Produlab Pharma

Certificate of Analysis

AST Farma BV
Wilgenweg 7
3421 TV Oudewater
Nederland

Manufacturer's batch certificate

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

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

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

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