



NATCO PHARMA LIMITED

Regd. Off: 'NATCO HOUSE', Road No. 2, Banjara Hills, Hyderabad-500 034,
Telangana, INDIA. Tel : +91 40 23547532, Fax : +91 40 23548243
CIN : L24230TG1981PLC003201, www.natcopharma.co.in

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT (UNIT-9))

PRODUCT NAME:: Dacikast 60

Generic Name:	Daclatasvir Dihydrochloride Tablets, 60 mg	Product Code:	GDA21AZ
Batch No.:	1903132	LIMS A.R. No.:	1900FPG22000281
Batch Size:	154432 Tablets	Sampled By:	Mriganka
Sampling Date:	02/09/2022	Sampling Quantity:	0 Tablets
Date Of Release:	03/09/2022 10:28	Mfg. Date:	08/2022
Specification No:	FP/SPC/006- 02	Exp. Date:	07/2025

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		
2.1	Identification By HPLC	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 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.
2.2	Identification By UV	The UV absorption spectrum of the sample solution and standard solution exhibits maxima at the same wavelengths.	The UV absorption spectrum of the sample solution and standard solution shall exhibit maxima at the same wavelengths.
3	Uniformity of dosage units USP <905> (By content uniformity)	Acceptance value: 1.45	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	306.71 mg	309.0 mg $\pm$ 5.0% (293.55 mg-324.45 mg)
5	Water content (% w/w, by KF) USP<921>	1.91% w/w	Not more than 5.0% w/w
6	Dissolution (By UV) USP <711>Apparatus -	Minimum: 100.5% Maximum: 102.3%	Not less than 80% (Q) of the labeled amount of Daclatasvir is dissolved in 45

Remarks: APPROVED (Sample Conforms to above Specification)

Comment(s): Approved

Checked By	badan.kalita	Checked On	02/09/2022 15:31
Approved By:	Pandalaneni.Murali Mohan Rao	Approved On	02/09/2022 16:10
Approved By:	hirakmoy.choudhury	Approved On	03/09/2022 10:28
Printed by: hirakmoy.choudhury		Printed on: 03/09/2022 10:28	
Copy No.: 1		Page No.: 1 of 2	

Note : This document has been generated electronically and is valid without signature.

Format No.QCS/157/F01-00



NATCO PHARMA LIMITED

Regd. Off : 'NATCO HOUSE', Road No. 2, Banjara Hills, Hyderabad-500 034,
Telangana, INDIA. Tel : +91 40 23547532, Fax : +91 40 23548243
CIN : L24230TG1981PLC003201, www.natcopharma.co.in

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT (UNIT-9))

PRODUCT NAME:: Dacikast 60

Generic Name:	Daclatasvir Dihydrochloride Tablets, 60 mg	Product Code:	GDA21AZ
Batch No.:	1903132	LIMS A.R. No.:	1900FPG22000281
Batch Size:	154432 Tablets	Sampled By:	Mriganka
Sampling Date:	02/09/2022	Sampling Quantity:	0 Tablets
Date Of Release:	03/09/2022 10:28	Mfg. Date:	08/2022
Specification No:	FP/SPC/006- 02	Exp. Date:	07/2025

	II(Paddle);Medium -pH 1.2 Hydrochloric acid Buffer 900 mL; RPM -50	Average: 101.4%	minutes.
7	Assay (By HPLC) Each film coated tablet contains Daclatasvir 60 mg	98.9%	Not less than 90.0% and not more than 110.0% of the labeled amount of Daclatasvir.
8	Related impurities (% w/w, By HPLC)		
8.1	Individual Unknown impurity (Maximum)	0.04%w/w	Not more than 0.5%w/w
8.2	Total Impurities	0.16%w/w	Not more than 2.0%w/w

Remarks: APPROVED (Sample Conforms to above Specification)

Comment(s): Approved

Checked By	badan.kalita	Checked On	02/09/2022 15:31
Approved By:	Pandalaneni.Murali Mohan Rao	Approved On	02/09/2022 16:10
Approved By:	hirakmoy.choudhury	Approved On	03/09/2022 10:28
Printed by: hirakmoy.choudhury		Printed on: 03/09/2022 10:28	
Copy No.: 1		Page No.: 2 of 2	

Note : This document has been generated electronically and is valid without signature.

Format No.QCS/157/F01-00