

**QUALITY CONTROL DEPARTMENT  
CERTIFICATE OF ANALYSIS**

Page 1 of 2

Product Name	: SUTEKAST 12.5	A.R. No.	: BDR/FP/21/00095
Generic name	: SUNITINIB MALATE CAPSULES 12.5 MG	Release Date	: 24/02/2021
Product Code / Master Code	: CSMD	T.R. No.	: FPTR200741
Batch No.	: DSMDN0321	Generic Batch No.	: CSMDN0321
Mfg. Date	: FEB-2021	Exp. Date	: JAN-2023
Market Pack Style	: 7 capsules in Alu-Alu blister	Batch Size	: 27500 Capsules
Specification No.	: BDR/SPC/FP/103-04	Packed Quantity	: 20000 Capsules
Destination Country	: DOMESTIC		

Sr. No	Test parameter	Result	Specification
1	Description	Yellow to orange free flowing granules filled in size "5" white to off white colored hard gelatin capsule.	Yellow to orange free flowing granules filled in size "5" white to off white colored hard gelatin capsule.
2	Identification A. By HPLC  B. By UV	Complies  Complies	The retention time for the Sunitinib peak in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation as obtained in the Assay.  The UV spectrum of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.
3	Average weight of filled capsule	97.9 mg	98.0 mg $\pm$ 7.5%
4	Average weight net content	69.8 mg	70.0 mg $\pm$ 7.5%

	PREPARED BY	CHECKED BY	APPROVED BY
Name & Designation	<i>Deebath shetye</i> Sr. Executive	<i>Deebath shetye</i> Sr. manager	<i>Amal Kishan</i> Sr. In-charge
Signature & Date	<i>[Signature]</i> 24/02/21	<i>[Signature]</i> 24/02/21	<i>[Signature]</i> 24/02/2021

Format No.: F/BDRP/QC/149/03-01

CIN No. - U24230MH2002PTC137329

WORKS / PLANT : R. S. No. 578, Near Effluent Channel Road, Village : Luna - 391 440. Tal. Padra, DIST. VADODARA. Factory : +91 97252 02649

HEAD OFFICE : 407/408, Sharda Chambers, 15, New Marine Lines, MUMBAI - 400 020. Phone : +91 22 4056 0560/1/2/3 Fax: +91-22-40560555

CITY OFFICE : 205-206, Lotus Plaza, Nr. Vishranti Heritage Bungalows, Opp. Yash Complex, 30 mtrs Road, Gotri, VADODARA - 390 021. Mo. +91-97252 06000

**BDR PHARMACEUTICALS INTERNATIONAL PVT. LTD.**



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5	Uniformity of Dosage Unit (By CU)	18.3	Acceptance value (AV) L1 ≤ 15 (for 10 units) L2 ≤ 25 (for 30 units)
6	Assay (By HPLC)	98.3%	Between 95.0% and 110.0% of L.C.
7	Related substance (By HPLC)		
	Impurity-1	0.02%	NMT 0.5%
	Impurity-2	Not Detected	NMT 0.5%
	Impurity-3	0.09%	NMT 0.5%
	Impurity-5	0.01%	NMT 0.5%
	Single highest unknown impurity	0.02%	NMT 0.5%
	Total impurities	0.19%	NMT 3.5%
8	Dissolution (By HPLC)	Min=86% Max=105% Avg=95%	Not less than 75% (D) of the labelled amount in 30 minutes
9	Water content (By KF)	1.9% w/w	NMT 5.0 % w/w
10	Disintegration time	05 minutes 38 seconds	Not more than 30 minutes

Remarks: Sample Complies/ Does not comply as per specification

	PREPARED BY	CHECKED BY	APPROVED BY
Name & Designation	D. S. Wadhvani Sr. Executive	Dashrath K. Sr. Manager	Arijal Kulkarni Sr. Exec. In-charge
Signature & Date	 24/02/21	 26/29/02/21	 26/02/2021

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