Produlab Pharma

QS geprüft
10.02.2014

Certificate of Analysis

CP Pharma GmbH
Ostlandring 13
D-31303 Burgdorf
Deutschland

Manufacturer's batch certificate Sample-code(s), 2014011114 Raamsdonksveer, 07-02-2014

Description of the product	**Dexamethason in DMSO**		
Pack size	Bottle of 100 ml		
Product number	P2134	Registration number	Zul.Nr.:6778053.00.00
Recipe/filling number	R0695 U0047	Order number	4578
Batch number	**13 L 024**	Batch size	4895 pcs
Manufacturing/output date	01-2014 / 01-2014	Expiry date	11-2016

Method	Description *Parameter*	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
LAF002A	Relative density	1.105		1.100	1.080	1.120		
LAF003A	Refractive index	1.469		1.475	1.450	1.500		
LAF008A	Appearance	reference suspension I		reference suspension I				
LAF011A	Colour	colourless		colourless				
LAF011B	Colour with reference solutions							
	Reference solution brown	>9			9			
LAF025A	Homogeneity	homogeneous		homogeneous				
LAV021B	Dexamethason and DMSO identification							
	Dexamethason	0.0513	mg/ml	0.050	0.0485	0.0525		
	Identification Dexamethason	positive		positive				
	Identification Dimethylsulfoxide	positive		positive				
LAV021E	Dexamethason impurities							
	Hydrocortison	< 0.05	%			0.2		
	Methylprednisolon	< 0.05	%			0.2		
	Betamethason	< 0.05	%			0.5		
	Dexamethason acetate	< 0.05	%			0.2		
	sum related substances	< 0.05	%			0.5		
	Unknown impurities single	0.8	%			2.0		
	sum unknown impurities	0.8	%			4.5		
LAF004E	Extractable volume (ml)	100.5	ml	101	100	102.5		
LAV509B	Microbial quality							
	Total viable aerobic microbial count	0	CFU/ml			100	0	
	Total combined yeast/mould count	0	CFU/ml			10	0	
	S. aureus	absent		absent				
	Pseudomonas aeruginosa	absent		absent				

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 and analysed at a qualified third party site, packaging and further quality control being performed at the below mentioned site in full compliance with the EU GMP requirements and with the specifications as agreed with the marketing authorization holder 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.

Initials qualified persons:

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NEW BANK ACCOUNT

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

Produlab Pharma

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10.04.2014

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Produlab Pharma b.v, Forellenweg 16, NL-4941 SJ Raamsdonksveer Manufacturing licence 1401-PLG

P.P.A. Rompa
Laboratory manager

H.J. Nooteboom
QA manager, QP

10. FEB. 2014

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