WHO-GMP Approved An ISO 9001-2006 Certified company

CIN :U24230GJ1993PTC020695

Factory : Sokhada-388 620, Ta.-Khambhat Dist.-Anand(Guj.) INDIA

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QUALITY CONTROL DEPARTMENT

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THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F)) FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name

: TRAMADOL HYDROCHLORIDE DROPS(20ML)

Packing

: 20 ML

Generic Name

: TRAMADOL HYDROCHLORIDE DROPS

Product Code

; BQE576A

Batch No.

: G018283

Actual Batch Size Packing Batch Size: 630 LTR

: 630 LTR (31500 BOT)

Sample Size Released Qty

: 6.000 BOT

: 630,000 LTR

LC NO.: K867301 DATED.: 10/08/2018

Mfg. Dt.

: AUG-2018 :JUL-2020

Exp. Dt.

Test Packing: 6 BOT

Mfg. Lic No.: G/1217

Test As Per : IHS

A.R. No.

: BGFP180302

Rel. Dt.

: 13-08-2018

T.R. Slip No.

: BG180307

T.R. Slip Dt.

: 10-08-2018

Analysis Date

Specification No.: SP/BQE576AFP-3

: 11-08-2018

Specification Dt.: 13-07-2019

Location

· GENERAL

Make

BAROQUE

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Sr.	Test	Result	Specification:
1	DESCRIPTION:	Pale yellow clear liquid	Pale yellow clear liquid
2	pH:	4.79	Between 4.5 to 6.0
3	WEIGHT / ML:	1.2467 gm/ml	1.210 gm/ml (± 10%) (Between 1.089 to 1.331 gm/ml)
4	DELIVERABLE VOLUME:	20.2 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) 99.70% = 99.7032 mg	1) Tramadol Hydrochloride 100MG [Limit :NLT 90.0% and NMT 110,0%]

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 result given above. "This computer generated certificate of analysis is valid without signature"

Analysed By / Date

JIGNISHA A. PATEL Q.C. OFFICER

Checked By / Date

SR. QC OFFICER

Klush · 13 · 08 · 4018 KHUSHBU B, RANA

Approved By / Date

13/08/2018 DARSHAN S. SHAH ASST. QC MANAGER

FOR BARDQUE PHARMACEUTICALS PVT. LTD.

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