



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#: 30000622
 Expiration Date: 30 Sep 2025

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 %	69.94 %
Specific Gravity at 20°C (kg/m ³)	0.872 to 0.883	0.8724
Refractometer	24 – 26	25.3
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

Irradiation Details

<u>Specified Dose (kGy)</u>		<u>Delivered Dose (kGy)</u>	
Min: 25	Max: 45	Min: 30.1	Max: 37.4

This product / product category has been validated for Sterility Assurance Level of SAL 10⁻⁶ with VD Max²⁵ 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 10⁻⁶.

Reviewed and Approved by:

Date:

QA Manager

07 Oct 2022