

Technical Datasheet

Analysis Name: Enterobacterial Count – Plate Method

Method Number: USP EB

Scope of Application: Nutritional supplements of all kinds, from raw materials to the finished

forms.

Description: This modified validated USP has an aligned procedure to ISO-21528-

2:2017 with differences in diluent and incubation temperature. These changes allow a more specific quantification of *Enterobacteriaceae* (EB) than the MPN procedure outlined by USP. Appropriate dilutions of sample are inoculated on a selective media (VRBG) using the pour plate method. The plates are incubated at 30°C - 35°C for 24 ± 2 hours. Characteristic colonies are counted and reported as EB.

Sample Weight 25g Required:

Method Reference: United States Pharmacopeia <2021> Microbial Enumeration Tests –

Nutritional and Dietary Supplements

ISO 21528-2:2017 Enumeration of Enterobacteriaceae: Colony

Counting Technique

Analytical Platform: Cultural Method

Special Information: Some Gram-negatives, other than Enterobacteriaceae, may be

included in the counts (e.g. Aeromonas spp., or Acinetobacter spp.)

Not validated for testing on foods or environmental samples.

For samples that require Preparatory Testing, see TDS for USP

Preparatory Testing.

Analyte Reported	Alias	Unit of Measure	Limit of Quantification	Reproducibility
EB Final Result		CFU/g	<10 CFU/g	
EB Final Result		CFU/mL	<1 CFU/mL	

TDS-USP 2021-2 EB 01/30/2025