



EMMENAR

Certificate of analysis

Name of the product : Tramadol hydrochloride IP. Batch No : TMD3-1703199
CAS No : 36282-47-0 AR. No : FP17-0312
Dispatch Qty : 200 kg's Mfg. Date : MAR- 2017
Drug license Number : 48/VP/AP/2011/B/R. Exp. Date : FEB -2022
Customer Name : M/s. ESPEE LIFESCIENCES PVT.LTD.

S.NO	Test parameter	Specification	Results
01	Description	A White or almost white, crystalline powder.	A White crystalline powder.
02	Solubility	Freely soluble in water and in methanol and very slightly soluble in acetone	Complies
03	Identification By A. IR	The Infra Red spectrum of sample is Concordant with standard spectrum of the Tramadol hydrochloride.	Complies
	B. 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)	Complies
	C. Reaction of Chlorides	A curdled, white precipitate is formed and dissolves easily in ammonia.	Complies
04	Appearance of solution	Solution S is clear and colorless.	The resulting solution is clear and colorless.
05	Acidity	Not more than 0.40 ml	0.30 ml
06	Optical rotation	Between -0.10° to $+0.10^{\circ}$	$+0.002^{\circ}$
07	Impurity-E by TLC	Not more than 0.20 %	Less than 0.20 %
08	Related substances by HPLC		
	a) Impurity-A	Not more than 0.20 %	0.01 %
	b) Any other impurities	Not more than 0.10 %	0.02 %
	c) Total impurities	Not more than 0.40 %	0.08 %
09	Heavy metals(ppm)	Not more than 20 ppm	Less than 20 ppm
10	Water content(% w/w)	Not more than 0.50 % w/w	0.28 % w/w
11	Sulfated Ash(% w/w)	Not more than 0.10 % w/w	0.06 % w/w
12	Assay	Not less than 99.0 and	99.92 % w/w
	(on anhydrous)(% w/w)	Not more than 101.0 % w/w	

Remarks: The above results complies as per IP Grade Specifications

Compiled by
B.Vassanth
Chemist-QA

[Signature]
17/03/17

Checked by
T. Venkaiah
Manager-QC

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17-03-17

Approved by
T.L.N. Gopal
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