

Certificate of Analysis

Product name: **Aciclovirum**

Batch number / Weight: **22A15-B02-223581 / 10 G**

Analysed according to: **Ph.Eur.10.8**

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
Residual solvents				
Toluene		<890	ppm	

Analysis performed by the authorized lab.

Release:

Dominika Soltysik

Qualified Person

16-08-2022

Expiration: 19-11-2024

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.