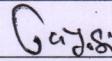


CERTIFICATE OF ANALYSIS

Brand Name of the Product:	DASAKAST -70 mgTablet		
Generic Name of the Product:	Dasatinib Tosylate Tablets (70 mg)		
Batch No.:	ACT2306DTA	A.R. Number:	FPACT2306DTA
Mfg. Date:	06/2023	Date of Sampling:	23/06/2023
Exp. Date:	05/2025	Date of release:	01/07/2023
Batch Size:	22000 Tablets	Reference:	IHS

S.NO	TEST	SPECIFICATION	RESULT
1.	Description	A peach colored, round shaped, biconvex film coated tablets, plain on both side. The tablet should be free from of all physical defects.	Complies.
2.	Identification [By HPLC]	The Retention time of major peak in the chromatogram of the sample preparation corresponds to that in the chromatogram of the Standard preparation as obtained in the assay.	Complies.
3.	Dissolution [By HPLC]	Not less than 70% (D) of the labeled amount of Dasatinib dissolved in 45minutes.	Minimum: 99.69% Maximum: 102.35% Average: 101.20%
4.	Average weight	300.000 mg \pm 5.0% w/w (285.00 mg- 315.0 mg)	308.02mg
5.	Uniformity of weight	Not more than 2 of the individual weights deviate from the average weight by more than 7.5% and none deviate by more than 15%.	- Ve variation: 1.60% +Ve variation: 0.84 %

Remarks : In the opinion of the undersigned the sample ~~complies~~ / ~~does not comply~~ with the IP/BP/USP/In-House Specifications.

Analysed By		Checked by		Approved By	
Name	Anil	Name	Gay Singh	Name	Bhanu
Date	01/07/2023	Date	01/07/2023	Date	01/07/2023

Manufacturing Plant: Aprazer Healthcare Pvt. Ltd. Village Kotla, PO - Barotiwala, Distt.: Solan, Himachal Pradesh – INDIA

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6.	Diameter	9.10 mm \pm 0.3mm (8.80 to 9.40mm)	9.10mm - 9.14mm
7.	Thickness	4.5 mm \pm 0.3mm (4.20mm to 4.80mm)	4.70 mm – 4.74mm
8.	Assay: [By HPLC] Dasatinib	Not less than 66.50 mg and not more than 73.50 mg (95.0% to 105.0% of the labeled amount)	70.31 mg 100.44 %
9.	Related substances : [HPLC]	Any unspecified degradation products- NMT 0.5% Total degradation products -NMT 2.0%	0.119% 0.314%
10.	Disintegration time	Not more than 30 minutes	4 minutes 50 seconds

Remarks : In the opinion of the undersigned the sample ~~complies~~ / ~~does not~~ comply with the ~~IP/BP/USP/In-House~~ Specifications.

Analysed By	<i>AE</i>	Checked by	<i>Gay S</i>	Approved By	<i>BP</i>
Name	<i>Amiax</i>	Name	<i>Gay Singh</i>	Name	<i>Bhram U</i>
Date	<i>01/07/2023</i>	Date	<i>01/07/2023</i>	Date	<i>01/07/2023</i>

Manufacturing Plant: Aprazer Healthcare Pvt. Ltd. Village Kotla, PO - Barotiwala, Distt.: Solan, Himachal Pradesh – INDIA