

QUALITY CONTROL DEPARTMENT
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)	
Generic Name : TRAMADOL HYDROCHLORIDE DROPS	
Product Code : BQE576A	Batch No. : G017193
Batch Size : 630 LTR	
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-2 Specification Dt. : 13-07-2017 Test As Per : IHS Test Packing : 10.000 BOT Sample Size : 10.000 BOT Mfg. Dt. : SEP-2017 Exp. Dt. : AUG-2019 T.R. Slip No. : B17179 T.R. Slip Dt. : 11-09-2017 Analysis Date : 12-09-2017 A.R. No. : BQFP17188 A.R. Dt. : 20-09-2017 Released Qty. : 630 LTR	

LC NO.: I085433 DATED.: 28/09/2017
APPLICANT REF. NO. IMP NO. 367/17

Sr.	Test	Result	Specification
1	DESCRIPTION:	Pale yellow clear liquid	Pale yellow clear liquid
2	pH:	5.09	Between 4.5 to 6.0
3	WEIGHT / ML:	1.2038 gm/ml	1.210 gm/ml (± 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) 99.56% = 99.56 mg	1) Tramadol Hydrochloride 100MG [Limit :NLT 90.0% and NMT 110.0%]
7	MICROBIAL PURITY :	-	-
	1 Total Aerobic Microbial Count :	11 CFU/ml	Not more than 10 ³ CFU/ml
	2 Total Yeast and Mould Count :	Nil	Not more than 10 ² CFU/ml
	3 E.Coli :	Absent	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. "This computer generated certificate of analysis is valid without signature"

Analysed By / Date Vishal 20/09/2017 VISHAL T. CHAUHAN Q.C. OFFICER	Checked By / Date D 20/09/2017 DARSHAN S. SHAH Q.C.EXECUTIVE	Approved By / Date 20/09/17 VINOD A.PATEL Q.C.MANAGER
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