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CERTIFICATE OF ANALYSIS

C28

CHLORPHENIRAMINE MALEATE WORKING STANDARD

QUANTITY : 5 GM

BATCH NO : GW/CPM20113

DOM: JAN 2013

DOE: JAN 2017

ANALYTICAL TESTS

SPECIFICATIONS

RESULTS

1. Description

White crystalline powder freely soluble in water, soluble in ethanol(96%) and slightly soluble in ether.

White crystalline powder freely soluble in water, soluble in ethanol(96%) and slightly soluble in ether.

4. Loss on drying

NMT 0.5% W/W

0.37% W/W

5. Potency

98.0 to 101.0%

99.79%

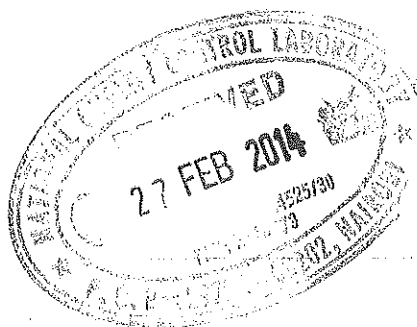
Prepared by:

Signature: *Mosw...*

Mr M. Okal

Q.C. Manager

Date: *20/02/14*



Approved by:

Signature: *Dr. R. Nyatangi*

Dr. R. Nyatangi

Q.A. Manager

Date: *20/02/14*

QC REF 172/13/R

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CERTIFICATE OF ANALYSIS

Analytical Report No. : TR No. 111 / January 2013

Name of the Product : **CHLORPHENIRAMINE MALEATE BP**

Batch No. : GW/CPM920113 Quantity of Batch : 300 kg

Date of Sampling : 21 January 2013 Date of Completion of Analysis : 22 January 2013

Date of Manufacture : January 2013 Wt. of Sample for Analysis : 25 gm

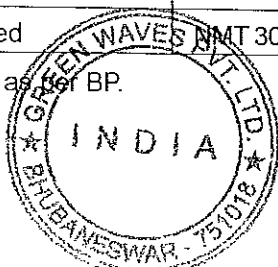
Date of Expiry : December 2017 Wt. of Control Sample : 20 gm

TEST	RESULTS	LIMITS
1. Characteristics	White Crystalline Powder	A white or almost white Crystalline Powder
2. Solubility	Complies	Freely soluble in water, soluble in Ethanol (96%)
3. Identification		
(A) Melting point	133°C	Between 130°C & 135°C
(B) Test as per BP	Complies	To Comply
(C) Test as per BP	Complies	-0.10 deg to + 0.10 deg
4. Clarity & colour solution	Complies	Solution must be clear and not more intensely coloured than the reference solution BY6
5. Related substances		As per Liquid Chromatography
(A) Test as per BP	Complies	Impurity A : (0.2%)
(B) Test as per BP	Complies	Impurities B,C,D : (0.1%)
(C) Test as per BP	Complies	Any other impurity : (0.1%)
(D) Test as per BP	Complies	Total (0.5%)
6. Heavy metals	Complies	NMT 20 ppm
7. Loss on drying	0.140%	NMT 0.5%
8. Sulphated ash	0.019%	NMT 0.1%
9. Assay of $C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$ (on dried basis)	99.60%	Between 98% to 101%
10. Residual Solvents		
Isopropanol	442ppm	NMT 5000ppm
Toluene	Not detected	NMT 2170ppm
Methanol	Not detected	NMT 3000ppm

The Sample Complies with specifications as per BP.

Rana

Quality Control Incharge
(R.C.Rana)



Date : 22 January 2013

