

DWARKESH HEALTHCARE

3222, PHASE-IV, G.I.D.C., VATVA, AHMEDABAD-382 445

Year : 2024-2025

FORM 39 RULE 150E (f)
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER.**QUALITY CONTROL DEPARTMENT**
CERTIFICATE OF ANALYSIS
FINISHED PRODUCT

Product	: TAMOXICAN 10	Control No	: FP/0415/24
Generic	: TAMOXIFEN CITRATE IP 10MG	Slip No	: 0415
Packing	: 10STRIP x 10TAB BOX	Testing Date	: 17-09-2024
Batch No	: 15661	Test Packing	: 3x20 TAB
Batch Size	: 200000 TAB	Test Quantity	: 60.0000 TAB
Mfg. Date	: Sep2024	Test As Per	: IP
Exp. Date	: Aug2026	Release Date	: 18-09-2024
Mfg.Lic. No:	G/28/1157		

TEST	RESULT	SPECIFICATIONS
DESCRIPTION	WHITE COLOURED ROUND SHAPED BICONVEX UNCOATED TAB WITH HAVING BOTHSIDE PLAIN	WHITE COLOURED ROUND SHAPED BICONVEX UNCOATED TAB WITH HAVING BOTHSIDE PLAIN
WEIGHT OF 20 TABLETS	3955.8MG	4000 MG $\pm$ 5% w/w
AVERAGE WEIGHT OF 20 TAB	197.8 MG	200 MG $\pm$ 7.5% w/w
UNIFORMITY OF WEIGHT	COMPLIES	200 MG $\pm$ 7.5% w/w
DISINTEGRATION TIME	00 MIN. 45 SEC.	NMT 15 MIN
THICKNESS	4.09 MM	3.80 TO 4.20 MM
HARDNESS	MIN: 3.0 KG/CM ² MAX: 3.5 KG/CM ²	NLT 3 KG/CM ²
FRIABILITY	0.41 %	NMT 1% w/w
IDENTIFICATION (A) UV	COMPLIES	SOLUTION SHOWS ABSORPTION MAXIMA AT ABOUT 237 NM AND 275 NM
(C) TLC	COMPLIES	PRINCIPAL SPOT IN CHROMATOGRAM OBTAINED WITH TEST SOLUTION CORRESPONDS TO THAT IN CHROMATOGRAM OBTAINED WITH REFERENCE SOLUTION
(D) CHEMICAL TEST	COMPLIES	PINK TO RED COLOUR IS PRODUCED

REMARKS : The Product conform to IP

Release Dt: 18-Sep-2024

Analysed By : ALPESH

Person Incharge of Testing: