Produlab Pharma

Certificate of Analysis

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							
	Reference solution yellow	**4**			3			
LAF028A	Tightness of closure	**leak tight**		leak tight				
LAF030A	Particulate matter	**absent**		absent				
LAV044C	Metamizol Sodium + impurities							
	Impurity A	**< 0.05**	%			0.5		
	Impurity B	**< 0.05**	%			0.5		
	Impurity C	**< 0.05**	%			1.0		
	Impurity D	**< 0.05**	%			0.5		
	Unknown impurities individual	**0.1**	%			0.5		
	Impurities total	**0.1**	%			2.0		
LAV044D	Metamizol Sodium							
	Metamizol sodium	**478.3**	mg/ml	474.4				
	Identification Metamizol	**positive**		positive				
	Metamizol sodium monohydrate	**504.1**	mg/ml	500	475	525	490	510
LAV063H	Benzylalcohol							
	Benzyl alcohol	**30.74**	mg/ml	30	28.5	31.5		
	Identification Benzyl alcohol	**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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Produlab Pharma bv, Forellenweg 16, NL-4941 SJ Raamsdonksveer **Manufacturing licence** 1401-FLG

P.P.A. Rompa
Laboratory manager

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QA manager, QP

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