

CERTIFICATE OF ANALYSIS

QA/F/01 Rev no. 03

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|--------------------------|--------------------------------|
| PRODUCT : | Diphtheria virulence agar base |
| PRODUCT CODE NO.: | B500 |

QUALITY CONTROL TESTS : DEHYDRATED MEDIUM

| PARAMETERS | SPECIFICATIONS/STANDARD VALUES |
|-------------------|--------------------------------|
| COLOR | Cream to yellow |
| APPEARANCE | Homogenous free flowing powder |

QUALITY CONTROL TESTS : REHYDRATED MEDIUM

| PARAMETERS | SPECIFICATIONS/STANDARD VALUES |
|------------------------------------|--------------------------------|
| pH(post autoclaving/heating) | 7.8+/-0.2 |
| COLOR (post autoclaving/heating) | Medium amber |
| CLARITY (post autoclaving/heating) | Clear to slightly opalescent |

QUALITY CONTROL TESTS : MICROBIOLOGICAL CULTURAL RESPONSE:

Cultural characteristics observed with added KL Virulence Enrichment (BF049) and 0.5 ml of 1% Potassium tellurite solution (BF010) after an incubation at 35-37°C for 24-72 hours.

| Organism Description | Inoculum (CFU) | Growth | Recovery | Line of precipitation |
|--|----------------------|-------------|----------|-----------------------|
| Bacillus subtilis ATCC 6633 | [>=10 ⁹] | [Inhibited] | [0%] | [-] |
| Corynebacterium diphtheriae type gravis | [50 - 100] | [Luxuriant] | [>=50%] | [Positive] |
| Corynebacterium diphtheriae type intermedius | [50 - 100] | [Luxuriant] | [>=50%] | [Positive] |
| Corynebacterium diphtheriae type mitis | [50 - 100] | [Luxuriant] | [>=50%] | [Positive] |
| Staphylococcus epidermidis ATCC12228 | [50 - 100] | [None-Poor] | [<=10%] | [-] |