



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: Natdac 60	B.No. : 1900506
Generic Name : Daclatasvir Dihydrochloride Tablets 60 mg	Product Code : GDA21
Batch size: 337453 Tablets	Sampling Date: 10/02/2017
Qty. Sampled: 1x28 Tablet	Mfg. Date: 01/2017
Analysis Date: 11/02/2017	Exp. Date: 12/2018
Reporting Date: 13/02/2017	A.R. No.: FP/AR/053/17

S.No	TEST	SPECIFICATION	RESULT
4.	Average weight per Tablet	309.0 mg \pm 5.0% (293.55 mg - 324.45 mg)	308.21 mg
5.	Water content (% w/w, by KF) USP<921>	Not more than 5.0	2.08
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 = 99.6 % Maximum = 100.5 % Average = 100.2 %
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.	100.2 %
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	0.02 0.08

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

	PREPARED BY	CHECKED BY	APPROVED BY
Sign			
Name	B. N. Chakrabarti	Sangay S. Chandra	Sangay S. Chandra
Designation	Officer - Q.A.	Sr manager - Q.A.	Sr manager - Q.A.

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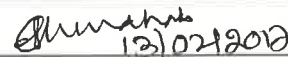

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CERTIFICATE OF ANALYSIS

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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)	Complies (Acceptance value is 1.56)

	PREPARED BY	CHECKED BY	APPROVED BY
Sign			
Name	B N Pentam	Sangay S. Chanthais	Sangay S. Chanthais
Designation	Officer - Q.C.	Sr manager	Sr manager

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