

CERTIFICATE OF ANALYSIS

Brand Name of the Product:	SUTEKAST-25		
Generic Name of the Product:	SUNITINIB MALATE CAPSULES (25 mg)		
Batch No.:	ACC2316STB	A.R. Number:	FPACC2316STB
Mfg. Date:	01/2024	Date of Sampling:	07/02/2024
Exp. Date:	12/2025	Date of release:	15/02/2024
Batch Size:	3000 CAPS	Reference:	IHS

S.NO	TEST	SPECIFICATION	RESULT
1.	Description	Green / Green "size 2" coloured hard gelatin capsules containing Yellow color powder.	Complies.
2.	Identification	The retention time of major peak in the chromatogram of the assay preparation correspond to that in the in the chromatogram of the standard preparation as obtained in the assay.	Complies.
3.	Average weight	320 mg \pm 5 % (304.0 mg to 330.0 mg)	321.63 mg
4.	Average fill Weight	250 mg \pm 5 % (237.5 mg to 262.5 mg)	256.84 mg
5.	Uniformity of Weight	315 mg \pm 5% (299.25 mg to 330.75 mg)	-1.18% +1.54%
6.	Dissolution	NLT – 70% (D)	MIN-98.90% MAX-101.95% MEAN- 100.11%

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>Asim</i>	Approved By	<i>Prashant</i>
Name	Amit Kumar	Name	Asim	Name	Prashant
Date	15/02/2024	Date	15/02/2024	Date	15/02/2024

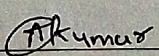

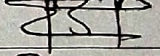
Manufacturing Plant: Aprazer Healthcare Pvt. Ltd. Village Kotla, PO - Barotiwala, Distt.: Solan, Himachal Pradesh – INDIA

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7.	Assay: Each hard gelatin capsule contain: Sunitinib Malate equivalent to Sunitinib (25 mg)	22.5.0 mg to 27.5 mg (90.0 % to 110.0 %)	24.83mg (99.32%)
8.	Microbial limit		
i)	Total aerobic microbial count	Not more than 1000 cfu /gm	30 cfu /gm
ii)	Yeast & moulds count	Not more than 100 cfu /gm	Less than 10 cfu /gm
iii)	E.coli	Should be absent	Absent
iv)	Salmonella Sp.	Should be absent	Absent
v)	S. aureus	Should be absent	Absent
vi)	P. aeruginosa	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		Checked By		Approved By	
Name	Amit Kumar	Name	Asim	Name	Bhanu
Date	15/02/2024	Date	15/02/2024	Date	15/02/2024

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