

Le Vet BV
Wilgenweg 7
3421 TV Oudewater
Nederland

Manufacturer's batch certificate

Sample-code(s), 2021091301 Raamsdonksveer, 11-11-2021

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 / 45 U0546
Batch number **21I109**
Manufacturing/output date 09-2021 / 09-2021

Registration number EU/2/10/111/002
Order number PO009034
Batch size 997 pcs
Expiry date 08-2024

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Method	Description Parameter	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
	Identification Sodiumbenzoate (RRT/UV scan to standard)	positive		positive				
LAF004C	Volume (ml, calculated)	50.8	ml		50.0	52.7		
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