

WRS

A15-4

[ANK] LYKA LABS LIMITED, ANKLESHWAR

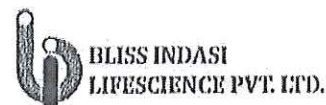
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CERTIFICATE OF ANALYSIS

AR No. F621511002 PRODUCT CODE. RT50100202		AR DATE 24-10-2015 PRODUCT NAME ARTSUNATE INJECTION 60MG.	
BATCH NO. TLR 60 BATCH SIZE 50000.00 SAMPLE QTY. 75.00 SAMPLED BY Akhil DT. OF ANALYSIS 10-10-2015	NOS NOS	T.R. NO. & DT PRD-1 I MFG. DATE 10/15 EXP. DATE 09/17	10-10-2015
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 JP/BP/USP/IN SPECIFICATIONS.			
<div style="display: flex; justify-content: space-between; align-items: flex-end;"> <div> <p>Analysed By <i>Akhil</i> DATE OF COMPLETION: 24-10-2015</p> </div> <div> <p>Reviewed By <i>Ja</i> 24/10/15</p> </div> <div> <p>Approved By <i>for 25/10/15</i> QUALITY ASSURANCE MANAGER</p> </div> </div>			



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15-4BLISS INDASI
LIFESCIENCE PVT. LTD.**WORKING STANDARD COA**

Item : ARTESUNATE
Working Standard No : WS/ATS/16/01
Date of Preparation : 06/04/2016
and Standardisation
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: 



Checked By: 