Produlab Pharma

Certificate of Analysis

CP Pharma GmbH
Ostlandring 13
D-31303 Burgdorf
Deutschland

Manufacturer's batch certificate

Sample-code(s), 2014021072 Raamsdonksveer, 22-04-2014

Description of the product	**CP-Tylosin 200**		
Pack size	Injection vial of 100 ml		
Product number	P2396	Registration number	2312/1/07
Recipe/filling number	R0026 U0001	Order number	5132 / HU/13
Batch number	**14 B 204**	Batch size	1000 pcs
Manufacturing/output date	02-2014 / 02-2014	Expiry date	01-2016

Method	Description *Parameter*	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
LAF001A	pH value	**5.81**			5.6	6.3		
LAF002A	Relative density	**1.082**		1.087	1.07	1.10		
LAF003A	Refractive index	**1.43428**		informative value				
LAF008A	Appearance	**clear**		clear				
LAF011A	Colour	**yellow**		yellow				
LAF025A	Homogeneity	**homogeneous**		homogeneous				
LAV024A	Tylosine tartrate							
	Tylosin A	**177.9**	mg/ml	informative value				
	Activity Tylosin A	**92.3**	%	informative value				
	Tylosin	**192.7**	mg/ml	200	190.0	210.0		
	Activity Tylosin	**850**	IU/mg	850				
	Tylosin tartrate	**226.8**	mg/ml	235.3	223.5	247.0		
LAV063C	Benzylalcohol							
	Benzyl alcohol	**39.92**	mg/ml	40.5	38.5	42.5		
LAF004E	Extractable volume (ml)	**100.1**	ml		100	103		
LAV502C	Sterility	**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.

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

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