



INNOVA CAPTAB LTD.
81-B, EPIP, PHASE-I, JHARMAJARI, BADDI (HP)

CERTIFICATE OF ANALYSIS

Serial No.: 12418342

Ref STP NO.: IC/STP/I221

ATR NO.: F- 12418340

Batch no: I2214003

Batch size: 2.00 Lac.

Mfg. Date: 03/2024

Analysis started on: 29/03/2024

Reference: In-House

GLYCITOP-MR 60

(Gliclazide sustained release Tablets 60mg)

Sampling done by : SK

Expiry Date: 02/2026

Analysis completed on: 16/04/2024

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Each uncoated extended release tablet contains:

Gliclazide IP
Excipients

60 mg
Q.S.

Sr. No.	Tests	Specifications	Results
1	Description	White coloured biconvex capsule shaped, uncoated tablets having a break line on one side.	White coloured biconvex capsule shaped, uncoated tablets having a break line on one side.
2	Identification	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the standard preparation obtained as directed in the assay.	Complies
3	Average weight of tablet	200 mg (limit $\pm 7.5\%$)	206.4mg
4	Uniformity of weight	It should not deviate $\pm 7.5\%$.	+1.39% to -1.74%
5	Hardness	Not less than 5.0 kg/cm ²	5.82-6.77kg/cm ²
6	Friability	Not more than 1.0%w/w	0.13%w/w
7	Dissolution (Gliclazide)	Time (hour) Drug should release 1 st hour NMT 50% 4 th hour Between 30% and 80% 24 th hour Not less than 70%	14.9% to 19.5% 44.1% to 51.4% 97.6% to 100.6%
8	Assay Each uncoated extended release tablet contains: Gliclazide IP 60mg	Between 54mg and 66mg (Between 90% and 110%)	61.62mg (102.7%)

Remarks: The above sample is complies as per Specification No.: IC/FPS/I221

Prepared by
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(IC/QC/050/F3)