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WORKING STANDARD CERTIFICATE

QUALIFICATION OF WORKING STANDARD

ITEM	: ARTESUNATE Ph.Int.	EVALUATED WITH: IPCRS/PCAS/04
DATE OF QUALIFICATION	: 05.09.2015	BATCH No. 713073
DIRECTION FOR STORAGE	: Store between 2°C to 8°C in well closed container. Protect from light. #	
DIRECTION FOR USE	: Use as such.	
VALIDITY OF USE	: 04.09.2017	
WORKING STANDARD No.	: WS/C/A91/04	
A.R.No.	: PG1514848	
SOURCE B. No.	: HW140168	SOURCE A.R.No.: PE1406549

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REFERENCE: PROTOCOL No.: WP/Ph.Int./WS/C/A91/01

Sr. No.	TESTS	STANDARDS	RESULTS
1)	DESCRIPTION	A fine, white crystalline powder.	Complies
2)	IDENTIFICATION A)* By Infrared Spectrophotometry	The infrared spectrum of the sample is concordant with the spectrum obtained from the similar determination of Artesunate RS or with reference spectrum of Artesunate.	Complies
3)	SPECIFIC OPTICAL ROTATION	Not less than + 4.50° and Not more than + 6.50°, calculated on anhydrous basis.	+ 5.60°
4)	SULFATED ASH	Not more than 1.00 mg/g.	0.39 mg/g.
5)	WATER	Not more than 5.00 mg/g.	0.20 mg/g.
6)	*RELATED SUBSTANCES (By HPLC)	Impurity A : Not more than 1.0 % Impurity B : Not more than 0.50 % Impurity C : Not more than 0.20 % Single maximum unknown impurity : Not more than 0.20 % Total Impurities : Not more than 2.0 %	0.1 Not Detected Below LOD (0.011%) 0.08 0.2
7)	*ASSAY (By HPLC)	Artesunate contains not less than 96.0 % w/w and not more than the equivalent of 102.0 % w/w of $C_{19}H_{28}O_8$, calculated with reference to the anhydrous substance.	99.6 % w/w
8)	*RESIDUAL SOLVENTS (By GC)	METHOD-I Methanol : Not more than 2000 ppm Ethyl acetate : Not more than 1500 ppm Tetrahydrofuran : Not more than 500 ppm METHOD-II Triethylamine : Not more than 320 ppm Other class 1, 2, 3 residual solvents and other organic solvents: Meets the requirement of other class 1, 2 and 3 residual solvents as per USP chapter <467> and no other organic solvents are present.	228 ppm Not detected Below LOD (7ppm) Not detected Complies
9)	PURITY (By Mass balance method)	On as such basis On anhydrous basis	99.7 % 99.7 %

REMARKS: *Test/s qualified with IPCRS. All other tests comply with International pharmacopoeia, and certified to be used as Working Standard.

NOTE # : Third party may store as per specification.

HEAD QUALITY CONTROL
DATE:

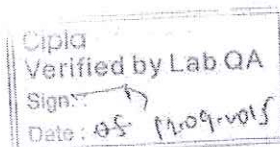
LAB QA HEAD
DATE:

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