

Alvetra GmbH
Am Anger 9
D-24539 Neumunster
Deutschland

Manufacturer's batch certificate

Sample-code(s), 2014030404

Raamsdonksveer, 22-04-2014

Description of the product **Chosalgan-S ds für Ungarn**
Pack size Injection vial of 100 ml
Product number P3640 Registration number 2956/1/11
Recipe/filling number R0805 U0002 Order number 1595
Batch number 14 C 053 Batch size 2498 pcs
Manufacturing/output date 03-2014 / 03-2014 Expiry date 02-2017

Method	Description Parameter	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
EP	Identification sodium	positive		positive				
LAF001A	pH value	6.59			6.0	7.0		
LAF002A	Relative density	1.163		1.162	1.155	1.175		
LAF008A	Appearance	clear		clear				
LAF011A	Colour	light yellow		light yellow				
LAF011B	Colour with reference solutions							
	<i>Reference solution yellow</i>	4			3			
LAF028A	Tightness of closure	leak tight		leak tight				
LAF030A	Particulate matter	absent		absent				
LAV044C	Metamizol Sodium + impurities							
	<i>Impurity A</i>	< 0.05	%			0.5		
	<i>Impurity B</i>	< 0.05	%			0.5		
	<i>Impurity C</i>	< 0.05	%			1.0		
	<i>Impurity D</i>	< 0.05	%			0.5		
	<i>Unknown impurities individual</i>	0.1	%			0.5		
	<i>Impurities total</i>	0.1	%			2.0		
LAV044D	Metamizol Sodium							
	<i>Metamizol sodium</i>	478.3	mg/ml	474.4				
	<i>Identification Metamizol</i>	positive		positive				
	<i>Metamizol sodium monohydrate</i>	504.1	mg/ml	500	475	525	490	510
LAV063H	Benzylalcohol							
	<i>Benzyl alcohol</i>	30.74	mg/ml	30	28.5	31.5		
	<i>Identification Benzyl alcohol</i>	positive		positive				
LAF004E	Extractable volume (ml)	101	ml		100	103		
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 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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Our delivery and sales conditions as deposited at the chamber of commerce under no. 18043243 apply on all deliveries and transactions.

Alvetra GmbH
Am Anger 9
D-24539 Neumunster
Deutschland

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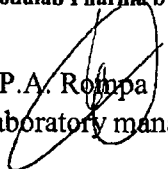
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Produlab Pharma bv, Forellenweg 16, NL-4941 SJ Raamsdonksveer Manufacturing licence 1401-FLG


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Laboratory manager


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