



NATCO PHARMA LIMITED

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CERTIFICATE OF ANALYSIS

Product Name: Dacikast™ -60 (Daclatasvir Dihydrochloride Tablets 60 mg)	B. No.: 408935	
Batch size: 1,80,000 Tablets	Sampling Date: 25/05/2018	Mfg. Date: May 2018
Qty. Sampled: 70 Tablets	Analysis Date: 25/05/2018	Exp. Date: Apr.2020
Sampled by: Ch.Mounika	Reporting Date: 01/06/2018	A.R.No.: U4/FP/257/18

S.No.	TEST	RESULT	SPECIFICATION
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 sample retention time corresponds with the standard retention time is obtained in the assay.	The retention time of the major peak in chromatogram of the sample preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the assay.
	b) UV	The peak maxima of the standard and sample spectra exhibit at same wavelengths.	The UV absorption spectrum of the sample solution and standard solution shall exhibit maxima (316 ± 2 nm) at the same wavelength.
3.	Uniformity of Dosage units (By Content Uniformity)	5.2	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).
4.	Average weight per tablet	311.4 mg	309.0mg ± 5.0%(293.6mg to 324.5mg)
5.	Water content (%w/w, by KF)	2.15%	Not more than 5.0 % w/w
6.	Dissolution (By UV)	100.8%	Not less than 80% (Q) of the labeled amount of Daclatasvir is dissolved in 45 minutes.
		99.7%	
		99.5%	
7.	Assay (By HPLC): Each film coated tablet contains: Daclatasvir 60 mg	100.4%	Not less than 90.0% and not more than 110.0% of the labeled amount of Daclatasvir.
8.	Related Impurities (% w/w, By HPLC)		
	A) Individual unknown impurity (Maximum)	0.06%	Not more than 0.5 %
	B) Total impurities	0.06%	Not more than 2.0 %
9.	Microbial Enumeration tests and Test for specified microorganisms		
	Total aerobic microbial count	Less than 10 cfu/g	Not more than 1000 cfu/g
	Total yeasts and molds count	Less than 10 cfu/g	Not more than 100 cfu/g
	Escherichia coli	Absent	Should be absent/g

Remarks: The above product **Conforms / Does Not Conforms** to Specification No: K/FPS/500-00.

Prepared by: *modh...*
Date: *01/06/2018*

Reviewed by: *And*
Date: *01/06/2018*

Approved by: *KSO*
Date: *01/06/2018*