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Sun Pharmaceutical Industries Ltd.
A-7/A-8, M.I.D.C Industrial Area,
Ahmednagar - 414 111, Maharashtra, India.
Tel. : (91-241) 2777329, 2777330, 2777359
Fax.: (91-241) 2777231
Website : www.sunpharma.com
CIN : L24230GJ1993PLC019050

CERTIFICATE OF ANALYSIS

SUN PHARMA

Order No. : 0730725792			
Product :	TRAMADOL HYDROCHLORIDE Ph.Eur.	A.R.NO. :	BD21007682
Batch No. :	ACTRMNF087	Mfg. Date :	May 2021
Release Date :	29.05.21	Exp. Date :	April 2026

Spec Code : BD0435P0DA Revision No : 14.0

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	A) Melting point :	182.1 ° 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	0.28 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 °	Between - 0.10° and +0.10°
6	Impurity - E (Thin layer chromatography)	No any secondary spot observed.	Any spot due to impurity E is not more intense 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	BQL	Not more than 0.10%
	UnKnown Impurities		
	Highest Unknown Impurity	0.053 %	Not more than 0.10 %
	Total impurities(Known + Unknown)	0.088 %	Not more than 0.4%

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8	Water content	0.17 % 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)	99.9 % 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	202 ppm	Not more than 1000ppm
	1,4-Dioxane	Not Detected	Not more than 50ppm
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

Impurity	Chemical Name
Impurity A	((1RS,2SR)-2-[(dimethylamino) methyl]-1-(3-methoxyphenyl) cyclohexan-1-ol
Impurity B	[2-(3-methoxyphenyl)cyclohex-1-en-1-yl]-N, N-dimethylmethanamine
Impurity C	[(1RS)-2-(3-methoxyphenyl) cyclohex-2-en-1-yl]-N,Ndimethylmethanamine
Impurity D	(1RS,2RS)-2-[dimethylamino) methyl]-1-(3-hydroxyphenyl) cyclohexan-1-ol
Impurity E	(2*RS*)-2-[(dimethylamino)methyl]cyclohexan-1-one

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

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Prepared by 30.05.21 Checked by 30-05-21 Approved by 30.05.21

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LSB/chp
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CERTIFICADO N° 0018/

El Jefe del Subdepartamento Control y Vigilancia de Medicamentos y Cosméticos de la Agencia Nacional de Medicamentos, Instituto de Salud Pública de Chile, certifica que el principio activo **TRAMADOL CLORHIDRATO** y el producto que lo contiene **TRAMADOL CLORHIDRATO SOLUCIÓN ORAL PARA GOTAS 100 mg/mL, Registro ISP N° F-3836/20**, no se encuentra sometido a las disposiciones de los Reglamentos de Productos Estupefacientes y Psicotrópicos, Decretos Supremos N° 404 y N° 405 de 1984, del Ministerio de Salud de Chile.

Este certificado se otorga a petición de LABORATORIO CHILE S.A., para ser presentado ante las Autoridades Sanitarias de India.

El presente documento será válido durante un año a partir de su fecha de emisión, para todas las importaciones y exportaciones que se efectúen respecto a los productos que contengan el principio activo antes individualizado.

SANTIAGO DE CHILE, FEB 2021

Q.F. CARLOS BRAVO GOLDSMITH
JEFE SUBDEPARTAMENTO CONTROL Y VIGILANCIA
DE MEDICAMENTOS Y COSMÉTICOS
DEPARTAMENTO AGENCIA NACIONAL DE MEDICAMENTOS
INSTITUTO SALUD PÚBLICA DE CHILE

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