Produlab Pharma

Certificate of Analysis

CP Pharma GmbH
Ostlandring 13
D-31303 Burgdorf
Deutschland

Manufacturer's batch certificate

Sample-code(s), 2011110605 Raamsdonksveer, 10-02-2012
Sample-code(s), 2011110614

Description of the product	**Cepesedan**		
Pack size	Injection vial of 5 ml		
Product number	P3740	Registration number	
Recipe/filling number	R1021 U0672	Order number	1706
Batch number	**11 K 032**	Batch size	600 pcs
Manufacturing/output date	/ 11-2011	Expiry date	10-2014

Method	Description *Parameter*	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
LAF001A	pH value	4.4			3.5	5.5		
LAF002A	Relative density	1.005			1.003	1.006		
LAF003A	Refractive index	1.33638			1.3300	1.3400		
LAF008A	Appearance	clear		clear				
LAF011B	Colour with reference solutions							
	Reference solution brown	9			9			
LAF030A	Particulate matter	absent		absent				
LAF037A	Osmolality	275	mosm/kg		240	340		
LAV190A	Detomidin HCl / Methylparaben							
	detomidin HCl	10.06	mg/ml	10.0	9.50	10.50		
	Identification Detomidin	positive		positive				
	Methyl hydroxybenzoate	0.9855	mg/ml	1.00	0.95	1.05		
	Identification Methyl-paraben	positive		positive				
LAV190B	Detomidin HCl impurities							
	4-Hydroxybenzoic acid (RRT 0.17)	< 0.06	%	informative value				
	Impurity A (RRT 0.40)	< 0.06	%			0.2		
	Impurity B (RRT 2.34)	< 0.06	%			0.2		
	Impurity C (RRT X.XX)	< 0.06	%			0.2		
	Unknown impurities individual	< 0.06	%			0.2		
	Unknown impurities total	< 0.06	%	informative value				
	Impurities total	0.084	%			1.0		
LAF004E	Extractable volume (ml)	5.1	ml		5.0	5.6		
LAF030A	Particulate matter	absent		absent				
LAV502A	Sterility	sterile		sterile				

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.

Initials qualified persons:

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