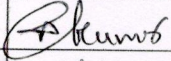
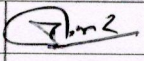



CERTIFICATE OF ANALYSIS

Brand Name of the Product:	SORAFEKAST-200		
Generic Name of the Product:	Sorafenib Tablet IP 200mg		
Product Code:	SF	A.R. Number:	FPACT2403SF
Batch No.:	ACT2403SF	Date of Sampling:	18/05/2024
Mfg. Date:	05/2024	Date of release:	12/06/2024
Exp. Date:	04/2026	Batch Size:	61000 TABLETS
Specification No.:	FG/SPA/SFT-01-02	Reference:	IP/IHS

S.NO	TEST	SPECIFICATION	RESULT
1.	Description	A Yellow coloured, round biconvex, film Coated tablets, plain on both sides.	A Yellow coloured, round biconvex, film Coated tablets, plain on both sides.
2.	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.
3.	Average weight	410.0 mg \pm 5.0 % (389.5 mg to 430.5 mg)	409.98 mg
4.	Uniformity of weight	Not more than two of the individual weights deviate from the average weight by more than the 5.0% and none should deviate by more than 10.0% percent of the average weight.	-ve variation= 1.04% +ve variation = 1.54%
5.	Diameter	10.90 mm \pm 0.2 mm (10.70 mm to 11.10 mm)	10.85 mm – 10.94 mm
6.	Thickness	5.0 mm \pm 0.3 mm (4.70 mm to 5.30 mm)	4.85 mm – 5.12 mm

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	Amit Kumar	Name	Raj Kumar	Name	J. P. Singh
Date	12/06/2024	Date	12/06/2024	Date	12/06/2024

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

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7.	Dissolution	Not less than 75.0% (D) of the stated amount of Sorafenib dissolved in 30 minutes.	Minimum-85.07 % Maximum- 106.02% Average- 92.02%
8.	Related substance	Any unspecified degradation product NMT 0.2% Total degradation product – NMT 1.5%	0.001% 0.001%
9.	Assay:	Limit	Assay:
	Assay-Each film coated tablet contains: Sorafenib IP 200 mg	180.0 mg to 220.0 mg (90.0% to 110.0% of the stated amount of Sorafenib)	198.22 mg (99.11%)
10.	Microbiological limit test		
	Total aerobic microbial count	Not more than 1000 cfu/gm	30 cfu /gm
	Yeast & molds count	Not more than 100 cfu/gm	Less than 10 cfu /gm
	E.coli	Should be absent	Absent

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

Analysed By	<i>Akumar</i>	Checked By	<i>Raj Kumar</i>	Approved By	<i>BP</i>
Name	<i>Amit Kumar</i>	Name	<i>Raj Kumar</i>	Name	<i>Bhaw</i>
Date	<i>12/06/2024</i>	Date	<i>12/06/2024</i>	Date	<i>12/06/2024</i>

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