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Drishiti Pharma

DEALERS IN : ALL SORTS OF CHEMICALS, VETERINARY, FEED PRODUCTS

32, EZRA STREET, TODI CORNER, 8TH FLOOR, R. No. : 859, KOLKATA - 700 001, Ph. 2235 6266 ; E-mail : mehtak9@gmail.com


To
Aries. Exim. Co. Pvt. Ltd.
STEPHENS ROAD.
4TH FLOOR, R. No. 598.
KOLKATA.
DR. SIR,

DT. 02/05/2015

Human Review 10 kg (2x5kg)
Amitriptyline Hydrochloride @ 2000 kg
* Day 1000. & obliged.

mehtak
02/05/2015

CERTIFICATE OF ANALYSIS

R L FINE CHEM	
Product Name: AMITRIPTYLINE HYDROCHLORIDE	R L FINE CHEM
Compendial Designation: IP	

Batch No: NAMT/1390

Mfg. Date : JANUARY 2015

Retest Date: DECEMBER 2019

TEST	OBSERVATION	SPECIFICATION	Reference to the test method
DESCRIPTION	A white crystalline powder.	Colourless crystals or a white or almost white powder, almost odorless.	IP
SOLUBILITY	Complies	Freely soluble in water, in ethanol (95%), in chloroform and in methanol; Practically insoluble in ether.	IP
IDENTIFICATION:			
A) 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 Amitriptyline Hydrochloride working standard.	IP
B) UV Absorbance	0.560 Abs	Absorbance at 239 nm. about 0.55.	IP
C) Quinhydrone test	No red colour was produced within 15 minutes	No red colour is produced within 15 minutes	IP
D) Test for Chloride	Complies	To comply	IP
APPEARANCE OF SOLUTION	Clear, less intensely coloured than reference solution BSS	The solution is clear and not more intensely coloured than reference solution BSS.	IP
pH	5.21	4.5 to 6.0	IP
Related substances by HPLC			
Amitriptyline Impurity A	Below detectable limit	Not more than 0.05 %	IP
Amitriptyline Impurity B	0.06 %	Not more than 0.1 %	
Any other secondary peak	Below disregard limit	Not more than 0.1 %	
Sum of all secondary peaks	0.06 %	Not more than 0.3 %	
HEAVY METALS	Less than 20 ppm	Not more than 20 ppm.	IP
LOSS ON DRYING	0.23 %	Not more than 0.5 %	IP
SULPHATED ASH	0.07 %	Not more than 0.1 %	IP
Assay by HPLC	99.42 %	99.0 % to 101.0% (Calculated with reference to the dried substance).	IP

Certification and Compliance statements

The above material complies as per IP

Prepared by

Y. Srinivasa Rao

Name: Y.Srinivasa Rao

Designation: Sr.Chemist - QC

Date of Approval: 10/01/2015

Checked By

T. Madan Mohan Reddy

Name: T.Madan Mohan Reddy.

Designation: Asst Manager - QC

Approved By

A.K. Bhattacharjee

Name: A.K.Bhattacharjee

Designation: Sr.Executive - QC

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8/14/2015