



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: QT2512-32

Description: Sterile 70% SDA, 30% WFI (BNB)

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 <sup>3</sup> )	0.875 to 0.892	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

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### Irradiation Details

#### **Specified Dose (kGy)**

Min: 25      Max: 45

#### **Delivered Dose (kGy)**

Min: 27.8      Max: 31.6

1. 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>.

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:

10 Feb 2023

QA Manager