≥ 18 doses	conform		conform				
	≤ 2 doses	conform		conform				
LAF006B	Viscosity (RotoVisco)	242	mPa·s	240	180	336		
LAF007A	Resuspendability	resuspendability <60sec.		resuspendability <60sec.				
LAF008A	Appearance	suspension		suspension				
LAF011A	Colour	yellow-green		yellow-green				
LAF014A	Particle size (volume)							
	10%	12.3	µm	informative value				
	20%	18.5	µm	informative value				
	50%	36.8	µm	informative value				
	80%	67.6	µm	informative value				
	90%	89.4	µm	informative value				
	100%	203.8	µm	informative value				
LAF015B	Sedimentation (Turbiscan)							
	sedimentation 1 hour	0	% v			2.5		
LAF025A	Homogeneity	homogeneous		homogeneous				
LAF026A	Dissolution							
	Method used for ...	LAV168J		informative value				
	Dissolution percentage	107	%		80			120
	Dissolution time	45	min.	45				
LAF029A	Odour	anise odour		anise odour				
LAV168B	Meloxicam + impurities							
	Impurity A	< 0.05	%			0.5		
	Impurity B	< 0.05	%			0.5		
	Impurity C	< 0.05	%			0.5		
	Impurity individual unknown	< 0.05	%			0.3		
	Impurities total	< 0.05	%			2.0		
LAV168C	Meloxicam / Sodium benzoate							
	Meloxicam	0.5	mg/ml	0.5	0.475	0.525		
	Identification Meloxicam (RRT/UV scan to standard)	positive		positive				
	Sodiumbenzoate	1.75	mg/ml	1.75	1.575	1.925		

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R0962_P4846_22L271_Meloxoral 0.5 mg/ml

AH_54647_LV_2301131220



Produlab Pharma b.v.

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as deposited at the chamber
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apply on all deliveries and
transactions.

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Continuation of previous page

Method	Description Parameter	Result	Unit	Target	Lower limit	Upper limit	Lower warning	Upper warning
	Identification Sodiumbenzoate (RRT/UV scan to standard)	positive		positive				
LAF004C	Volume (ml, calculated)	25.5	ml		25.0	26.4		
LAV510C	Microbial quality							
	Total viable aerobic microbial count	<10	CFU/ml			1000	0	
	Total combined yeast/mould count	<10	CFU/ml			100	0	
	E. coli	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


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Signed by Qualified person