

**Alvetra GmbH**  
Am Anger 9  
D-24539 Neumunster  
Deutschland

**Manufacturer's batch certificate**

Sample-code(s), 2020040469 Raamsdonksveer, 05-05-2020

Description of the product	<b>Chosalgan-S Ungarn</b>	Registration number	2956/1/11
Pack size	Injection vial of 100 ml	Order number	2308
Product N° PP / client	P3640 / 5 402308	Batch size	2271 pcs
Recipe/filling number	R0805 / 13 U0002	Expiry date	03-2023
Batch number	<b>20 D 014</b>		
Manufacturing/output date	04-2020 / 04-2020		

Method	Description Parameter	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
<u>EP</u>	<u>Identification sodium</u>	positive		positive				
<u>LAF001A</u>	<u>pH value</u>	6.63			6.0	7.0		
<u>LAF002A</u>	<u>Relative density</u>	1.164		1.162	1.155	1.175		
<u>LAF008A</u>	<u>Appearance</u>	clear		clear				
<u>LAF011A</u>	<u>Colour</u>	light yellow		light yellow				
<u>LAF011B</u>	<u>Colour with reference solutions</u>							
	<u>Reference solution yellow</u>	4			3			
<u>LAF028A</u>	<u>Tightness of closure</u>	leak tight		leak tight				
<u>LAF030A</u>	<u>Particulate matter</u>	absent		absent				
<u>LAV044C</u>	<u>Metamizol Sodium + impurities</u>							
	<u>Impurity A</u>	< 0.05	%			0.5		
	<u>Impurity B</u>	< 0.05	%			0.5		
	<u>Impurity C</u>	3.98	%			5.0		1.0
	<u>Impurity D</u>	0.08	%			0.5		
	<u>Unknown impurities individual</u>	0.09	%			0.5		
	<u>Impurities total</u>	4.05	%			5.0		2.0
<u>LAV044D</u>	<u>Metamizol Sodium</u>							
	<u>Metamizol</u>	435.6	mg/ml	443.1				
	<u>Identification Metamizol</u>	positive		positive				
	<u>Metamizol sodium</u>	466.2	mg/ml	474.3				
	<u>Metamizol sodium monohydrate</u>	491.5	mg/ml	500	475	525		
<u>LAV063H</u>	<u>Benzylalcohol</u>							
	<u>Benzyl alcohol</u>	30.28	mg/ml	30	28.5	31.5		
	<u>Identification Benzyl alcohol</u>	positive		positive				
<u>LAF004E</u>	<u>Extractable volume (ml)</u>	100.9	ml		100	103		
<u>LAV502A</u>	<u>Sterility</u>	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.

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 major deviations are mentioned below.

Initials qualified persons: AB / [Signature]

Continuation on following page Page 1 of 2

AH\_46157\_2005051638

GMP

**Produlab Pharma b.v.**  
Innellenweg 16  
NL-4941 SJ Raamsdonksveer  
The Netherlands

Phone: +31 (0)1162 323000  
mail: info@produlabpharma.nl  
www.produlabpharma.nl

Bank: Rabobank  
BIC/SWIFT: RABO NL2U  
IBAN: NL 4415 0516 3801 0001  
VAT: NL804254242801

Our delivery conditions are deposited at the chamber of commerce under no. 18043343 apply on all deliveries and transactions.



**Alvetra GmbH**  
Am Anger 9  
D-24539 Neumunster  
Deutschland

**Manufacturer's batch certificate**

Sample-code(s), 2020040469 Raamsdonksveer, 05-05-2020

Description of the product	<b>Chosalgan-S Ungarn</b>	Registration number	2956/1/11
Pack size	Injection vial of 100 ml	Order number	2308
Product N° PP / client	P3640 / 5 402308	Batch size	2271 pcs
Recipe/filling number	R0805 / 13 U0002	Expiry date	03-2023
Batch number	<b>20 D 014</b>		
Manufacturing/output date	04-2020 / 04-2020		

Continuation of previous page

Method	Description Parameter	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
--------	--------------------------	--------	------	--------	----------------	-----------------	------------------	-------------------

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

*A.M.G. van Bragt*  
A.M.G. van Bragt  
QC Delegate

N.D.M.J. van Zon- Jacobs, MSc QP  *H.J. Nootboom*  
Senior QP

*[Signature]*  
**KERESKEDELMI CÉLRA  
FELSZABADÍTVA**  
**DR LENGYEL TAMÁS**  
minőségügyi felelős