WRS
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[ANK] LYKA LABS LIMITED, ANKLESHWAR

CERTIFICATE OF ANALYSIS

AR No.	F621511002		AR DATE	24-10-2015	
PRODUCT CODE.	RT50100202		PRODUCT NAME	ARTSUNATE INJECTION 60MG.	
BATCH NO.	TLR 60				
BATCH SIZE	50000.00	NOS	T.R. NO. & DT	PRD-1 I	10-10-2015
SAMPLE QTY.	75.00	NOS			
SAMPLED BY	Akhil		MFG. DATE	10/15	
DT. OF ANALYSIS	10-10-2015		EXP. DATE	09/17	

TESTS	RESULTS	SPECIFICATIONS
DESCRIPTION	7.5ml USP TYPE III clear vial containing white powder.	7.5ml USP TYPE III clear vial containing white to almost white powder.
IDENTIFICATION	Complies	Should comply-By HPLC In the test for assay, the retention time of the major peak as obtained in the chromatogram of the sample preparation should correspond to that as obtained in the chromatogram of the standard preparation.
AVERAGE NET CONTENT	60.7mg	Informative
UNIFORMITY OF WEIGHT	-4.61% to +5.11%	±10% of Average Net Content
pH	7.69	7.50 to 8.50
COMPLETENESS & CLARITY OF SOLUTION.	The solution is essentially free from foreign matter particles.	The solution should be essentially free from foreign matter particles.
STERILITY	Complies	Should comply.
BACTERIAL ENDOTOXIN	< 5.83 EU/mg	NMT 5.83 EU/mg
ABSORABANCE AT 430NM	0.036A	NMT 0.08A
ASSAY	Artesunate 60.23mg i.e. 100.38% of L.A.	Each vial contains: Artesunate 57.0mg to 66.0mg 95.00% to 110.00% of L.A

OPINION: The Product Complies/~~Does not comply~~ with the prescribed standards of quality as per ~~IP/BP/USP/IH~~ SPECIFICATIONS.

Analysed By
DATE OF COMPLETION: 24-10-2015

Reviewed By 24/10/15

Approved By 24/10/15
QUALITY ASSURANCE MANAGER

NATIONAL QUALITY CONTROL LABORATORY
RECEIVED
28 JUN 2016
TEL: 2726963 / 3544525/30
FAX: 2718073
P. O. Box 29726 – 00202, NAIROBI

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BLISS INDASI LIFESCIENCE PVT. LTD.

WORKING STANDARD COA

Item : **ARTESUNATE**
Working Standard No : WS/ATS/16/01
Date of Preparation and Standardisation : 06/04/2016
Validity of Use (Period) : 05/04/2018
Direction For Use : Use as such
A. R. No. : WS/2016/03
Source Batch No. : ATS-029-15

Sr. No.	Test	Specification	Results
1.	Description	A white crystalline powder.	White crystalline powder.
2.	Identification	Should comply –By IR	Complies
3.	pH	3.5 to 4.5 (1.0% w/v suspension in water)	4.00
4.	Specific optical rotation	+ 4.5^0 to 6.5^0	(+) 4.98^0
5.	Loss on drying	NMT 0.5%w/w	0.11%
6.	Related Substance	Single Impurity : NMT 0.5% Any other Impurity : NMT 0.25% Total Impurities : NMT 1.0%	Not Detected Not Detected Not Detected
7.	Assay (By HPLC)	97.0% to 102.0% w/w (ODB)	99.8% on anhydrous basis.

Remark: The product complies as per In House specification.

Storage Condition : Store in a cool place.

Analysis By:

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Checked By: