

## **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  $30^{\circ}\text{C}$ - $35^{\circ}\text{C}$  for  $24 \pm 2$  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	Alias	Unit of	Limit of	Reproducibility
Reported		Measure	Quantification	
EB Result		CFU / g	< 10 CFU / g	
EB Result		CFU / mL	<10 CFU / mL	

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TDS-USP 2021-1 EB 8/29/2023