Fagron

Certificate of Analysis

Productname: **Aciclovirum**

Number of analysis/Inspection Code: 1 / KEUR-180592B

Batchnumber: **19I17-F02-366977**

Reference code / No.: 4013 / ACV1019008

Analysed according to: **PH.EUR 9.8**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
IR-spectrum	Conform	Conform		
Appearance of solution	Clear <=Y7	Conform		1% m/V in 0.1M NaOH
Related substances	Conform	Conform		
Impurity B	<=0,7	0,1	%	
Sum of impurities O + Q	<=0,3	0,0	%	
Sum of impurities K + R	<=0,2	<0,03	%	
Impurity A	<=0,2	<0,03	%	
Impurity G	<=0,2	0,0	%	
Impurity J	<=0,2	<0,03	%	
Impurity N	<=0,2	<0,03	%	
Impurity P	<=0,2	<0,03	%	
Impurity C	<=0,1	0,0	%	
Impurity F	<=0,1	0,0	%	
Impurity I	<=0,1	<0,03	%	
Unspecified impurities	<=0,05	<0,03	%	
Total impurities	<=1,5	0,1	%	
Water (Karl Fischer)	<=6,0	4,6	%	
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Aciclovir	98,5 - 101,0	100,3	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

02/21/20

Expiration: 04-2024

Conclusion: APPROVED

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