

CERTIFICATE OF CONFORMITY/ ANALYSIS


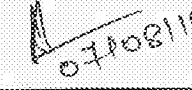

**SCHOTT
KAISHA**

Product Description	: 10ml Amber Vial Fiolax	Customer Name	: CLARIS INJECTABLES LIMITED
Material Code	: 5000000123	Batch Size	: 99,696 EA
Batch No	: SKV1802491	Released Qty.	: 99,696 EA
Customer Drawing No.	: CLAV10AIP01	Lot No.	: 40000025677
Month of Manufacture	: Aug-2018	Country of Origin	: INDIA
Plant of Manufacture	Schott Kaisha Private Limited 1369, Baroda Jambusar Highway, Ankhi, Jambusar Bharuch 392150 Gujarat India		

Attestation: We herewith confirm that the product manufactured according to ISO 9001:2015 and ISO 15378:2015 QMS. It fulfills customer's specifications. Inspection data are available in our batch records. The glass tubing fulfills glass Type I requirements as per latest edition of USP and EP.

Sr.no	Test	Specification	Result	Conclusion
1	SURFACE GLASS TEST-IP	NMT 0.80 mL of 0.01 M HCl per 100 mL of test solution	0.500 ml	Complies
2	CAMERA INSPECTION	Dimensional and Cosmetic	OK	OK

**** END OF STATEMENT ****

Prepared By QC		Released by QA	
Dispatch Quantity	99696 Nos	Sign/ Date :	
Invoice No.	IN1824001351		


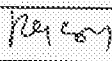
Claris Injectables Limited
QUALITY CONTROL DEPARTMENT

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.: 1 / 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

A. Physical / Dimensional Tests:

Sr. No.	Test	Specification	Observation	Reference to Test Method
1.0	Characteristics (Visual Examination)	A clear/amber glass vial (Drawing No. for clear: CLAV10CIP01 and for amber: CLAV10AIP01)	A amber glass container (Drawing No : CLAV10AIP01)	PPT/QC/01b
2.0	Total height	Between 54.00 mm and 55.00 mm	54.42 mm	
3.0	Vial tube outer diameter	Between 21.00 mm and 22.00 mm	21.90 mm	
4.0	Collar diameter	Between 19.75 mm and 20.25 mm	19.92 mm	
5.0	Neck inner diameter	Between 12.50 mm and 12.90 mm	12.60 mm	
6.0	Rim thickness	Between 3.50 mm and 4.00 mm	3.87 mm	
7.0	Tube wall thickness	Between 0.95 mm and 1.05 mm	1.00 mm	
8.0	Bottom thickness	Not Less Than 0.70 mm	1.22 mm	
9.0	Stability on flat surface	Stable	Conforms	

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

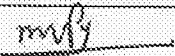
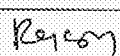
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B. Physico-Chemical Tests:

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	

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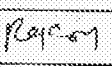
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Sr. No.	Test	Specification	Observation	Reference to Test Method
5.0	*Light transmission	Maximum % of light transmission at wave length between 290 – 450 nm in container should not exceed 13%	Conforms	Ph. Eur. 8.0 (3.2.1) PPT/QC/01b
6.0	Bio burden Bacteria Fungus	Not More Than 35 CFU/piece Should be absent	Bacteria : Nil Fungus : Absent	Ph. Eur. 8.0 (2.6.12) PPT/ QC/151

* This test is applicable only for coloured light protecting glass container.

Conclusion: The material conforms as per specification.

Signature		
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