

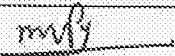
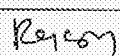
**Claris Injectables Limited**  
**QUALITY CONTROL DEPARTMENT**

**Primary Packing Material Certificate of Analysis**

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