Natco Pharma Limited
Regd. Off : 'NATCO HOUSE', Road No. 2, Banjara Hills, Hyderabad-500 003. INDIA.
Tel : +91 40 23547532, Fax : +91 40 23548243

CERTIFICATE OF ANALYSIS

Product Name: NATDAC 60 Generic Name : Daclatasvir Tablet's 60mg		B. No.: 1900064
Batch size: 63,256 Tablets	Sampling Date : 22/12/2015	Mfg. Date: 12/2015
Qty. Sampled: 1 x 28 Tablets	Analysis Date : 22/12/2015	Exp. Date: 11/2017
Sampled by: Ch. Bhargavi	Reporting Date: 23/12/2015	A.R. No.: FP/AR/132/15

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 0.7)
4.	Average weight per Tablet	309.0 mg ±5.0% (293.55mg - 324.45mg)	309.9 mg
5.	Water content (% w/w, by KF) USP<921>	Not more than 5.0 % w/w	1.3 %

WORKS : PHARMA DIVISION, Kokjhar, Mirza, Kamrup (R),
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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 = 98.70 % Maximum = 101.40 % Average = 100.19 %
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.	99.56 %
8.	Related impurities (% w/w, By HPLC)		
	A) Individual Unknown impurity (Maximum)	Not more than 0.5%	0.02 %
	B) Total Impurities	Not more than 2.0%	0.13 %

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

PREPARED BY 23/12/2015

CHECKED BY 23/12/2015

APPROVED BY 23/12/2015

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