

Le Vet BV
Wilgenweg 7
3421 TV Oudewater
Nederland

Manufacturer's batch certificate

Sample-code(s), 2020034526 Raamsdonksveer, 17-06-2020

Description of the product **Meloxoral 0.5 mg/ml**
Pack size **PE bottle of 25 ml**
Product N° PP / client **P4846 / 1 871797356937** Registration number **EU/2/10/111/004**
Recipe/filling number **R0962 / 41 U0547** Order number **PO008637**
Batch number **20 C 266** Batch size **497 pcs**
Manufacturing/output date **/ 04-2020** Expiry date **02-2023**

Method	Description	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
<u>LAF001A</u>	<u>pH value</u>	4.5			4.2	4.6		
<u>LAF002B</u>	<u>Absolute density</u>	1.077	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>	230	mPa.s	240	180	336		
<u>LAF007A</u>	<u>Resuspendability</u>	resuspendability <10sec.		resuspendability <10sec.				
<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>	11.8	µm	informative value				
	<u>20%</u>	19.3	µm	informative value				
	<u>50%</u>	41.4	µm	informative value				
	<u>80%</u>	82.2	µm	informative value				
	<u>90%</u>	116.5	µm	informative value				
	<u>100%</u>	507.4	µm	informative value				
<u>LAF015B</u>	<u>Sedimentation (Turbiscan)</u>							
	<u>sedimentation 1 hour</u>	0.2	% 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>	84.2	%		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>	0.499	mg/ml	0.5	0.475	0.525		
	<u>Identification Meloxicam (RRT UV scan to standard)</u>	positive		positive				
	<u>Sodiumbenzoate</u>	1.745	mg/ml	1.75	1.575	1.925		
	<u>Identification Sodiumbenzoate (RRT UV scan to standard)</u>	positive		positive				

Initials qualified persons: AB / AO

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