



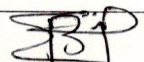
CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Brand Name of the Product:	ACALAKAST - 100 MG		
Generic Name of the Product:	ACALABRUTINIB CAPSULES (100 mg)		
Product Code:	AL	A.R. Number:	FPACC2409ALC
Batch No.:	ACC2409ALC	Date of Sampling:	11/02/2025
Mfg. Date:	02/2025	Date of release:	20/02/2025
Exp. Date:	01/2027	Batch Size:	2400 CAPS.
Specification No.:	FG/SPA/ALC-01-00	Reference:	IHS

S.NO	TEST	SPECIFICATION	RESULT
1.	Description	Dark blue/ Yellow "#1" coloured hard gelatin capsules containing off white powder.	Dark blue/ Yellow "#1" coloured hard gelatin capsules containing off white powder.
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.	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.
3.	Average Weight	356.0mg ± 7.5% (329.3 mg to 382.7 mg)	357.0 mg
4.	Average fill Weight	280.0mg ± 7.5% (259.0mg to 301.0 mg)	281.53 mg
5.	Uniformity of fill Weight	Not more than two of the individual weights deviate from the average weight by more than the 7.5 percent and none should deviate by more than 15.0 percent of the average weight.	Min= 3.30 % Max= 2.44%
6.	Disintegration time	NMT 30 minutes.	11 minutes 45 seconds.

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

Prepared By		Checked By		Approved By	
Name	Shankil	Name	Asim	Name	Bhanu
Date	20/02/2025	Date	20/02/2025	Date	20/02/2025

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7.	Related substances : (By HPLC)	Single unknown impurity - NMT 1.0% Total impurities -NMT 2.0%	0.029% 0.113%
8.	Dissolution (By HPLC)	Not less than – 70% (Q)	MIN-98.08 % MAX-99.91 % MEAN- 98.79 %
9.	Assay: (By HPLC) Each hard gelatin capsule shell contain: Acalabrutinib 100 mg	90.0mg to 110.0mg (90.0% to 110.0%)	100.0 mg (100.0 %)
10.	Microbial Limit Test		
(i)	Total aerobic microbial count	Not more than 1000 cfu/gm	20 cfu/gm
(ii)	Yeast & molds 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
(vii)	Shigella boydii	Should be absent	Absent
(viii)	Candida albicans	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.

Prepared By		Checked By		Approved By	
Name	Sharika	Name	Asim	Name	Bhanu
Date	20/02/2025	Date	20/02/2025	Date	20/02/2025