Produlab Pharma

Certificate of Analysis

CP Pharma GmbH
Ostlandring 13
D-31303 Burgdorf
Deutschland

Manufacturer's batch certificate

Sample-code(s), 2013110251 Raamsdonksveer, 11-02-2014

Description of the product	**Dexamethason Inj. A.U.V.**		
Pack size	Injection vial of 100 ml		
Product number	P2640	Registration number	2039/2/06
Recipe/filling number	R0749 U0364	Order number	HU/10
Batch number	**13 K 075**	Batch size	2866 pcs
Manufacturing/output date	/ 11-2013	Expiry date	10-2015

Method	Description *Parameter*	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
LAF001A	pH value	**7.5**		7.4	7.0	7.6		
LAF002A	Relative density	**1.008**		1.007	0.997	1.017		
LAF003A	Refractive index	**1.33528**		1.3360	1.3340	1.3380		
LAF008A	Appearance	**clear**		clear				
LAF011A	Colour	**colourless**		colourless				
LAF029A	Odour	**specific**		specific				
LAF030A	Particulate matter	**absent**		absent				
LAV020D	Dexamethason Sodiumphosphate / Chlorocresol							
	Dexamethason	**1.992**	mg/ml	2.00	1.90	2.10		
	Identification Dexamethason	**positive**		positive				
	Dexamethason sodium phosphate	**2.62**	mg/ml	2.63	2.50	2.76		
	Chlorocresol	**1.032**	mg/ml	1.00	0.95	1.05		
	Identification Chlorocresol	**positive**		positive				
LAV020E	Dexamethason Sodiumphosphate / Chlorocresol / im							
	Dexamethason (impurity)	**< 0.05**	%			0.5		
	Unknown impurities individual	**< 0.05**	%			0.5		
	Unknown impurities total	**< 0.05**	%			1.0		
LAV090C	Unknown impurities Chlorocresol							
	Unknown impurities total	**< 0.05**	%			1.0		
LAF004E	Extractable volume (ml)	**100.7**	ml		100	103		
LAV502A	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

P.P.A. Rompa
Laboratory manager

H.J. Nooteboom
QA manager, QP

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GMP

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