

Le Vet BV
 Wilgenweg 7
 3421 TV Oudewater
 Nederland

Sample-code(s), 2015062049 Raamsdonksveer, 18-08-2015

Manufacturer's batch certificate

Description of the product	Dilaterol				
Pack size	PE bottle of 355 ml				
Product N° PP / client	P4287	871846944330	Registration number	3249/1/12	
Recipe/filling number	R1167	U0581	Order number	PO 4467	
Batch number	15 F 224		Batch size	197 pcs	
Manufacturing/output date	06-2015 / 06-2015		Expiry date	05-2017	

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Method	Description Parameter	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
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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. Zeros in decimal values after the last reported digit (other than zero) are suppressed in the reporting system. Such a reported value conforms to the specification limit.
 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; other applicable deviations are mentioned below.

The batch is released into the market.

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

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