

Certificate of Analysis

Product name: Aciclovirum
Batch number / Weight: 24C11-B01-236312 / 10 g
Producer / Producer Batch Number: Yung Zip Chemical Ind. Co., Ltd. / ACV1023003
Analyzed according to: Ph. Eur.11.5
Number of Analysis / Certificate no.: 24C11-B01 / QO0005892

	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	0,12	%	
Sum of impurities O + Q	<=0,15	0,066	%	
Sum of impurities K + R	<=0,15	0,032	%	
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 for each	<0,03	%	
Total impurities	<=1,0	0,25	%	
Water (Karl Fischer)	<=6,0	4,93	%	
Sulfated ash	<=0,1	0,02	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	98,5 - 101,0 (anhydrius substance)	99,89	% m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		DP

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 Fagron PL lab

Release:

27-10-2024
 Dominika Sołtysik
 Qualified Person

Expiration: 26-4-2028

Conclusion: APPROVED

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