WRS A5-8



CERTIFICATE OF ANALYSIS

WORKING STANDARD

Product Name

ARTEMETHER

Batch No.

WS-02/15

A. R. No.

71. Mfg. Date

: 03/07/2015

Date of analysis

RTM/15/WS-02

Use before date

: 02/07/2016

Ref. Standard Batch No.

WS-08/14

03/07/2015

Sr. No.	Test	Result	Specification.
10	Description	A white crystalline powder.	A white crystals or white crystalline powder.
02	Solubility	Complies	Practically insoluble in water, very soluble in dichloromethane and Acetone, Freely soluble in ethyl acetate and dehydrated ethanol.
63	Melting Range	86.7°C to 87.7°C	Between 86.0 C to 90.0 C
04	Related substances by HPLC		
	(1) Single impurity	0.27 %	1. Not more than 0.50 %
}	(2) Any other impurity	0.21 %	2. Not more than 0.25 %
ļ	(3) Total impurities	0.56 %	3. Not more than 1.00 %
05	Loss on drying	0.28 %	Not more than 0.50 %
4 .06	Assay (On dry basis)	99.85 %	Not less than 97.00 % and Not more than 102.00 %
07	Residual Solvent		
<u></u>	(1) Methanol	Not detected	Not more than 3000 ppm

OPINION: The product Complies as per In House specification.

A.K. Patel 2015

Prepared by A. K. Patel Chemist - QC

12 /07/2015

Checked by H. I. Patel Chemist - QC onlon low

Approved By R. R. Patel Chemist - QC

Themis Medicare Limited

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