WRS LI-9



CERTIFICATE OF ANALYSIS

WORKING STANDARD

Product Name

LUMEFANTRINE

Batch No.

: WS-04/15³

A. R. No.

LUM/15/WS-04

Mfg. Date

: 04/07/2015

Date of analysis

04/07/2015

Use before date

: 03/07/2016

Ref. Standard Batch No.

WS-09/14

Sr.	Test	Result	Specification
No.			<u>.</u>
01	Description	A yellow crystalline powder with characteristic odour.	A yellow crystalline powder with characteristic odour.
02	Identification By IR	Complies	The IR spectrum of sample is concordant with the IR spectrum of standard.
03	Loss on drying	0.22 %	Not more than 0.5 %
()4	Melting point	125.8°C	Between 125.0°C to 130.0°C
0.5	Impurity profile 1) 2.7-Dichloro-4-oxirany; fluorenyl	Not detected	Not more than 0.15 %
	2) 2.7-dichloro-alpha- [(dibutylamino)methyl]-9H- fluorene-4-methanol	Not detected	Not more than 0.15 %
	3) Unknow Impurity 4) Total Impurities	0.03 % 0.07 %	Not more than 0.5 % • Not more than 2.0 %.
06	Assay (On dried basis)	99.79 %	Not less than 98.0 % and not more than 100.5 %

OPINION: The product Complies as In House specification.

A. K. 1 201

Prepared by A. K. Patel Chemist - QC Checked by

Checked by H. I. Patel Chemist - QC Approved By

Approved By R. R. Patel Chemist - QC

Themis Medicare Limited

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