



Natco Pharma Limited

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

CERTIFICATE OF ANALYSIS

Product Name: Daclakem 60	B. No.: 1900128	
Generic Name : Daclatasvir Tablet's 60mg		
Batch size: 168843 Tablets	Sampling Date : 02/04/2016	Mfg. Date: 02/2016
Qty. Sampled: 1 x 28 Tablets	Analysis Date : 02/04/2016	Exp. Date: 01/2018
Sampled by: Bhargavi	Reporting Date: 04/04/2016	A.R. No.: FP/AR/112/16

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.	Complies
2.	Identification a) HPLC	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.	Complies.
	b) UV	The UV absorption spectrum of the Sample solution and standard solution shall exhibit maxima at the same wavelengths.	Complies
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 0.53)
4.	Average weight per Tablet	309.0 mg \pm 5.0% (293.55mg – 324.45mg)	310.20 mg
5.	Water content (% w/w, by KF) USP <921>	Not more than 5.0 % w/w	1.9 %



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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 = 100.13 % Maximum = 101.04 % Average = 100.76 %
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.	99.2 %
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 % 0.12 %

Remarks: The product is complies as per Specification No. : FP/SPC/006-00

N. S.
04/04/2016

PREPARED BY

N. S.
04/04/2016

CHECKED BY

Aje
04/04/2016

APPROVED BY