

AST Farma BV
Wilgenweg 7
3421 TV Oudewater
Nederland

Sample-code(s), 2013100056 Raamsdonksveer, 23-10-2013

Manufacturer's batch certificate

Description of the product	Cavasan oogzalf	Registration number	REG NL 4006
Pack size	Tube of 5 g	Order number	IO005275
Product number	P0202	Batch size	28992 pcs
Recipe/filling number	R0518 U0035	Expiry date	08-2015
Batch number	13 I 162		
Manufacturing/output date	09-2013 / 10-2013		

Method	Description <i>Parameter</i>	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
<u>LAF002A</u>	Relative density	0.867		informative value				
<u>LAF006B</u>	Viscosity (RotoVisco)	145	mPa·s	informative value				
<u>LAF008A</u>	Appearance	ointment		ointment				
<u>LAF011A</u>	Colour	light yellow		light yellow				
<u>LAF014B</u>	Particle size 5 µm (number)	96	%		50			
<u>LAF014B</u>	Particle size 10 µm (number)	99	%		95			
<u>LAF025A</u>	Homogeneity	homogeneous		homogeneous				
<u>LAV015A</u>	Choramphenicol	19.71	mg/g	20.0	19.0	21.0		
<u>LAV025G</u>	Vitamins oily soluble							
	<i>Retinol palmitate</i>	14330	IU/g	15000	13500	16500		
<u>LAF004F</u>	Extractable weight (g)	4.67	g		4.5	5.1		
<u>LAV500A</u>	Sterility							
	<i>Sterility (14 days)</i>	sterile		sterile				
	<i>Sterility (21 days)</i>	sterile		sterile				

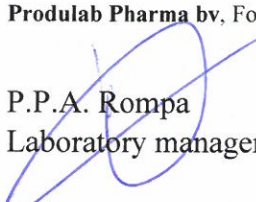
All mentioned limits are equal to or stricter than the limits mentioned in the available documentation. Additional items may be specified without actual impact on the product specifications. LAV901A = component(s) not tested; result declared on the basis of the production amounts. LAV903A = component(s) not tested; result is declared amount according the composition.

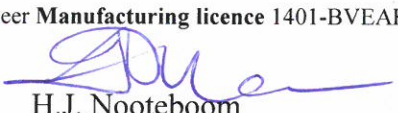
Produlab Pharma retains samples till 1 year after the expiry date. Records of the analysis are retained for 7 years and are available on request.

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.
The batch is released into the market.

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


P.P.A. Rompa
Laboratory manager


H.J. Nooteboom
QA manager, QP