A 15-5



Working Standard

Name of Material:,	Artesunate IH	A.R.No:	ART/16001 to 16003
Batch No of RM:	ATS-008-16	WS lot no.	ART/WS/16001
Manufacturer:	Arihantanam lifecare (P) Ltd	Mfg. date:	07/2016
Standardised against	IPRS/88/10	Exp. date:	06/2020
Sampled qty:	300 gm	Sampled by	Rahul
Total qty prepared:	13 x 2 gm + 200 gm	Date of analysis:	20/08/2016
Date of release:	22/08/2016	Valid up to	21/08/2017

RESULTS OF ANALYSIS

S.No	Test	Specification	Result	
1.	Description	White crystalline Powder.	White crystalline Powder.	
2.	Solubility	Very slightly soluble in water. Very soluble in dichloromethane; freely soluble in ethanol and acetone.	Very slightly soluble in water, Very soluble in dichloromethane; freely soluble in ethanol and acetone.	
3.	Identification: A. By IR	The infrared spectrum is concordant with the reference spectrum of Artesunate WS or with the reference spectrum of Artesunate	Complies	
4	pH (determined on 1.0%W/v solution in water)	Between 3.50 to 4.50	3.86	
5.	α-Artenimol and β-Artenimol (Imp. A) Artemisinin: (Imp. B) Impurity C: Any other Impurity: Total impurity;	NMT 1.0 % NMT 0.5 % NMT 0.2 % NMT 0.2 % NMT 2.0 %	Not detected Not detected Not detected Not detected Not detected Not detected	
6.	Loss on Drying	NMT 0.5 %	0.12 %	
7.	Assay (By HPLC)	NLT 97.0 % and NMT 102.0 % on dried basis.	99.67 % on dried basis i.e.99.54 % on as basis	

CONCLUSION: The above sample Complies / Does Not Comply as per IH specifications.

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Authorised Signatory

	Analyzed by	Checked by	Approved By
Name	Rabul Patil	Mincul Partel	Desport Kouch
Designation:	acchemist	ac obsider	moulager are
Sign	(ROSK)	KINS.	24
Date:	22/08/120/6	22/08/2016	22/08/2016
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