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: DaciHep 60 Generic Name : Daclatasvir Dihydrochloride Tablets 60mg		B. No.: 1900412
Batch size: 1,68,280 Tablets	Sampling Date : 30/09/2016	Mfg. Date: 09/2016
Qty. Sampled:1x28 Tablets	Analysis Date : 30/09/2016	Exp. Date: 08/2018
Sampled by: Hirumoni	Reporting Date: 30/09/2016	A.R. No.: FP/AR/470/16

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.	Orange coloured, round Biconvex film coated tablets debossed with "D" on one side and "60"on other side.
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.	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.
	b) UV	The UV absorption spectrum of the Sample solution and standard solution shall exhibit maxima at the same wavelengths.	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 6.1)
4.	Average weight per Tablet	309.0 mg ±5.0% (293.55mg – 324.45mg)	309.77 mg

WORKS : PHARMA DIVISION, Kokjhar, Mirza, Kamrup (R),
Guwahati, Assam, 781125, Office : + 91-362-3230471, 472, 473

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S.No	TEST	SPECIFICATION	RESULT
5.	Water content (% w/w, by KF) USP<921>	Not more than 5.0	1.9
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 % Maximum = 101 % Average = 100 %
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.	100.4 %
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 0.06

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

PREPARED BY 30/09/2016

CHECKED BY 30/09/2016

APPROVED BY 30/09/2016

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