



NO.11, LINTANG BERINGIN 3, OFF JALAN PERMATANG DAMAR LAUT,  
11960 BAYAN LEPAS, PENANG.  
(QuantumTec Life Science Solutions is A Division of PMA Manufacturing Sdn Bhd)

Product Code: QT1510-32  
Description: Sterile 70% IPA, 30% WFI 1L (BNB)  
Lot#: 30000223  
Expiration Date: 28 Feb 2026

## CERTIFICATE OF ANALYSIS

<u>Parameters</u>	<u>Specification</u>	<u>Result</u>
Colour	Colourless	Colourless
Odour	Alcohol – like	Alcohol – like
Clarity	Clear	Clear
Filtered	To 0.2 microns	Using 0.2 microns
IPA Content	68.0 to 72.0 %	68.87%
Specific Gravity at 20°C (kg/m <sup>3</sup> )	0.872 to 0.883	0.8730
Refractometer	24 – 26	25.5
Bacteria Endotoxin Test (LAL kit by Cape Cod)	< 0.25 EU/ml	< 0.25 EU/ml
Sterility Test (USP 71 method)	No growth observed	No growth observed

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### Irradiation Details

<u>Specified Dose (kGy)</u>		<u>Delivered Dose (kGy)</u>	
Min: 25	Max: 45	Min: 27.8	Max: 31.6

- This product / product category has been validated for Sterility Assurance Level of SAL 10<sup>-6</sup> with VD Max<sup>25</sup> Method as per ISO EN 11137-2:2015: Sterilization of healthcare products – Radiation Part 2 – Establishing the Sterilization Dose; with a conclusion of a dose of 25kGy will provide Sterility Assurance Level of SAL 10<sup>-6</sup>.*
- BSE/TSE Statement: There are no materials of animal origin in the raw materials or manufacturing process of our products.*

Reviewed and Approved by:

Date:

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QA Manager

07 Mar 2023