



Gallene Sciences Pvt. Ltd.

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

COMMERCIAL NAME	NOLVAGEN				
PRODUCT NAME	TAMOXIFEN CITRATE USP TABLET 20 MG				
BATCH NO	180221	REFERENCE	HPLC		
MFG DATE	02/2018	A.R. NO	DF/17/221		
EXPIRY DATE	01/2021	DATE OF SAMPLING	11/03/2018		
SAMPLE QUANTITY	100 TABLETS	DATE OF RELEASE	16/03/2018		
BATCH SIZE	1.05 LAC TAB				
SR. NO	TESTS	OBSERVATIONS	LIMITS/ SPECIFICATION		
1	DESCRIPTION	White Colour Concave shape uncoated tablets	White to Off White Colour Concave shape uncoated tablets		
2	IDENTIFICATION	Complies	As per usp		
3	WEIGHT OF 20 TABLETS	03.991 gm	04.010 gm \pm 3.0 %		
4	UNIFORMITY OF WEIGHT	199.56 MG	200.50 mg \pm 7.5 %		
5	UNIFORMITY OF CONTENT	Complies	NLT 85 % and NMT 115 %		
6	DISINTEGRATION TIME	3 min 33 sec	NMT 15 min		
7	HARDNESS	4.0 kg/cm ²	NLT 3.0 kg/cm ²		
8	FRIABILITY	0.57 % w/w	NMT 1.0 % w/w		
9	RELATED SUBSTANCES Single Impurity Total Impurities	COMPLIES COMPLIES	NMT 3% NMT 5.7 %		
10	ASSAY Each uncoated tablet contains Tamoxifen	Obtained 19.83 mg	% 99.19 %	Label Claim 20 mg	Limit NLT 90 % and NMT 110 %

CONCLUSION : In the opinion of the undersigned, the sample referred to above is **OF STANDARD QUALITY / IS NOT OF STD. QUALITY** of IP / ~~BP~~ / USP / ~~IHS~~ as of in above respects defined in the act and the rules made there under.

ANALYSIS BY		Q.C INCHARGE	
DATE	16/03/2018	DATE	16/03/2018