

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**

<b>Product</b> : TAMOXICAN 20 TAB	<b>Control No</b> : FP/585/23
<b>Generic</b> : TAMOXIFEN CITRATE IP 20MG	
<b>Packing</b> : 10STRIP x 10TAB BOX	<b>Slip No</b> : 585
<b>Batch No</b> : 15031	<b>Testing Date</b> : 03-01-2024
<b>Batch Size</b> : 300000 TAB	<b>Test Packing</b> : 3X20 TAB
<b>Mfg. Date</b> : Dec2023	<b>Test Quantity</b> : 60.0000 TAB
<b>Exp. Date</b> : Nov2025	<b>Test As Per</b> : IP
<b>Mfg.Lic. No</b> : G/28/1157	<b>Release Date</b> : 05-01-2024

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	4032.3 MG	4000 MG ± 5% W/W
AVERAGE WEIGHT OF 20 TAB	201.6 MG	200 MG ± 7.5% W/W
UNIFORMITY OF WEIGHT	COMPLIES	200 MG ± 7.5% W/W
DISINTEGRATION TIME	01 MIN. 56 SEC.	NMT 15 MIN
THICKNESS	4.01 MM	3.80 TO 4.20 MM
HARDNESS	MAX: 4.0 KG/CM <sup>2</sup> MIN: 3.0 KG/CM <sup>2</sup>	NLT 3 KG/CM <sup>2</sup>
FRIABILITY	0.17 %	NMT 1% W/W
IDENTIFICATION (B) UV	COMPLIES	ABSORPTION MAXIMA AT ABOUT 237NM AND 275 NM
(C) TLC	COMPLIES	PRINCIPAL SPOT IN CHROMA- TOGRAM OBTAINED WITH TEST SOLUTION CORRESPONDS TO THAT IN CHROMATOGRAM OBT- AINED 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: 05-Jan-2024

Analysed By : NIDHI

Person Incharge of Testing:

*P* 05/01/24

*DP* 05/01/24

DWARKESH HEALTHCARE

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

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TAMOXIFEN CITRATE IP 20MG  
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Lic. No. : G/28/1157 Release Date : 05-01-2024

TEST	RESULT	SPECIFICATIONS
DISSOLUTION	MIN:84.25% AVG:85.99%	ING TAMOXIFEN E-ISOMER IS NMT 0.5% NMT 75.0%
UNIFORMITY OF CONTENT	COMPLIES	85.0% TO 115.05%
ASSAY EACH UNCOATED TAB CONTAIN TAMOXIFEN CITRATE EQ. TO TAMOXIFEN IP 20 MG	19.61 MG 98.05%	90.0% TO 110.0%

REMARKS : The Product conform to IP

Release Dt: 05-Jan-2024

*P*  
05/01/24  
Analysed By : NIDHI

*Q.P*  
05/01/24  
Person Incharge of Testing:  
(Q.A./Q.C. Incharge)