



Gallene Sciences Pvt. Ltd.

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

COMMERCIAL NAME	OXAGEN 10		
PRODUCT NAME	OXANDROLONE USP TABLET 10 MG		
BATCH NO	180224	REFERENCE	HPLC
MFG DATE	02/2018	A.R. NO	DF/17/224
EXPIRY DATE	01/2021	DATE OF SAMPLING	15/03/2018
SAMPLE QUANTITY	100 TABLETS	DATE OF RELEASE	17/03/2018
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	04.002 gm	04.010 gm \pm 3.0 %	
4	UNIFORMITY OF WEIGHT	200.12 MG	200.50 mg \pm 7.5 %	
5	UNIFORMITY OF CONTENT	Complies	NLT 85 % and NMT 115 %	
6	DISINTEGRATION TIME	3 min 19 sec	NMT 15 min	
7	HARDNESS	4.0 kg/cm ²	NLT 3.0 kg/cm ²	
8	FRIABILITY	0.59 % 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 Oxandrolone	Obtained 09.91 mg	% 99.16 %	Label Claim 10 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 / HIS~~ as of in above respects defined in the act and the rules made there under.

ANALYSIS BY		Q.C INCHARGE	
DATE	17/03/2018	DATE	17/03/2018