

Certificate of Quality

Product Name: Isol Contact TSA w/w 10/pk
Lot Number: 285306

Product Number: R111820
Expiration Date: 2018-07-31
 (YYYY-MM-DD)

This product has been manufactured, processed and packaged in accordance with Quality Systems Regulation, 21 CFR Part 820. Representative samples were tested per Remel Inc., a part of Thermo Fisher Scientific Quality Control specifications and were found to meet performance criteria for this product.

Organism Challenge	ATCC	Results
Aspergillus brasiliensis	16404	Pass
Bacillus subtilis	6633	Pass
Candida albicans	10231	Pass
Escherichia coli	8739	Pass
Pseudomonas aeruginosa	9027	Pass
Staphylococcus aureus	6538	Pass
Kocuria rhizophila	9341	Pass
Staphylococcus epidermidis	12228	Pass

A pass result indicates organism produced the expected colony size, number, and morphology, indicative of the challenge organism and level for the media formulation, within the required time period. Inoculation levels of 10-100 CFUs were used, and incubation was conducted at 20-25°C for fungi, for not more than 5 days, and at 30-35°C for bacteria for not more than 72 hours. The results meet or exceed USP Growth Promotion requirements.

Physical Characteristics:

Appearance: Light to Medium Amber, Clear Agar
 pH @ 20-25°C: 7.3 +/- 0.2

Sterility Assurance Level:

This product has been terminally sterilized to an SAL level of 10⁻⁶ by irradiation exposure to be within 13.0-22.0 kGy. Manufactured lot has been statistically sampled. Samples were acceptable for microbial content and aesthetic value following 7 days at 20-25°C.

Certificate results were obtained at time of release. End users are encouraged to assure product meets internal standards at time of use.

Signed



Quality Assurance Supervisor