

Le Vet BV
Wilgenweg 7
3421 TV Oudewater
Nederland

Manufacturer's batch certificate

Sample-code(s), 2021030576 Raamsdonksveer, 24-03-2021

Description of the product **Meloxoral 1.5 mg/ml**
Pack size PE bottle of 50 ml
Product N° PP / client P4847 871797356940 Registration number EU/2/10/111/002
Recipe/filling number R0897 / 43 U0546 Order number PO008962
Batch number **21C041** Batch size 497 pcs
Manufacturing/output date 03-2021 / 03-2021 Expiry date 02-2024

Method	Description Parameter	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
<u>LAF001A</u>	<u>pH value</u>	4.48			4.2	4.6		
<u>LAF002B</u>	<u>Absolute density</u>	1.075	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 (RotoVisco)</u>	232	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>							
	10%	12.8	µm	informative value				
	20%	22.1	µm	informative value				
	50%	49.1	µm	informative value				
	80%	98.7	µm	informative value				
	90%	139.2	µm	informative value				
	100%	432	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>	89	%		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>	1.502	mg/ml	1.5	1.425	1.575		
	<u>Identification Meloxicam (RRT/UV scan to standard)</u>	positive		positive				
	<u>Sodiumbenzoate</u>	1.736	mg/ml	1.75	1.575	1.925		
	<u>Identification Sodiumbenzoate (RRT/UV scan to standard)</u>	positive		positive				

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