

DWARKESH HEALTHCARE

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

Year : 2023-2024

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/381/23
Generic	: TAMOXIFEN CITRATE IP 10MG		
Packing	: 10STRIP x 10TAB BOX	Slip No	: 381
Batch No	: 14827	Testing Date	: 21-09-2023
Batch Size	: 102000 TAB	Test Packing	: 3X20 TAB
Mfg. Date	: Sep2023	Test Quantity	: 60.0000 TAB
Exp. Date	: Aug2025	Test As Per	: IP
Mfg.Lic. No	: G/28/1157	Release Date	: 29-09-2023

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	4032 MG	4000 MG $\pm$ 5% w/w
AVERAGE WEIGHT OF 20 TAB	201.6 MG	200 MG $\pm$ 7.5% w/w
UNIFORMITY OF WEIGHT	COMPLIES	200 MG $\pm$ 7.5% w/w
DISINTEGRATION TIME	00 MIN. 58 SEC.	NMT 15 MIN
THICKNESS	3.93 MM	3.70 TO 4.10 MM
HARDNESS	MIN: 3.0 KG/CM ² MAX: 3.5 KG/CM ²	NLT 3 KG/CM ²
FRIABILITY	0.15 %	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 CHROMA- TOGRAM 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: 29-Sep-2023

Analysed By : NIDHI

Person Incharge of Testing:

DWARKESH HEALTHCARE

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TEST	RESULT	SPECIFICATIONS
RELATED SUBSTANCE	COMPLIES	TOTAL IMPURITY EXCLUDING E-ISOMER PEAK: NMT 0.5%
DISSOLUTION	MIN:81.60% MAX:89.20%	NLT 75.0% (Q)
UNIFORMITY OF CONTENT	MIN:95.26% MAX:99.38%	85.0% TO 115.0%
ASSAY EACH UNCOATED TAB CONTAIN TAMOXIFEN CITRATE IP EQ. TAMOXIFEN	9.812 MG 98.12%	90.0% TO 110.0%

REMARKS : The Product conform to IP

GP
29/09/23

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Release Dt: 29-Sep-2023

Analysed By : NIDHI

Person Incharge of Testing:

(Q.A./Q.C. Incharge)