

CERTIFICATE OF ANALYSIS

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PRODUCT: TRAMADOL HYDROCHLORIDE Ph.Eur.			
Mfg. Date	Jan/2019	Batch No. : TRMNF19015	A.R No. : QFP/19/0135
Exp. Date	Dec/2023	Batch Size : 718.7 kg	Release date : 30/01/2019

Sr.	Test	Observation/Results	Specification
1	Characters		
1.1	Appearance	A white crystalline powder.	A white crystalline powder.
1.2	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.
2	Identification		
2.1	Identification - A	181.4 ° C	Melting point : Between 180°C and 184°C
2.2	Identification- B	The Infrared spectrum of sample is concordant with the spectrum of Tramadol Hydrochloride working standard.	The Infrared spectrum of sample should be concordant with the spectrum of Tramadol Hydrochloride working standard.
2.3	Identification- C	Thin Layer Chromatography : In the test for "Impurity E - by TLC", the principal spot in the chromatogram obtained with the test solution (b) is similar in position and size to the principal spot in the chromatogram obtained with the reference solution (a).	Thin Layer Chromatography : In the test for "Impurity E - by TLC", the principal spot in the chromatogram obtained with the test solution (b) should be similar in position and size to the principal spot in the chromatogram obtained with the reference solution (a).
2.4	Identification-D	Chloride : Aqueous solution is produce white precipitate when treated with silver nitrate solution.	Chloride : Aqueous solution should produce white precipitate when treated with silver nitrate solution.
3	Appearance of solution	The solution "S" is clear and colourless.	The solution "S" should be clear and colourless.
4	Acidity	0.3 ml	Not more than 0.4 ml of 0.01 M Sodium Hydroxide solution required to change the colour of indicator to yellow.

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5	Optical rotation	0 °	Between - 0.10° and +0.10°
6	Impurity - E (Thin layer chromatography)	No any secondary spot observed.	Any spot corresponding to impurity E should not more intense and not greater than the spot in the chromatograms obtained with reference solution (b) (Not more than 0.2 %).
7	Related Substances (By HPLC)		
	Known Impurities		
	Impurity A	0.025 %	Not more than 0.1%
	Impurity B	BQL	Not more than 0.10%
	Impurity C	BQL	Not more than 0.10%
	Impurity D	BQL	Not more than 0.10%
	UnKnown Impurities		
	Highest Unknown Impurity	0.015 %	Not more than 0.10%
	Total impurities(Known + Unknown)	0.04 %	Not more than 0.4%
8	Water content	0.14 % w/w	Not more than 0.5 % w/w
9	Sulphated Ash	0.05 % w/w	Not more than 0.1%w/w
10	Assay (By Potentiometry)	99.4% w/w	Between 99.0 % and 101.0 % w/w (On anhydrous basis.)
11	Residual Solvents (By GC)		
	Ethyl acetate	Not Detected	Not more than 500ppm
	Isopropyl alcohol	245 ppm	Not more than 1000ppm
	1,4-Dioxane	Not Detected	Not more than 50ppm

BQL = Below Quantification Limit

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Chemical name of impurities:

Impurity A: (1RS,2SR)-2-[(dimethylamino) methyl]-1-(3-methoxyphenyl) cyclohexanol

Impurity B: [2-(3-methoxyphenyl)cyclohex-1-enyl]-N, N-dimethylmethanamine

Impurity C: (1RS)-[2-(3-methoxyphenyl) cyclohex-2-enyl]-N,Ndimethylmethanamine

Impurity D: (1RS,2SR)-2-[(dimethylamino) methyl]-1-(3-hydroxyphenyl) cyclohexanol

Remarks : The above Product is satisfactory to the prescribed standard of quality in respect of the above test as per Ph.Eur.& In-house specification.

Data Entered By	Checked By	Approved By
Duvad M Shaikh - E69406 30/01/2019 06:04:46 PM	M.N.Kale - E12907 30/01/2019 06:10:38 PM	S.A.PAWAR - E26817 (30/01/2019 07:21:56 PM)

NOTE -REPRODUCED FROM ORIGINAL REPORT

Date of Issue of COA: 25.02.19

Prepared by: 
Date: 25.02.19

Verified by:
Date:


25.02.19.