

CP Pharma GmbH  
Ostlandring 13  
D-31303 Burgdorf  
Deutschland

Sample-code(s), 2013080323 Raamsdonksveer, 23-09-2013

**Manufacturer's batch certificate**

Description of the product CP-Xylazine 2%  
Pack size Injection vial of 50 ml  
Product number P2637  
Recipe/filling number R0401 U0108  
Batch number 13 H 073  
Manufacturing/output date 08-2013 / 08-2013

Registration number 2303/3/07  
Order number Mail Moni 18-2-2013  
Batch size 4970 pcs  
Expiry date 07-2016

Method	Description Parameter	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
LAF001A	pH value	5.47		5.5	5.0	6.0		
LAF002A	Relative density	1.01		1.008	1.003	1.020		
LAF002B	Absolute density	1.008	g/ml	1.004	1.003	1.020		
LAF003A	Refractive index	1.33974		informative value				
LAF008A	Appearance	clear		clear				
LAF011A	Colour	colourless		colourless				
LAF025A	Homogeneity	homogeneous		homogeneous				
LAF030A	Particulate matter	absent		absent				
LAV059C	Xylazine HCl / Methyl-paraben / Propyl-paraben							
	Xylazin	20.17	mg/ml	20.0	19.0	21.0		
	Identification Xylazin	positive		positive				
	Xylazin HCl	23.52	mg/ml	23.31				
	Methyl hydroxybenzoate	1.802	mg/ml	1.8	1.62	1.98		
	Identification Methyl hydroxybenzoate	positive		positive				
	Methyl hydroxybenzoate sodium	2.063	mg/ml	2.060				
	Propyl hydroxybenzoate	0.1865	mg/ml	0.2	0.18	0.22		
	Identification Propyl hydroxybenzoate	positive		positive				
	Propyl hydroxybenzoate sodium	0.2093	mg/ml	0.2244				
LAV059D	Xylazine HCl (Impurities)							
	2,6-Dimethylanilin	< 0.05	%			0.2		
	Propanol-thiourca int.	< 0.05	%			0.2		
	N-(2,6)-dimethylphenyl	< 0.05	%			0.2		
	Unknown impurities individual	< 0.05	%	informative value				
	Impurities total (unknown)	< 0.05	%	informative value				
LAF004E	Extractable volume (ml)	51.2	ml		50	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. LAV901A = component(s) not tested; result declared on the basis of the production amounts. LAV903A = component(s) not tested; result is declared amount according to 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.

Initials qualified persons:

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Produlab Pharma b.v.

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BIC: FVNB22

IBAN: NL14FVNB0225627876

VAT: NL8042 54 242 801

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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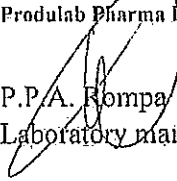
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Pack size **Injection vial of 50 ml**  
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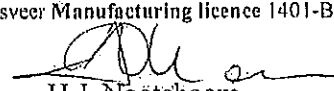
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Produlab Pharma b.v, Forellenweg 16, NL-4941 SJ Raamsdonksveer Manufacturing licence 1401-BVEAK

  
P.P.A. Rompa  
Laboratory manager

  
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