



SALUS PHARMACEUTICALS
480/211, Vill. Harraipur, P.O. Gurumajra, Nalagarh Road
Baddi -173205

QUALITY
CONTROL
DEPARTMENT

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)
Mfg. License No.: MNB/06/382&MB/06/383

Product Name	Telmafox-AM Tablets	A.R. No.	FP122402683
Generic Name	Telmisartan and Amlodipine Tablets IP	Batch Size	1.0 lac
Batch No:	SPT242631	Sample Qty	60 Tabs
Mfg. Date	12/2024	Sampled By	Manish Rai
Exp. Date	11/2026	Date of Sampling	20/12/2024
Mfd. By	Salus Pharmaceuticals	Date of Completion	25/12/2024

RESULT OF ANALYSIS

S.No.	TEST PARAMETER	SPECIFICATION	RESULT
01.	Description	White colour one side & blue colour other side, round shape, biconvex, uncoated bilayered tablet having plain on both side.	White colour one side & blue colour other side, round shape, biconvex, uncoated bilayered tablet having plain on both side.
02.	Identification	To be comply	Complies
03.	Average weight	310mg \pm 5%w/w	308.03mg
04.	Uniformity of weight	310mg \pm 5%w/w	-1.01% to +1.17%
05.	Dissolution		
	Telmisartan	Q. Not less than 80%	89.20%
	Amlodipine	Q. Not less than 80%	92.95%
06.	Disintegration Time	Not more than 15 minutes	6 min 22 sec
07.	Uniformity of content. Amlodipine	85.0% to 115%	97.55%
08.	Friability	Not more than 1.0%	0.30%
09.	Thickness	Limit 3.80 \pm 0.2mm	3.83mm
10.	Hardness	Not less than 5.0 Kg/cm ²	9.43kg/cm ²
11.	Related substances	To be comply	Complies
12.	Microbial limit Test TAMC TYMC	NMT 1000cfu/gm NMT 100cfu/gm	20cfu/gm <10cfu/gm
13.	Pathogens (E. coli, S. aureus, C. albicans, Pseu. aeruginosa, Salmonella, Shigella)	Should be absent/gm	Absent/gm
14.	Assay: - Each uncoated bilayered tablet contains.		
	Telmisartan IP 40 mg	36.0mg to 44.0mg (90.0% to 110.0%)	38.852mg (97.13%)
	Amlodipine Besylate IP Eq. to Amlodipine 5mg	4.50mg to 5.50mg (90.0% to 110.0%)	5.334mg (106.68%)

Remark: In the opinion of undersigned the sample referred to above is of Standard Quality/Not standard quality as defined in the Act and rules made there under for reason(s) given below complies with above test IP/BP/USP/1-House Specification.

S. No.	Analyzed By	Checked By	Approved By
Designation	Q.C. Chemist	SR.QC Executive	QC Manager
Sign. & Date		 25/12/2024	 25/12/2024