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CERTIFICATE OF ANALYSIS

R L FINE CHEM No. 15, KHB Industrial Area, Yelahanka, Bangalore - 560064 (new-560106), India Contact No.: 080-28561041, 28561042. Fax No.: 080-28566630		
Product Name : CLOMIPRAMINE HYDROCHLORIDE Compendial Designation : BP 2014		
Batch No: CLM/399		R L FINE CHEM

 Mfg Date : AUGUST 2015
 Retest Date: JULY 2020

TEST	OBSERVATION	SPECIFICATION	Reference to the test method
DESCRIPTION	White crystalline powder Slightly hygroscopic	White or slightly yellow, crystalline powder, slightly hygroscopic	BP 2014
SOLUBILITY	Complies	Freely soluble in water and in methylene chloride, soluble in alcohol	BP 2014
IDENTIFICATION:			
A) Melting Point	192.8°C - 194.1°C	191°C to 195°C	BP 2014
B) IR absorption spectrum	The IR spectrum of the sample was concordant with working standard spectrum	The IR spectrum of the sample should be concordant with that of the working standard spectrum	BP 2014
C) Thin - layer chromatography	Identical with working standard	To comply	BP 2014
D) Nitric acid test	Complies	An intense blue color develops	BP 2014
E) Test for chloride	Complies	To comply	BP 2014
APPEARANCE OF SOLUTION	Clear, less intensely coloured than reference solution Y ₃	Solution is clear and not more intensely coloured than reference solution Y ₅ .	BP 2014
pH	3.92	3.5 to 5.0	BP 2014
RELATED SUBSTANCE (BY HPLC)			
A) Impurity B	0.01 %	Not more than 1.0 %	BP 2014
B) Impurity C	0.02 %	Not more than 0.2 %	
C) Impurity D	0.08 %	Not more than 0.2 %	
D) Impurity F	Below detectable limit	Not more than 0.1 %	
E) Any other impurity	0.06 %	Not more than 0.1 %	
F) Total of other impurities	0.10 %	Not more than 0.2 %	
G) Total impurities	0.21 %	Not more than 1.0 %	
HEAVY METALS	Less than 20 ppm	Not more than 20 ppm.	BP 2014
LOSS ON DRYING	0.31 %	Not more than 0.5 %.	BP 2014
SULPHATED ASH	0.07 %	Not more than 0.1 %.	BP 2014
ASSAY (POTENTIOMETRIC)	100.26 %	99.0 % to 101.0 % (Calculated on dried basis)	BP 2014
RESIDUAL SOLVENTS			
Toluene	01 ppm	Not more than 890 ppm	IHT
Acetone	1592 ppm	Not more than 5000 ppm	
Isopropyl alcohol	196 ppm	Not more than 3000 ppm	
PARTICLE SIZE	Complies	90% Less than 50 microns 10% Less than 200 microns	IHT

Certification and Compliance statements

The above material complies as per BP 2014/IHT

Prepared by

Checked by

Approved by

 Name: Y. Srinivasa Rao
 Designation: Sr. Chemist - QC
 Date of Approval: 10/09/2015

 Name: A. Srinivasa Rao
 Designation: Asst. Chemist - QC

 Name: T.R. Govindan
 Designation: A.G.M - QC
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