

**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  
Recipe/filling number R1027 U0244  
Batch number **12 H 063**  
Manufacturing/output date 08-2012 / 08-2012

Registration number REG NL 01620  
Order number IO004740  
Batch size 10000 pcs  
Expiry date 07-2017

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

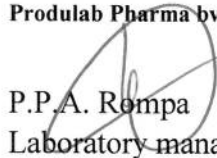
All mentioned limits are equal to or more strict than the limits mentioned in the available documentation. LAV901A = component(s) not tested; result declared on the basis of the production amounts. LAV903A = component(s) not tested; result is declared amount according the composition.

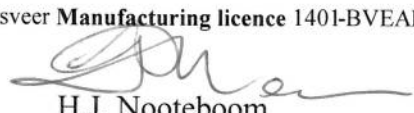
Produlab Pharma retains samples till 1 year after the expiry date. Records of the analysis are retained for 7 years and are available on request.

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