

Le Vet BV
 Wilgenweg 7
 3421 TV Oudewater
 Nederland

Manufacturer's batch certificate

Sample-code(s), 2015080622 Raamsdonksveer, 24-08-2015

Description of the product **Nerfasin 20 mg/ml**
 Pack size **Injection vial of 50 ml**
 Product N° PP / client **P4283 871846944594** Registration number **3415/3/13**
 Recipe/filling number **R1131 U0023** Order number **PO 4478**
 Batch number **15 H 044** Batch size **1710 pcs**
 Manufacturing/output date **08-2015 / 08-2015** Expiry date **07-2018**

Method	Description Parameter	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
LAF001A	pH value	5.24		5.0	4.0	6.0		
LAF002A	Relative density	1.007		1.007	0.987	1.027		
LAF003A	Refractive index	1.33886		1.339	1.312	1.366		
LAF008A	Appearance	clear		clear				
LAF011A	Colour	colourless		colourless				
LAF025A	Homogeneity	homogeneous		homogeneous				
LAF030A	Particulate matter	absent		absent				
LAV059B	Xylazine HCl / Methyl-paraben / Propyl-paraben							
	Xylazin	19.2	mg/ml	20.0	19.0	21.0		
	Identification Xylazin	positive		positive				
	Xylazin HCl	22.38	mg/ml	23.32				
	Methyl hydroxybenzoate	0.9912	mg/ml	1.0	0.9	1.1		
	Identification Methyl hydroxybenzoate	positive		positive				
	Methyl hydroxybenzoate sodium	1.135	mg/ml	informative value				
LAV059F	Xylazine HCl (impurities)							
	Impurity A	< 0.01	%			0.010		
	Impurity B	< 0.05	%			0.2		
	Impurity C	< 0.05	%			0.2		
	Impurity D	< 0.05	%			0.2		
	Impurity E	< 0.05	%			0.2		
	Unknown impurities individual	< 0.05	%			0.2		
	Impurities total (B,C,D,E excluded)	< 0.05	%			0.5		
LAF004E	Extractable volume (ml)	52	ml		50.0	52.0		
LAV502A	Sterility	sterile		sterile				


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.

LAV901A = component(s) not tested; result declared on the basis of the production amounts. LAV903A = component(s) not tested; result is declared amount according the composition.


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 deviations are mentioned below. The batch is released into the market.

Initials qualified persons: 

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NEW BANKACCOUNT

Bank: ABN-AMRO
 IBAN: NL92 04 17 05 30 50 01 23 12 34 56 78 90
 BIC: ABNANL33

Our delivery and sales conditions as deposited at the chamber of commerce under no. 18043243 apply on all deliveries and transactions.

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Produlab Pharma bv, Forellenweg 16, NL-4941 SJ Raamsdonksveer Manufacturing licence 1401-FLG

A. van der Heiden
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Substitute laboratory manager

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