

Certificate of Analysis

Product name: **Aciclovirum**
Batch number / Weight: **21C17-B06-213263 / 10 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
IR-spectrum	Conform	Conform		
Appearance of solution	Clear $\leq Y7$	Conform		
Related substances	Conform	Conform		
Impurity B	$\leq 0,7$	0,08	%	
Sum of impurities O + Q	$\leq 0,15$	0,04	%	
Sum of impurities K + R	$\leq 0,15$	$< 0,03$	%	
Impurity J	$\leq 0,2$	$< 0,03$	%	
Impurity N	$\leq 0,15$	$< 0,03$	%	
Impurity P	$\leq 0,15$	$< 0,03$	%	
Impurity C	$\leq 0,15$	0,00	%	
Unspecified impurities	$\leq 0,05$	$< 0,03$	%	
Total impurities	$\leq 1,0$	0,11	%	
Water (Karl Fischer)	$\leq 6,0$	5,12	%	
Sulphated ash	$\leq 0,1$	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	100,41	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Dominika Sołtysik
 Qualified Person

29-09-2021

Expiration: 19-11-2024

Conclusion: APPROVED

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