

FORM 39 RULE 150E (f)
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER.

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS
FINISHED PRODUCT

Product	: TAMOXICAN 20 TAB	Control No	: FP/0476/24
Generic	: TAMOXIFEN CITRATE IP 20MG	Slip No	: 0476
Packing	: 10STRIP x 10TAB BOX	Testing Date	: 17-10-2024
Batch No	: 15722	Test Packing	: 3x20 TAB
Batch Size	: 318000 TAB	Test Quantity	: 60.0000 TAB
Mfg. Date	: Sep2024	Test As Per	: IP
Exp. Date	: Aug2026	Release Date	: 17-10-2024
Mfg.Lic. No:	G/28/1157		

TEST	RESULT	SPECIFICATIONS
DESCRIPTION	WHITE COLOURED ROUND SHAPED BICONVEX UNCOATED TAB WITH HAVING BOTH SIDE PLAIN	WHITE COLOURED ROUND SHAPED BICONVEX UNCOATED TAB WITH HAVING BOTH SIDE PLAIN
WEIGHT OF 20 TABLETS	4077.6 MG	4000 MG $\pm$ 5% W/W
AVERAGE WEIGHT OF 20 TAB	203.8 MG	200 MG $\pm$ 7.5% W/W
UNIFORMITY OF WEIGHT	COMPLIES	200 MG $\pm$ 7.5% W/W
DISINTEGRATION TIME	01 MIN. 12 SEC.	NMT 15 MIN
THICKNESS	4.00 MM	3.80 TO 4.20 MM
HARDNESS	MAX: 5.5 KG/CM ² MIN: 4.0 KG/CM ²	NLT 3 KG/CM ²
FRIABILITY	0.28 %	NMT 1% W/W
IDENTIFICATION (B)UV	COMPLIES	ABSORPTION MAXIMA AT ABOUT 237NM AND 275 NM
(C) TLC	COMPLIES	PRINCIPAL SPOT IN CHROMATOGRAM OBTAINED WITH TEST SOLUTION CORRESPONDS TO THAT IN CHROMATOGRAM OBTAINED WITH REFERENCE SOLN
(D) CHEMICAL TEST	COMPLIES	PINK TO RED COLOUR IS PRODUCED
RELATED SUBSTANCE	COMPLIES	TOTAL IMPURITIES EXCLUD-

REMARKS : The Product conform to IP

Release Dt: 17-Oct-2024

Analysed By : ALPESH

Person Incharge of Testing: