

Le Vet BV
Wilgenweg 7
3421 TV Oudewater
Nederland

Manufacturer's batch certificate

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

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

Method	Description Parameter	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
<u>LAF001A</u>	pH value	6.89			6.5	7.5		
<u>LAF002A</u>	Relative density	1.059			1.050	1.065		
<u>LAF003A</u>	Refractive index	1.371			1.3675	1.3775		
<u>LAF006B</u>	Viscosity (RotoVisco)	2830	mPa·s		1350	5000		
<u>LAF008A</u>	Appearance	clear		clear				
<u>LAF011B</u>	Colour with reference solutions Reference solution yellow	>7			6			
<u>LAF025A</u>	Homogeneity	homogeneous		homogeneous				
<u>LAV165A</u>	<u>Clenbuterol HCl / Parabens</u>							
	Clenbuterol	0.0227	mg/ml	0.02209				
	Clenbuterol HCl	0.02569	mg/ml	0.025	0.02375	0.02625		
	Identification Clenbuterol HCl	positive		positive				
	Methyl hydroxybenzoate	2.031	mg/ml	2.02	1.92	2.12		
	Identification Methyl hydroxybenzoate	positive		positive				
	Propyl hydroxybenzoate	0.2637	mg/ml	0.26	0.25	0.27		
	Identification Propyl hydroxybenzoate	positive		positive				
<u>LAV165B</u>	<u>Clenbuterol HCl (Impurities)</u>							
	Impurity B	< 2.57	%			2.57		
	Impurity C	< 1.94	%			1.94		
	Impurity D	< 1.91	%			1.91		
	Impurity E	< 2.60	%			2.60		
	Known impurities total	< 2.60	%			2.60		
	Unknown impurities individual	< 1.3	%			1.3		
	Unknown impurities total	< 1.3	%			1.3		
	Impurities total	< 4.0	%			4.0		
<u>LAF004C</u>	Volume (ml, calculated)	361.7	ml		355.0			
<u>LAV510C</u>	<u>Microbial quality</u>							
	Total viable aerobic microbial count	0	CFU/ml			100	0	
	Total combined yeast/mould count	0	CFU/ml			10	0	
	E. coli	absent		absent				

Initials qualified persons:  / 

Continuation on following page Page 1 of 2

 AH_32031_1508181339



Produlab Pharma b.v.
P.O. Box 431
NL-4940 AK Raamsdonksveer
Forellenweg 16
NL-4941 SJ Raamsdonksveer
The Netherlands

Phone +31(0)162 523000
mail@produlabpharma.nl
www.produlabpharma.nl

NEW BANKACCOUNT
Rabobank
BIC/SWIFT RABOIN21
IBAN NL 63RAB00101326831
WAT NL8042 54 242 801

Our delivery and sales conditions as deposited at the chamber of commerce under no.: 18043243 apply on all deliveries and transactions.

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

Continuation of previous page

Method	Description Parameter	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
--------	--------------------------	--------	------	--------	----------------	-----------------	------------------	-------------------

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**

P.P.A. Rompa
P.P.A. Rompa
Laboratory manager

W.L. Leung
QA officer, QP

H.J. Nooteboom
 H.J. Nooteboom
QA manager, QP