



Natco Pharma Limited

Regd. Off : 'NATCO HOUSE', Road No. 2, Banjara Hills, Hyderabad-500 034, INDIA
Tel : +91 40 23547532, Fax : +91 40 23548243

Email: info@natcopharma.co.in

CERTIFICATE OF ANALYSIS

Product Name: Dacikast 60	B.No. : 1901040
Generic Name : Daclatasvir Dihydrochloride Tablets	Product Code : GDA21AZ
Batch size: 167445 Tablets	Sampling Date: 24/10/2018
Qty. Sampled: 01 Containers	Analysis Date: 24/10/2018
Sampled by: Priyanka	Reporting Date: 25/10/2018
	Mfg. Date: 10/2018
	Exp. Date: 09/2020
	A.R. No.: FP/AR/334/18

S.No	TEST	SPECIFICATION	RESULT
1.	Description	Orange coloured, round Biconvex film coated tablets debossed with "D" on one side and "60" on other side.	Orange coloured, round Biconvex film coated tablets debossed with "D" on one side and "60" on other side.
2.	Identification a) HPLC b) UV	The retention time of the major peak in the chromatogram of the sample preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the Assay. The UV absorption spectrum of the Sample solution and standard solution shall exhibit maxima at the same wavelengths.	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the Assay. The UV absorption spectrum of the Sample solution and standard solution exhibits maxima at the same wavelengths.
3.	Uniformity of dosage units USP <905> (By content uniformity)	The acceptance value of the first 10 dosage units is less than or equal to L1 (L1 is 15.0 and L2 is 25.0)	Acceptance value = 3.84

	PREPARED BY	CHECKED BY	APPROVED BY
Sign	<i>Shuhan</i> 25/10/2018	<i>Devi</i> 25/10/2018	<i>Shunitha</i> 25/10/2018
Name	Samir phukan	Badam khatun	Sangay S. Chundris
Designation	Asst. Chemist - GC	Asst Manager QC	Sr manager qc

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S.No	TEST	SPECIFICATION	RESULT
4.	Average weight per Tablet	309.0 mg \pm 5.0% (293.55 mg - 324.45 mg)	307.54 mg
5.	Water content (% w/w, by KF) USP<921>	Not more than 5.0	2.32
6.	Dissolution (By UV) USP <711> Apparatus - II (Paddle); Medium - pH 1.2 Hydrochloric acid Buffer 900 mL; RPM -50	Not less than 80% (Q) of the labeled amount of Daclatasvir is dissolved in 45 minutes.	Minimum = 100.3 % Maximum = 101.7 % Average = 101.1 %
7.	Assay (By HPLC) Each film coated tablet contains Daclatasvir 60 mg	Not less than 90.0% and not more than 110.0% of the labeled amount of Daclatasvir.	99.9 %
8.	Related impurities (% w/w, By HPLC) A) Individual Unknown impurity (Maximum) B) Total Impurities	Not more than 0.5 Not more than 2.0	0.04 0.13

Remarks: The product complies as per Specification No. : FP/SPC/006-01

	PREPARED BY	CHECKED BY	APPROVED BY
Sign	<i>Priyanka</i> 25/10/2018	<i>Deepa</i> 25/10/2018	<i>Sanjay S. Chandra</i> 25/10/2018
Name	Sanjay S. Chandra	Badin Kaita	Sanjay S. Chandra
Designation	Asst. Chemist - QC	Asst. Manager QC	Sr manager

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