Produlab Pharma

Certificate of Analysis

CP Pharma GmbH
Ostlandring 13
D-31303 Burgdorf
Deutschland

Manufacturer's batch certificate

Sample-code(s), 2013061388 Raamsdonksveer, 01-08-2013

Description of the product	**CP-Oxytocin**		
Pack size	Injection vial of 50 ml		
Product number	P3315	Registration number	2293/2/07
Recipe/filling number	R0741 U0024	Order number	HU/3
Batch number	**13 F 209**	Batch size	2498 pcs
Manufacturing/output date	/ 06-2013	Expiry date	05-2016

Method	Description *Parameter*	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
LAF001A	pH value	**3.41**			3.0	4.0		
LAF002A	Relative density	**0.997**		0.995	0.990	1.020		
LAF003A	Refractive index	**1.33506**			1.333	1.337		
LAF008A	Appearance	**clear**		clear				
LAF011A	Colour	**colourless**		colourless				
LAF025A	Homogeneity	**homogeneous**		homogeneous				
LAV047B	Oxytocin acetate / Chlorobutanol							
	Oxytocin	**9.926**	IU/ml	10.0	9.50	10.50		
	Identification Oxytocin	**positive**		positive				
	Chlorobutanol	**2.8**	mg/ml	informative value				
	Chlorobutanol hemihydrate	**2.942**	mg/ml	3.0	2.85	3.15		
	Identification Chlorobutanol hemihydrate	**positive**		positive				
LAV047C	Oxytocin acetate impurities							
	Impurity individual	**1.04**	%	1.5		1.5		
	Impurities total	**2.77**	%	5.0		5.0		
LAF004E	Extractable volume (ml)	**50.5**	ml		50	52.0		
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

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