



Gallene Sciences Pvt. Ltd.

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

COMMERCIAL NAME	ANAGEN		
PRODUCT NAME	ANASTROZOLE USP TABLET 0.5 MG		
BATCH NO	180222	REFERENCE	HPLC
MFG DATE	02/2018	A.R. NO	DF/17/222
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 film coated tablets	White to Off White Colour Concave shape film coated tablets		
2	IDENTIFICATION	Complies	As per usp		
3	WEIGHT OF 20 TABLETS	04.009 gm	04.010 gm \pm 3.0 %		
4	UNIFORMITY OF WEIGHT	200.48 MG	200.50 mg \pm 7.5 %		
5	UNIFORMITY OF CONTENT	Complies	NLT 85 % and NMT 115 %		
6	DISINTEGRATION TIME	8 min 29 sec	NMT 15 min		
7	HARDNESS	4.0 kg/cm ²	NLT 3.0 kg/cm ²		
8	FRIABILITY	0.56 % w/w	NMT 1.0 % w/w		
9	RELATED SUBSTANCES Single Impurity Total Impurities	COMPLIES COMPLIES	NMT 3% NMT 5.7 %		
10	ASSAY Each film coated tablet contains Anastrozole	Obtained 0.49 mg	% 99.76 %	Label Claim 0.5 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~~ / ~~III~~ as of in above respects defined in the act and the rules made there under.

ANALYSIS BY

DATE

16/03/2018

Q.C
INCHARGE

DATE

16/03/2018