

CERTIFICATE OF ANALYSIS

| | | |
|-----------------------|----------------|---|
| PRODUCT | PO5501B | TRIPLE WRAP STERILE TSA + NEUTRALIZERS |
| LOT NUMBER | 6283854 | |
| EXPIRY DATE | 2026.04.13 | |
| TEST DATE | 2025.06.25 | |
| REPORTING DATE | 2025.06.30 | |

| General Characteristics | Results | Specification |
|--|----------|---------------------------|
| Colour | Conforms | Ivory |
| Appearance | Conforms | Transparent |
| pH | 7.2 | 7.1 -7.5 |
| Packaging / Presentation | Conforms | Conforms to specification |
| Average irradiation dose (kGy) | 15.92 | 14.00 - 22.00 |
| Cont. check @ 20-25 & 30-35°C for >=120h | Conforms | No Contamination |

| Microbiological Performance | Control c.f.u | Test Result | Specification |
|---------------------------------------|---------------|-------------|---|
| Up to 3 days @ 30 - 35°C | | | |
| Escherichia coli ATCC®8739 | 81 | 72 | 2-10 mm, cream colonies. |
| Staphylococcus aureus ATCC®6538 | 62 | 48 | 1-2 mm, cream, shiny colonies. |
| Pseudomonas aeruginosa ATCC®9027 | 84 | 73 | 3-8 mm, green-yellow colonies. |
| Bacillus subtilis ATCC®6633 | 88 | 92 | 4-8 mm, cream colonies. |
| Staphylococcus epidermidis ATCC®12228 | 72 | 74 | 1 mm, cream colonies. |
| Kocuria rhizophila ATCC®9341 | 55 | 52 | 0,5-0,75 mm, yellow colonies. |
| Up to 2 days @ 32°C, anaerobic | | | |
| Clostridium sporogenes ATCC®19404 | 57 | 47 | 1-2 mm, cream colonies. |
| Up to 5 days @ 30 - 35°C | | | |
| Candida albicans ATCC®10231 | 86 | 82 | 2 mm, cream colonies. |
| Aspergillus brasiliensis ATCC®16404 | 37 | 33 | 10-30 mm, white mycelium, black spores. |
| Up to 3 days @ 20 - 25°C | | | |
| Bacillus subtilis ATCC®6633 | 88 | 88 | 4-8 mm, cream colonies. |
| Up to 5 days @ 20 - 25°C | | | |
| Candida albicans ATCC®10231 | 86 | 82 | 2 mm, cream colonies. |
| Aspergillus brasiliensis ATCC®16404 | 37 | 33 | 10-30 mm, white mycelium, black spores. |

Moderate to heavy growth of the tested organisms. Recovery greater than 50% and less than 150% of the control and is comparable to a previously released batch.

Tested in accordance with the methods described in the current United States pharmacopoeia for the microbiological control and monitoring of aseptic processing environments.

The quality control methods meet requirements of ISO 11133.



The testing laboratory of Oxoid Deutschland GmbH is accredited by the German accreditation body DAKKS according to DIN EN ISO/IEC 17025 for the performance testing of media for microbiology to DIN EN ISO11133 and registered under D-PL-20190-01-00.

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Sterility Assurance Level:

This product has been terminally sterilized to a SAL level of 10^{-5} by irradiation exposure to be within 14.0 - 22.0 kGy.

The information given is believed to be correct. However, both the information and the product are offered without warranty for any specific application other than that specified. The results reported were obtained at the time of release.

This certificate is produced electronically and valid without a signature

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