Claris Injectables Limited
QUALITY CONTROL DEPARTMENT

Primary Packing Material Certificate of Analysis

Material	**: Tubular Glass Vial Type – I Ph. Eur. 10 ml (Schott Kaisha Manufacturer Pvt. Ltd.)**		
Mfg/Supp. By : Schott Kaisha Private Limited			**A.R. No:** A0PMB03048
Issue No.: 02	**Issue Date:** 23/12/16	**Review Date:** 22/12/18	**Page No.:** 2 / 3
Rev. No.: 00	**Effective Date:** 24/12/16	**Specification No.:** PPM/QC/110b	
Received Qty:	99,696 Nos	**Qty. Sampled:**	500 Nos
Date of Analysis:	08/09/18	**Date of Release:**	16/09/18

B. Physico-Chemical Tests:

Sr. No.	Test	Specification	Observation	Reference to Test Method
1.0	Hydrolytic resistance of the inner surface of glass containers (Surface test)	Not More Than 1.00 ml of 0.01 M Hydrochloric Acid for 100 ml of test liquid	0.60 ml of 0.01 M Hydrochlorid Acid for 100 ml of test liquid	Ph. Eur. 8.0 (3.2.1) PPT/QC/01b
2.0	Hydrolytic resistance of glass grains (glass grains test)	Not More Than 1.00 ml of 0.02 M Hydrochloric Acid should be required for 10.00 g	0.40 ml of 0.02 M Hydrochloric Acid is required for 10.00 g	
3.0	Hydrolytic resistance of the etched surface of the container (etching test)	Not More Than 1.00 ml of 0.01 M Hydrochloric Acid for 100 ml of test liquid	0.60 ml of 0.01 M Hydrochloric Acid for 100 ml of test liquid	
4.0	Arsenic	Not More Than 0.1 ppm	Not More Than 0.1 ppm	

Signature	mitul	Rajesh
Date	16/09/18	16/09/18
Name	Mitul Patel	Rajesh Patel
Designation	QC Analyst	QC Head / Manager