

WHO-GMP Approved
An ISO 9001-2008
Certified company

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 **BAROQUE**
PHARMACEUTICALS PVT. LTD

QUALITY CONTROL DEPARTMENT

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THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT STAGE)

Product Name : TRAMADOL HYDROCHLORIDE DROPS(20ML)	Batch No. : G015117	Batch Size : 630 LTR
Generic Name : TRAMADOL HYDROCHLORIDE DROPS		
Product Code : BQE576A		
Label Claim Each ml contains: Tramadol Hydrochloride BP 100mg Flavoured syrupy base Q.S.	Location : KHAMBHAT Make : BAROQUE Mfg. Lic No. : G/1217 Specification No. : SP/BQE576AFP-0 Specification Dt. : 15-07-2013 Test As Per : IHS Test Packing : 10.000 BOT Sample Size : 10.000 BOT Mfg. Dt. : JUL-2015 Exp. Dt. : JUN-2017 T.R. Slip No. : B15116 T.R. Slip Dt. : 04-07-2015 Analysis Date : 05-07-2015 A.R. No. : BQFP15113 A.R. Dt. : 10-07-2015 Released Qty. : 630 LTR	

LC NO.: 5-133516 DATED.: 18/06/2015

Sr.	Test	Result	Specification
1	DESCRIPTION:	Pale yellow clear liquid	Pale yellow clear liquid
2	pH:	5.27	Between 4.5 to 6.0
3	WEIGHT / ML:	1.2235 gm/ml	1.210 gm/ml ($\pm 10\%$) (Between 1.089 to 1.331 gm/ml)
4	DELIVERABLE VOLUME:	20.5 ml	Not less than 20.0 ml
5	IDENTIFICATION:	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with standard solution.	In the assay, the principal peak in the chromatogram obtained with the test solution should be corresponds to the peak in the chromatogram obtained with standard solution.
6	Assay:	1) 99.45% = 99.45 mg	1) Tramadol Hydrochloride 100MG [Limit : NLT 90.0% and NMT 110.0%]
7	MICROBIAL PURITY : 1 Total Aerobic Microbial Count : 2 Total Yeast and Mould Count : 3 E.Coli :	- 40 CFU/g Nil Absent	- Not more than 10^3 CFU/g Not more than 10^2 CFU/g Should be absent.

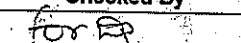
Conclusion : The above sample complies as per IHS

In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the reasons given above.

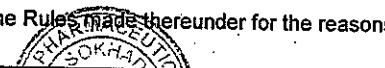
Analysed By


PAYAL K. PATEL
Q.C. OFFICER

Checked By


IMROZKHAN . PATHAN
Q.C. EXECUTIVE

Approved By


VINOD A. PATEL
Q.C. MANAGER

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