Gallene Sciences Pvt. Ltd.

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

		TURIGEN 10					
PRO	DUCT NAME	CHLORDEHY	DROMETHY	LTEST	OSTERONE TA	ABLET 10 MG	
BATCH NO		180223		REFERENCE		HPLC	
MFG DATE		02/2018		A.R. NO		DF/17/223	
EXPIRY DATE		01/2021		DATE OF SAMPLING 13/03/2018		13/03/2018	
SAMPLE QUANTITY		100 TABLETS		DATE OF RELEASE 1		16/03/2018	
BAT	CH SIZE	1.05 LAC TAB			· · · · · · · · · · · · · · · · · · ·		
SR. NO	TESTS	OBSERVAT	IONS		LIMITS/ SPE	CIFICATION	
1	DESCRIPTION	White Color		shape	White to Off White Colour Concav shape uncoated tablets		
2	IDENTIFICATION	Complies			As per BP		
3	WEIGHT OF 20 TABLETS	03.978 gm		04.010 gm ± 3.0 %		0 %	
4	UNIFORMITY OF WEIGHT	198.94 MG			200.50 mg ± 7.5 %		
5	UNIFORMITY OF CONTENT	Complies			NI.T 85 % and NMT 115 %		
6	DISINTEGRATION TIME	3 min 43 see			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			NMT 3% NMT 5.7 %		
10	ASSAY	Obtained	%		Label Claim	Limit	
	Each uncoated tablet contains Chlordehydromethyltest estosterone	09.90 mg	99.03 %		10 mg	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 46/03/2018	DATE 16/03/2018