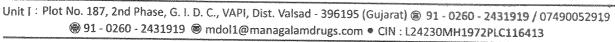
## F. & A. PHARMA-Handels-GmbH Bonhoefferring 41 • D - 46286 Dorsten • Germany Bonhoefferring 41 • D-46286 Dorsten • Germany Phone: +49(0)2369 261947 • Fax: +490()2369 9261950 Read The Company of the Comp





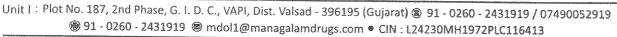
## CERTIFICATE OF ANALYSIS

Name of the Mater	rial: Aciclovir Ph. Eur.		Page No. 1 of 2
Mfg. License No.	G/725	CAS No.	50277 00 2
Batch No.	ACL-1A-202001	Batch Size	59277-89-3
Mfg. Date	February-2020	Retest Date	434.00 Kgs
Received Date	22/02/2020	Release Date	January-2023
A. R. No.	ACL-20/01		12/03/2020
Storage Conditions Preserve in tight containers, Store at room temperature, Protected from light and moisture			
DESILITE OF ANALYSIST			

RESILTS OF ANALYSIS

0	RESULTS OF ANALYSIS				
Sr. No.	Test	Observation	Specification		
Pha	rmacopoeial Tests:				
01	Appearance	White crystalline powder	White or almost white, crystalline powder		
02	Solubility	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in heptane. It dissolves in dilute solutions of mineral acids and alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in heptane.		
03	Identification Test: (By Infrared Absorption Spectrophotometry)	The Infrared spectrum of the sample is corresponding to that of the spectrum of the Aciclovir WS	The Infrared spectrum of the sample should be corresponding to that of the spectrum of the Aciclovir RS/WS.		
04	Appearance of solution	The solution is clear and not more intensely coloured than reference solution Y <sub>7</sub> .	The solution is clear and not more intensely coloured than reference solution Y <sub>7</sub> .		
05	Water Content (By KF)	5.07 % w/w	Not more than 6.0% w/w		
06	Sulfated Ash	0.04 % w/w	Not more than 0.1% w/w		
07	Related substance (By HPLC	():	1100 more than 0.170 w/w		
-	Impurity – B	0.33 % w/w	Not more than 0.7% w/w		
-	Impurity – C Impurity – J	Below detection limit	Not more than 0.15% w/w		
}	Impurity – N	0.01 % w/w	Not more than 0.2% w/w		
F	Impurity – P	0.02 % w/w	Not more than 0.15% w/w		
-		0.01 % w/w	Not more than 0.15% w/w		
-	Sum of Impurities O and Q	0.01 % w/w	Not more than 0.15% w/w		
-	Sum of Impurities K and R	Below detection limit	Not more than 0.15% w/w		
-	Unspecified impurity	0.01% w/w	Not more than 0.05% w/w		
08	Total impurities	0.43 % w/w	Not more than 1.0% w/w		
	Assay (By Potentiometrically)	100.1% w/w	Not less than 98.5% and not more than 101.0% of C <sub>8</sub> H <sub>11</sub> N <sub>5</sub> O <sub>3</sub> , calculated on the anhydrous basis.		
			, a. Cas Odsis.		

Prepared By Gails	Checked By	Approved By
	(Sr. Executive Q. C.)	(Sr. Manager Q. A)
ivis. Kaksiia Desai		Dr. Bhavin Naik





## CERTIFICATE OF ANALYSIS

Page No. 2 of 2

Name of the Mater	rial: Aciclovir Ph. Eur.		1 age 140. 2 01 2
Mfg. License No.	G/725	CAS No.	59277-89-3
Batch No.	ACL-1A-202001	Batch Size	434.00 Kgs
Mfg. Date	February-2020	Retest Date	January-2023
Received Date	22/02/2020	Release Date	12/03/2020
A. R. No.	ACL-20/01		
Storage Conditions	Preserve in tight containe	ers. Store at room temperature	e, Protected from light and moisture
			, i totoctou mom ngm and moisture

## RESULTS OF ANALYSIS

Sr. No.	Test	Observation	Specification			
Add	itional In-House Tests:					
09						
	Methanol	Below detection limit	Not more than 3000 ppm			
10	Benzene Content (By GC-HS)*	Not Detected	Not more than 2 ppm			
11	Bulk density:					
	Untapped density	0.35 gm/ml	For Record			
	Tapped density	0.50 gm/ml	For Record			
12	Particle size (By sieve)	99.9% Sample Passing through 40 mesh	For Record			

Chemical Name of impurities:

Traine of imputities.			
Aciclovir Impurity-B	ı	2-amino-1,7-dihydro-6 <i>H</i> -purin-6-one (guanine).	
Aciclovir Impurity-C	:	2-amino-7-[(2-hydroxyethoxy) methyl]-1,7- dihydro-6 <i>H</i> -purin-6-one.	
Aciclovir Impurity-J	:	9,9'-[ethane-1,2-diylbis(oxymethylene)]bis(2-amino-1,9-dihydro-6 <i>H</i> -purin-6-one)	
Aciclovir Impurity-K	:	2, 2'-(methylenediazanediyl)bis[9-[(2-hydroxyethoxy)methyl]-1,9-dihydro-6 <i>H</i> -purin-6-one].	
Aciclovir Impurity-N	:	N	
Aciclovir Impurity-O	:		
Aciclovir Impurity-P	:	2-amino-9-(2-hydroxyethyl)-1,9- dihydro-6H-purin-6-one.	
Aciclovir Impurity-Q	:	Mixture of 2-amino-9-[[2-(hydroxyethoxy)methoxylmethyl]-1 9-dihydro-6H-purin	
	,	6-one and 2-amino-9-[[2-(hydroxymethoxy)ethoxy]methyl]-1,9-dihydro-6 <i>H</i> -purin-	
V.		o-one.	
Aciclovir Impurity-R	:	9,9'-[methylenebis(oxyethane-2,1-di-yloxymethylene)]bis(2-amino-1,9-dihydro-	
		6H-purin-6-one.	
Note * Tost norform		0.7.(0.0.10.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0	

Note: \*Test performed on 07/09/2020.

Remark: - The material Complies as per Ph. Eur. & IH Specification.

Prepared By	Checked By	Approved By
(Officer Q. C.) 17/04/2021	(Sr. Executive Q. C.)	(Sr. Manager Q. A.)
Ms. Kaksha Desai	Ms. Vaishali Bhandare	Dr. Bhavin Naik