CERTIFICADO DE ANÁLISIS DE MATERIA PRIMA

WHO-GMP Approved
An ISO 9001-2008
Certified company

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

CERTIFICATE OF ANALYSIS

MATERIAL CODE : 100143B	A.R.NO : BQRM130565
MATERIALNAME : TRAMADOL HYDROCHLORIDE	Date of Analysis : 21/10/2013
BATCH NO : TDH 1309511	MFG.DATE : SEP' 2013
QTY.RECEIVED : 25.00 KG	EXP DATE : AUG' 2018
SAMPLE QTY. : 0.020 KG	SPECIFICATION : As per BP
RECEIPT DATE : 18/10/2013	SPECIFICATION NO: SP/100143B-0
MFG.BY : EMMENNAR BIOTECH	Working standard Number : WS100143
SUPPLIED BY : DEEPEN DRUGS	

Sr. No.	TEST	OBSERVATION	LIMIT
1.	Description	White crystalline powder	White or almost white, crystalline powder
2.	Solubility	Freely soluble in water and in methanol, very slightly soluble in acetone	Freely soluble in water and in methanol, very slightly soluble in acetone
3.	Identification* (A) By Melting point	182°c	Between 180°c to 184°c
	(B) By IR	The IR spectrum of test is concordant with IR spectrum of standard.	The IR spectrum of test should be concordant with IR spectrum of standard.
	(C) By TLC.	The principal spot in the chromatogram obtained with test solution (b) is similar in position and size to the principal spot in the chromatogram obtained with reference solution (a).	The principal spot in the chromatogram obtained with test solution (b) should be similar in position and size to the principal spot in the chromatogram obtained with reference solution (a).
	(D)Reaction (a) of chlorides	The precipitate is dissolve easily with the possible	The precipitate should dissolve easily with the possible

PREPARED BY / DATE	CHECKED BY / DATE	APPROVED BY / DATE
23/10/2013	23/10/2013	23/10/2013
DARSHAN SHAH	HARSHAD PATEL	VINOD PATEL
Q.C. OFFICER	Q.C. EXECUTIVE	Q.C. MANAGER

Corp.off.: D-403, Titanium Square, Nr. Thaltej Cross Road, S.G. Highway Ahmedabad-380054. Phone : (079)40009421

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Sr. No.	TEST	OBSERVATION	LIMIT
		exception of a few large particles which dissolve slowly.	exception of a few large particles which dissolve slowly.
4.	Appearance of solution	Solution S is clear and colourless.	Solution S should be clear and colourless.
5.	Acidity	Less than 0.4 mL of 0.01 M sodium hydroxide is required to change the colour of the indicator to yellow	Not more than 0.4 mL of 0.01 M sodium hydroxide is required to change the colour of the indicator to yellow
6.	Optical rotation	+ 0.08°	- 0.10° to + 0.10°
7	Impurity E	Less than 0.2%	Not more than 0.2%.
8	Related substances (A) Impurity A	Not detected	Not more than 0.2%.
	(B) Unspecified impurity	0.042%	Not more than 0.1%.
	(C) Total impurity	0.081%	Not more than 0.4%.

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Sr. No.	TEST	OBSERVATION	LIMIT
9.	Heavy metals (Method A)	Less than 20 ppm	Not more than 20 ppm
10.	Water*	0.17%	Not more than 0.5%
11.	Sulphated Ash	0.05%	Not more than 0.1%
12	Assay*	99.29%	Tramadol hydrochloride contains not less than 99.0% and not more than 101.0% calculated on Anhydrous basis.

* This test is performed at choksi laboratories report No: PHR/6532/221013/10

Storage conditions: Protect from light & store in a closed container at room temperature conditions.

REMARK: THE MATERIAL COMPLIES AS PER BP2013 SPECIFICATION.

RELEASE DATE: 23/10/2013

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