



Unit I : Plot No. 187, 2nd Phase, G. I. D. C., VAPI, Dist. Valsad - 396195 (Gujarat) ☎ 91 - 0260 - 2431919 / 07490052919  
☎ 91 - 0260 - 2431919 ✉ mdol1@managalamdrugs.com • CIN : L24230MH1972PLC116413

## CERTIFICATE OF ANALYSIS

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Name of the Material: Aciclovir Ph. Eur.			
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 containers, Store at room temperature, Protected from light and moisture		

## RESULTS OF ANALYSIS

Sr. No.	Test	Observation	Specification
<b>Pharmacopoeial Tests:</b>			
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. It dissolves in dilute solutions of mineral acids and alkali hydroxides.
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):		
	Impurity – B	0.33 % w/w	Not more than 0.7% w/w
	Impurity – C	Below detection limit	Not more than 0.15% w/w
	Impurity – J	0.01 % w/w	Not more than 0.2% w/w
	Impurity – N	0.02 % w/w	Not more than 0.15% w/w
	Impurity – P	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
	Total impurities	0.43 % w/w	Not more than 1.0% w/w
08	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.

Prepared By <i>Devi</i> (Officer Q. C.) 17/04/2021 Ms. Kaksha Desai	Checked By <i>Vaishali</i> (Sr. Executive Q. C.) 17/04/2021 Ms. Vaishali Bhandare	Approved By <i>Bhavin</i> (Sr. Manager Q. C.) 17/04/2021 Dr. Bhavin Naik
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### RESULTS OF ANALYSIS

Sr. No.	Test	Observation	Specification
<b>Additional In-House Tests:</b>			
09	Residual solvent by GC-HS:		
	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:

Aciclovir Impurity-B	:	2-amino-1,7-dihydro-6H-purin-6-one (guanine).
Aciclovir Impurity-C	:	2-amino-7-[(2-hydroxyethoxy) methyl]-1,7- dihydro-6H-purin-6-one.
Aciclovir Impurity-J	:	9,9'-[ethane-1,2-diylbis(oxyethylene)]bis(2-amino-1,9-dihydro-6H-purin-6-one)
Aciclovir Impurity-K	:	2, 2'-(methylenediazanediyl)bis[9-[(2-hydroxyethoxy)methyl]-1,9-dihydro-6H-purin-6-one].
Aciclovir Impurity-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)methoxy]methyl]-1,9-dihydro-6H-purin-6-one and 2-amino-9-[[2-(hydroxymethoxy)ethoxy]methyl]-1,9-dihydro-6H-purin-6-one.
Aciclovir Impurity-R	:	9,9'-[methylenebis(oxyethane-2,1-di-yloxymethylene)]bis(2-amino-1,9-dihydro-6H-purin-6-one).

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

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

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