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SUN PHARMA

CERTIFICATE OF ANALYSIS

Order No. : 006ESH3573			
Product :	Tramadol Hydrochloride Ph. Eur.	A.R.NO. :	QFP/17/0301
Batch No. :	AHQTRMFL022	Mfg. Date :	February 2017
Release Date :	27.02.17	Exp. Date :	January 2022

Specification No. : BD0435P0DA **Rev. No. : 11**

Sr.	Test	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	A) Melting point :	182.7°C	Between 180°C and 184°C
2.2	B) Infrared spectrum	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	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)	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	D) Chloride :	Aqueous solution is produce white precipitate when treated with silver nitrate solution.	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.
5	Optical rotation	0.0°	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	BQL	Not more than 0.1%
	Impurity B	BQL	Not more than 0.10%
	Impurity C	BQL	Not more than 0.10%
	Impurity D	0.023 %	Not more than 0.10%

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Sr.	Test	Results	Specification
	Unknown Impurities		
	Highest Unknown Impurity	0.036 %	Not more than 0.10 %
	Total impurities(Known + Unknown)	0.059 %	Not more than 0.4%
8	Heavy metals	Less than 10 ppm.	Not more than 10 ppm.
9	Water content	0.08 % w/w	Not more than 0.5 % w/w
10	Sulphated Ash	0.04 % w/w	Not more than 0.1%w/w
11	Assay (By Potentiometry)	100.1 % w/w	Between 99.0 % and 101.0 % w/w (On anhydrous basis.)
12	Residual Solvents (By GC)		
	Ethyl acetate	Not Detected	Not more than 500ppm
	Isopropyl alcohol	242 ppm	Not more than 1000ppm
	1,4-Dioxane	Not Detected	Not more than 50ppm
13	Total aerobic microbial count	Less than 10 CFU/ gm	Not more than 1000 CFU/ gm
14	Total combined yeast & Mould count	Less than 10 CFU/ gm	Not more than 100 CFU/ gm
15	Escherichia coli	Not detected	Should be absent
16	Salmonella species	Not detected	Should be absent
17	Pseudomonas aeruginosa	Not detected	Should be absent
18	Staphylococcus aureus	Not detected	Should be absent
19	Gram-Negative Bile-Tolerant Bacteria	Not detected	Should be absent
20	Endotoxin (by LAL test)	Less than 1.4 EU/mg	Not more than 1.4 EU/mg

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

Conclusion : Product complies with the quality standard as per **Ph. Eur. & In-house** specifications.

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Prepared by 02.05.17 Checked by 02.05.17 Approved by 02.05.17

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