



2004000 18P

CERTIFICATE OF ANALYSIS

Page 02 of 02

Order No. : 0730359870	
Product : TRAMADOL HYDROCHLORIDE Ph.Eur.	A.R.NO. : QFP/19/1638
Batch No. : TRMNF19214	Mfg. Date : November 2019
Release Date : 31.12.19	Exp. Date : October 2024

Spec Code: BD0435P0DA		Revision No : 12.0	
Sr.	Test	Observation/Results	Specification
	UnKnown Impurities		
	Highest Unknown Impurity	0.036 %	Not more than 0.10 %
	Total impurities(Known + Unknown)	0.064 %	Not more than 0.4%
8	Water content	0.2 % W/W	Not more than 0.5 % w/w
9	Sulphated Ash	0.04 % w/w	Not more than 0.1%w/w
10	Assay (By Potentiometry)	99.9 %	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	37 ppm	Not more than 1000ppm
	1,4-Dioxane	Not Detected	Not more than 50ppm
Additional tests.			
12	Total aerobic microbial count	Less than 10 CFU/ gm	Not more than 1000 CFU/ gm
13	Total combined yeast & Mould count	Less than 10 CFU/ gm	Not more than 100 CFU/ gm
14	Escherichia coli	Not detected	Should be absent
15	Salmonella species	Not detected	Should be absent
16	Pseudomonas aeruginosa	Not detected	Should be absent
17	Staphylococcus aureus	Not detected	Should be absent
18	Gram-Negative Bile-Tolerant Bacteria	Not detected	Should be absent
19	Endotoxin (by LAL test)	Less than 0.1 EU/mg	Not more than 0.1 EU/mg

BQL = Below Quantification Limit

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.

Date of Issue: 03.01.20

Prepared by Vansule
03-01-20

Checked by Ash
03-01-20

Approved by [Signature]
03-01-20

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