Laboratory	**Analytical Services Laboratory, Sequent Research Limited, No. 120 A & B, Industrial Area, Baikampady, Mangalore, Karnataka**
Accreditation Standard	**ISO/IEC 17025: 2005**
Certificate Number	**TC-5252** ***(In lieu of T-3016 & T-3015)*** **Page 1 of 5**
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BIOLOGICAL TESTING

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
I.	**DRUGS & PHARMACEUTICALS**			
1.	**Artemether**	Total aerobic microbial count	In-house method Based on USP harmonized method (chapter 61 & 62) (ASD565 – R0) Dt. 10.03.2014	Min 10 cfu /gm
		Total yeast and mold count		Min 10 cfu /gm
		Staphylococcus aureus		Presence/absence in 10g
		Pseudomonas aeruginosa		Presence/absence in 10g
		Escherichia coli		Presence/absence in 10g
		Salmonella		Presence/absence in 10g
II.	**WATER**			
1.	**Purified Water**	Total aerobic microbial count	In-house method Based on USP harmonized method (chapter 61 & 62) (ASD515-R5) Dt. 24.03.2015	Min1cfu /mL
		Total yeast and mold count		Min1cfu /mL
		Staphylococcusaureus		Presence/absence in 10ml
		Pseudomonas aeruginosa		Presence/absence in 10ml
		Escherichia coli		Presence/absence in 10ml
		Salmonella		Presence/absence in 10ml

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Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection

CHEMICAL TESTING

I.	**DRUGS & PHARMACEUTICALS**			
1.	**Drug Intermediates and Raw Materials**			
a.	**General Tests**	Description	IP 2014, P-174, BP 2015 USP 38 Supplement II, 2015	NA
		Solubility	IP 2014, P-147 BP 2015, Gen notices USP 38 Supplement II, 2015, Gen notices	NA
		Identification Chemical reactions UV Spectrophotometry IR Spectrophotometry	 USP 38 Supplement II, 2015 IP 2014, P-87 BP 2015, A266 IP 2014, P-134 BP 2015, A169,A162	 Qualitative test UV-VIS 200 nm to 600 nm 400 to 4000 cm-1
		Heavy Metals	IP 2014, P-96 BP 2015, A272 USP 38 Supplement II, 2015	Qualitative test
		Arsenic	IP 2014, P-96 BP 2015, A271	Qualitative test
		Iron	IP 2014, P-97 BP 2015, A275 USP 38 Supplement II, 2015	Qualitative test
		Chloride	IP 2014, P-96 BP 2015, A272 USP 38 Supplement II, 2015	Qualitative test

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Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Sulphate	IP 2014, P-98 BP 2015, A279 USP 38 Supplement II, 2015	Qualitative test
		Loss on drying % w/w	IP 2014, P-162 BP 2015, A309 USP 38 Supplement II, 2015	0.1% to 30%
		pH	IP 2014, P-169 BP 2015, A252 USP 38 Supplement II, 2015	1.0 to 13.0
		Specific gravity	IP 2014, P-208 BP 2015, A245 USP 38 Supplement II, 2015	0.6 to 2.0
		Sulphated ash % w/w	IP 2014, P-98 BP 2015, A306	0.01% to 10%
		Residue on Ignition % w/w	USP 38 Supplement II, 2015	
		Chloride	IP 2014, P-96, BP 2015, A272, USP 38 Supplement II, 2015	Qualitative test
		Sulphate	IP 2014, P-98 BP 2015, A279 USP 38 Supplement II, 2015	Qualitative test
		Loss on drying % w/w	IP 2014, P-162 BP 2015, A309 USP 38 Supplement II, 2015	0.1% to 30%
		pH	IP 2014, P-169 BP 2015, A252 USP 38 Supplement II, 2015	1.0 to 13.0

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Specific gravity	IP 2014, P-208 BP 2015, A245 USP 38 Supplement II, 2015	0.6 to 2.0
		Sulphated ash % w/w	IP 2014, P-98 BP 2015, A306	0.01% to 10%
		Residue on Ignition % w/w	USP 38 Supplement II, 2015	
		Water by KF % w/w	IP 2014, P-113 BP 2015, A307 USP 38 Supplement II, 2015	0.05% to 30%
		Clarity &Colour of Solution	IP 2014, P-129 BP 2015, A234, A236 USP 38 Supplement II, 2015	Qualitative test
2.	**Specific Raw Materials**			
a.	**Artemether**	Assay by HPLC	Int. Pharmacopeia 5th edition 2015	70% to 120%
		Related Substance by HPLC -Sum of all impurities	Int. Pharmacopeia 5th edition 2015	Artemisinin – 0.02% - 10 % Anhydrodihydroartemisin – 0.01% - 10% Alpha Artemether – 0.08% -10% Dihydroartemisinin – 0.08% - 10 % Unknown impurities – 0.02% - 10 %
		Residual Solvents -Methanol -Methyl Acetate ppm	USP 38 Supplement II, 2015,Test-467	Methanol – 20 – 20000 mg/kg Methyl acetate – 10 – 20000 mg/kg

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Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
b.	**Oseltamivir Phosphate**	Chromatographic purity by HPLC	IH, BAS/STP/R5, 2015	70% to 110%
		Assay by HPLC	IH, BAS/STP/R5, 2015	70% to 120%
c.	**Praziquantel**	Assay by HPLC	USP 38 Supplement II, 2015	70% to 120%
		Purity by HPLC (100 – total impurities)	IH, BAL/STP/R5, Validated in house [USP 38 Supplement II, 2015]	70% to 110%

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