Gallene Sciences Pvt. Ltd.

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

COMMERCIAL NAME		DIANAGEN 10				
PRO	DUCT NAME	METHANDIENC	ONE TABL	ET 10 M	1G	
BATCH NO MFG DATE EXPIRY DATE		180225 02/2018 01/2021		REFERENCE HPLC A.R. NO DF/17/225 DATE OF SAMPLING 15/03/2018		_
						SAMPLE QUANTITY
BATCH SIZE		1.05 LAC TAB				
SR. NO	TESTS	OBSERVATIO	ONS		LIMITS/ SPE	CIFICATION
1	DESCRIPTION	White Colour uncoated tablets		shape	White to Off Wi	hite Colour Concavi
2	IDENTIFICATION	Complies			As per USP	
3	WEIGHT OF 20 TABLETS	03.982 gm 04.010 gm ± 3.0 %		0 %		
4	UNIFORMITY OF WEIGHT	199.11 MG		200.50 mg ± 7.5 %		
5	UNIFORMITY OF CONTENT	Complies		NLT 85 % and NMT 115 %		
6	DISINTEGRATION TIME	3 min 13 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	COMPLIES			NMT 3%	
	Total Impurities	COMPLIES			NMT 5.7 %	
10	ASSAY	Obtained	%		Label Claim	Limit
	Each uncoated tablet contains	09.92 mg	99.28 %		10 mg	NLT 90 % and NMT 110 %
	Methandienone CLUSION: In the opinion					

ANALYSIS BY	Q.C INCHARGE 1202
DATE 16/03/2018	DATE 15/03/2018