Technical Data Sheet

ABSL004 Buffered Sodium Chloride Peptone Solution

Buffered Sodium Chloride-Peptone Solution pH 7.0 is recommended as a diluent for carrying out microbial limit testing from pharmaceutical products in accordance with the microbial limit testing by harmonized methodology.

Composition	**Ingredients Gms / Litre**
Potassium hydrogen phosphate	3.600
Di sodium hydrogen phospate di hydrate	7.200
Sodium chloride	4.300
Peptone from meat	1.000

Appearance:

Sterile clear colorless Buffered Sodium Chloride Peptone Solution in glass bottles with screw cap

pH (at 25°C):

7.00

Principle:

The composition of this medium is as per USP and is in accordance with the harmonized methodology of USP/EP/BP/JP. This medium is recommended for preparation of stable test strain suspension employed for validating the microbiological testing procedures of non-sterile products. The standardized stable suspensions are used so that the suitability of this test to detect microorganism in presence of product can be established. Non-fatty products insoluble in water and water- soluble products are diluted/dissolved using this solution. Peptone serves as nutrient source and maintains the cell viability. Phosphates in the medium act as good buffering agents. Sodium chloride maintains the osmotic balance and cell integrity. Pre-enrichment in Buffered Sodium chloride-Peptone solution pH 7.0 at 35°C for 18-24 hours results in repair of injured cells. This medium supports the repair of injured cells that have sensitivity to low pH. It is also recommended for pre-enrichment and repair of injured cells.

Quantity of Medium

200 ml in 500 ml bottle with screw cap

Cultural Response

Cultural characteristics observed after incubation at 30-35°C for 24 hours and recovery should be greater than 70%.

Sterilization Method

Sterilized by autoclaving at 121 °C as per validated cycle

Sterility Test:

Passes release criteria.

Shelf Life and Storage Conditions:

Use before expiry date on the label and store below 25°C.

Reference Pharmacopoeia:

USP/EP / BP / JP