

Certificate of Analysis

Name: *Clostridium difficile* Toxoid B

Product code: CDB-TDL-100

Batch #: 42131

Description: Native toxin B purified from *C. difficile* strain VPI10463 (toxintype 0), converted to inactive toxoid form

Amount: 100µg

Purity: >95% pure by SDS-PAGE

Presentation: Bubbly/glassy residue due to lyophilisation in 5% sucrose to increase product stability

Buffer: Contents when reconstituted in 250µl sterile distilled water will contain: Toxoid B at a concentration of 0.4mg/ml in 0.05M Hepes, 0.15M NaCl and 5% sucrose

Inactivation: Inactivated using formaldehyde. No cell rounding in the sensitive verocytotoxicity assay at 2µg/ml compared to active toxin lethal dose of 4pg/ml.

Usage guidelines

Storage: Lyophilised vial: +2°C to +8°C

Reconstituted liquid: +2°C to +8°C

Stability: Lyophilised vial: 1 year after date of receipt

Reconstituted liquid: 1 month

Freezing: Reconstituted liquid can be frozen at -80°C to -20°C to extend stability to 1 year; however every freeze/thaw cycle will cause increased aggregation. Avoid multiple freeze/thaw cycles and multiple temperature fluctuations.

Mixing: Swirl or pipette gently to mix. Vortexing promotes aggregation.



10th August 2015

QC Officer

Date

