



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: QT2510-32
 Description: Sterile 70% SDA, 30% WFI
 Lot#: 30000422
 Expiration Date: 30 Sep 2025

CERTIFICATE OF ANALYSIS

<u>Parameters</u>	<u>Specification</u>	<u>Result</u>
Colour	Colourless	Colorless
Odour	Alcohol – like	Alcohol-like
Clarity	Clear	Clear
Filtered	To 0.2 microns	Using 0.2 microns
SDA Content	68.0 to 72.0 %	69.39%
Specific Gravity at 20°C (kg/m ³)	0.862 to 0.885	0.8811
Bacteria Endotoxin Test <i>(LAL kit by Cape Cod)</i>	< 0.25 EU/ml	< 0.25 EU/ml
Sterility Test <i>(USP 71 method)</i>	No growth observed	No growth observed

Irradiation Details

Specified Dose (kGy)		Delivered Dose (kGy)	
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:

03 Nov 2022

QA Manager