



NO.11, LINTANG BERINGIN 3, OFF JALAN PERMATANG DAMAR LAUT,
1960 BAYAN LEPAS, PENANG.

(QuantumTec Life Science Solutions is A Divison of PMA Manufacturing Sdn Bhd)

Product Code: QT2514-128

Description: Sterile 70% SDA, 30% WFI with cap

Lot#: 30000822

Expiration Date: 30 Nov 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 %	68.48%
Specific Gravity at 20°C (kg/m ³)	0.875 to 0.892	0.8811
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

Specified Dose (kGy)

Min: 25 Max: 45

Delivered Dose (kGy)

Min: 26.0 Max: 29.4

1. 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.

2. 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:

11 May 2023

QA Manager