Produlab Pharma

Certificate of Analysis Q

QS geprüft
19.02.2014

CP Pharma GmbH
Ostlandring 13
D-31303 Burgdorf
Deutschland

Manufacturer's batch certificate — Sample-code(s), 2013080688 — Raamsdonksveer, 11-02-2014

Description of the product	**CP-Phenylbutazon 20% inj.**		
Pack size	Injection vial of 100 ml		
Product number	P4187	Registration number	3251/2/12
Recipe/filling number	R0717 U0177	Order number	HU/8 - 4878
Batch number	**13 H 205**	Batch size	1195 pcs
Manufacturing/output date	/ 08-2013	Expiry date	07-2015

Method	Description *Parameter*	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
LAF001A	pH value	9.6			9.5	10.0		
LAF002A	Relative density	1.074		1.075	1.05	1.10		
LAF003A	Refractive index	1.41848		informative value				
LAF008A	Appearance	clear		clear				
LAF011A	Colour	light yellow		light yellow				
LAF011B	Colour with reference solutions							
	Reference solution brown-yellow	>5			5			
LAF025A	Homogeneity	homogeneous		homogeneous				
LAF028A	Tightness of closure	leak tight		leak tight				
LAF029A	Odour	specific		specific				
LAF030A	Particulate matter	absent		absent				
LAV049E	Phenylbutazon							
	Phenylbutazon	196.4	mg/ml	200.0	190.0	210.0		
	Identification Phenylbutazon	positive		positive				
LAV049F	Phenylbutazon (impurities)							
	Imp A (RRT 0.80)	< 0.15	%			0.25		
	Imp B (RRT 0.60)	< 0.005	%			0.25		
	Imp C (RRT 0.77)	< 0.03	%			0.1		
	Imp D (RRT 1.97)	< 0.005	%			0.1		
	Imp E (RRT 0.26)	< 0.003	%			0.1		
	Unknown impurities single	0.343	%			1.0		0.5
	Unknown impurities total	0.99	%			1.5		1.0
LAV063I	Benzylalcohol							
	Benzyl alcohol	20.05	mg/ml	20.0	19.0	21.0		
	Identification Benzyl alcohol	positive		positive				
LAV903A	Sodium Edetate							
	Sodium edetate	0.5	mg/ml	0.5	0.45	0.525		
	Identification Sodium edetate	positive		positive				
LAF004E	Extractable volume (ml)	100.3	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.

Initials qualified persons: ______

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GMP

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Produlab Pharma bv, Forellenweg 16, NL-4941 SJ Raamsdonksveer Manufacturing licence 1401-FLG

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19. FEB. 2014

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