

Alvetra GmbH  
Am Anger 9  
D-24539 Neumunster  
Deutschland

Manufacturer's batch certificate

Sample-code(s), 2015100649 Raamsdonksveer, 23-10-2015

Description of the product **Chosalgan-S ds für Ungarn**

Pack size Injection vial of 100 ml

Product N° PP / client P3640 402308 Registration number 2956/1/11

Recipe/filling number R0805 U0002 Order number 1766

Batch number 15 J 061 Batch size 2336 pcs

Manufacturing/output date 10-2015 / 10-2015 Expiry date 09-2018

Method	Description	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
<b>EP</b>	<b>Identification sodium</b>	positive		positive				
<b>LAF001A</b>	<b>pH value</b>	6.53			6.0	7.0		
<b>LAF002A</b>	<b>Relative density</b>	1.163		1.162	1.155	1.175		
<b>LAF008A</b>	<b>Appearance</b>	clear		clear				
<b>LAF011A</b>	<b>Colour</b>	light yellow		light yellow				
<b>LAF011B</b>	<b>Colour with reference solutions</b>							
	<i>Reference solution yellow</i>	5			3			
<b>LAF028A</b>	<b>Tightness of closure</b>	leak tight		leak tight				
<b>LAF030A</b>	<b>Particulate matter</b>	absent		absent				
<b>LAV044C</b>	<b>Metamizol Sodium + impurities</b>							
	<i>Impurity A</i>	< 0.05	%			0.5		
	<i>Impurity B</i>	< 0.05	%			0.5		
	<i>Impurity C</i>	1.41	%			5.0		1.0
	<i>Impurity D</i>	< 0.05	%			0.5		
	<i>Unknown impurities individual</i>	0.1	%			0.5		
	<i>Impurities total</i>	1.51	%			5.0		2.0
<b>LAV044D</b>	<b>Metamizol Sodium</b>							
	<i>Metamizol sodium</i>	465.2	mg/ml	474.4				
	<i>Identification Metamizol</i>	positive		positive				
	<i>Metamizol sodium monohydrate</i>	490.3	mg/ml	500	475	525	490	510
<b>LAV063H</b>	<b>Benzylalcohol</b>							
	<i>Benzyl alcohol</i>	29.35	mg/ml	30	28.5	31.5		
	<i>Identification Benzyl alcohol</i>	positive		positive				
<b>LAF004E</b>	<b>Extractable volume (ml)</b>	100.6	ml		100	103		
<b>LAV502A</b>	<b>Sterility</b>	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.

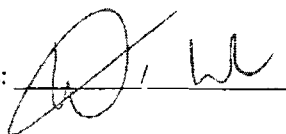
LAV901A = component(s) not tested; result declared on the basis of the production amounts. LAV903A = component(s) not tested; result is declared amount according the composition.

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.

Initials qualified persons:



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NEW BANKACCOUNT



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

**Alvetra GmbH**  
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D-24539 Neumunster  
Deutschland

**Manufacturer's batch certificate**

Sample-code(s), 2015100649 Raamsdonksveer, 23-10-2015

Description of the product	<b>Chosalgan-S ds für Ungarn</b>		
Pack size	Injection vial of 100 ml		
Product N° PP / client	P3640	402308	Registration number 2956/1/11
Recipe/filling number	R0805	U0002	Order number 1766
Batch number	<b>15 J 061</b>		Batch size 2336 pcs
Manufacturing/output date	10-2015 / 10-2015		Expiry date 09-2018

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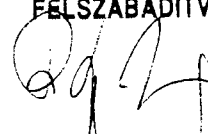
Produlab Pharma bv, Forellenweg 16, NL-4941 SJ Raamsdonksveer Manufacturing licence 1401-FLG

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**DR LENGYEL TAMÁS**  
minőségügyi felelős