Produlab Pharma

QS geprüft
16.4.2013

Certificate of Analysis

CP Pharma GmbH
Ostlandring 13
D-31303 Burgdorf
Deutschland

Sample-code(s). 2013031151 Raamsdonksveer, 10-04-2013

Manufacturer's batch certificate

Description of the product	CP-Oxytocin	Registration number	2293/3/07
Pack size	Injection vial of 100 ml	Order number	Mail Moni Arvai 17-1-2013
Product number	P2638	Batch size	4857 pcs
Recipe/filling number	R0741 U0002	Expiry date	02-2016
Batch number	13 C 077		
Manufacturing/output date	03-2013 / 03-2013		

Method	Description *Parameter*	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
LAF001A	pH value	3.54			3.0	4.0		
LAF002A	Relative density	0.997		0.995	0.990	1.020		
LAF003A	Refractive index	1.33507			1.333	1.337		
LAF008A	Appearance	clear		clear				
LAF011A	Colour	colourless		colourless				
LAF025A	Homogeneity	homogeneous		homogeneous				
LAV047B	Oxytocin acetate / Chlorobutanol							
	Oxytocin	9.985	IU/ml	10.0	9.50	10.50		
	Identification Oxytocin	positive		positive				
	Chlorobutanol	2.77	mg/ml	informative value				
	Chlorobutanol hemihydrate	2.91	mg/ml	3.0	2.85	3.15		
	Identification Chlorobutanol hemihydrate	positive		positive				
LAV047C	Oxytocin acetate impurities							
	Impurity individual	0.39	%	1.5		1.5		
	Impurities total	0.39	%	5.0		5.0		
LAF004E	Extractable volume (ml)	101.5	ml		100	103		
LAV502A	Sterility	sterile		sterile				
LAV512A	Endotoxins	2.5	IU/ml			5		

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.

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-BVEAK

P.P.A. Rompa
Laboratory manager

H.J. Nooteboom
QA manager, QP

16.APR.2013

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GMP
Produlab Pharma b.v.
P.O. Box 421
NL-4940 AK Raamsdonksveer
Forellenweg 16
NL-4941 SJ Raamsdonksveer
The Netherlands

phone +31(0)162 523000
fax +31(0)162 523024

mail@produlabpharma.nl
www.produlabpharma.nl

F. van Lanschot Bankiers N.V.
Breda, acc.no. 22.54.77.87e
BIC: FVLBNL22
IBAN: NL14FVLB0225477876
VAT No. 8043.54.142.B01