Produlab Pharma

Certificate of Analysis

AST Farma BV
Wilgenweg 7
3421 TV Oudewater
Nederland

Sample-code(s), 2012080911 Raamsdonksveer, 05-10-2012

Manufacturer's batch certificate

Description of the product	**Aureomycin oogzalf**		
Pack size	Tube of 5 g		
Product number	P1447	Registration number	REG NL 01620
Recipe/filling number	R1027 U0244	Order number	IO004740
Batch number	**12 H 063**	Batch size	10000 pcs
Manufacturing/output date	08-2012 / 08-2012	Expiry date	07-2017

Method	Description *Parameter*	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
LAF002A	Relative density	**0.861**		informative value				
LAF006B	Viscosity (RotoVisco)	**75.2**	cP	informative value				
LAF008A	Appearance	**ointment**		ointment				
LAF011A	Colour	**yellow**		yellow				
LAF014B	Particle size 25 µm (number)	**100**	%		100			
LAF025A	Homogeneity	**homogeneous**		homogeneous				
LAV135A	Chloortetracycline HCl							
	Chlortetracycline	**9.749**	mg/g	9.758				
	Chlorotetracycline HCl	**10.49**	mg/g	10.5	9.5	11.0		
LAV800A	Water according to Karl-Fischer	**0.11**	%			0.5		
LAF004F	Extractable weight (g)	**4.79**	g		4.5	5.1		
LAV500A	Sterility							
	Sterility (14 days)	**sterile**		sterile				
	Sterility (21 days)	**sterile**		sterile				

All mentioned limits are equal to or more strict than the limits mentioned in the available documentation. 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.
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

GMP

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