Certificate of Analysis

Product name: **Aciclovirum**

Batch number / Weight: **22A15-B02-226856 / 25 G**

Analysed according to: **Ph.Eur.11.0**

Number of analysis / Inspection Code **22A15-B02 / INS-22-2983**

Reference Code / No.: **V01478 / ACV1019015**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
IR-spectrum	Conform	Conform		
Appearance of solution	Clear <=Y7	Conform		
Related substances	Conform	Conform		
Impurity B	<=0,7	0,08	%	
Sum of impurities O + Q	<=0,15	0,04	%	
Sum of impurities K + R	<=0,15	<0,03	%	
Impurity J	<=0,2	<0,03	%	
Impurity N	<=0,15	<0,03	%	
Impurity P	<=0,15	<0,03	%	
Impurity C	<=0,15	0,000	%	
Unspecified impurities	<=0,05	<0,03	%	
Total impurities	<=1,0	0,11	%	
Water (Karl Fischer)	<=6,0	4,7	%	
Sulphated ash	<=0,1	0,03	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Aciclovir	98,5 - 101,0	99,6	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Endotoxins		<0,5	IU/mg	
Total aerobic microbial count (TA		Conform	CFU/g	
Total yeasts and moulds (TYMC)		Conform	CFU/g	
Residual solvents				
Toluene		<890	ppm	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAPL, ElSpol, CBMiA

Release:
Dominika Sołtysik
Qualified Person

16-01-2023

Expiration: 19-11-2024

Conclusion: APPROVED

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