AuSaMicS™ Life Science

Technical Data Sheet

Catalogue No. AS-1414

Technical Data Sheet

Diluting Fluid K (Peptone-Polysorbate Diluent), Dehydrated

Product	Form	Dispatch
Diluting Fluid K	Dehydrated powder	Melbourne, Australia

Parameter	Details
Product	Diluting Fluid K (Peptone-Polysorbate Diluent)
Catalogue number	AS-1414
Manufacturer	AuSaMicS Life Science, Melbourne, VIC, Australia
Form supplied	Dehydrated powder medium
Prepared composition	Peptone 5.0 g/L; beef extract equivalent 3.0 g/L; polysorbate 80 10.0 g/L
Final pH	6.9 ± 0.2 at 25°C
Primary application	Preparation of pharmacopeial-style rinsing and diluting fluid for sterility testing and method suitability studies
Standards concept	USP <71>, Ph. Eur. 2.6.1, JP concept

Intended use

- Rinsing fluid for membrane filtration sterility testing.
- Method suitability studies involving bacteriostasis and fungistasis assessment.
- Rinsing of sterile pathways of medical devices and assemblies.
- Supportive fluid for oily, petrolatum-containing, or difficult-to-wet samples where enhanced wetting is beneficial.

Composition and performance

Attribute	Specification
Prepared composition	Peptone 5.0 g/L; beef extract equivalent 3.0 g/L; polysorbate 80 10.0 g/L
pH after preparation	6.9 ± 0.2 at 25°C
Typical application	Rinse / diluent medium for sterility testing and method suitability
Physical support	Enhanced wetting support for hydrophobic or oily residues

Preparation instructions

Parameter	Details
Reconstitution	Suspend 18.0 g in 1000 mL purified water and dissolve completely, heating if required.

Sterilization	Dispense and sterilize at 121°C for 15 minutes, or by an equivalent validated cycle.
Appearance - powder	Cream to yellow, homogeneous, free-flowing powder.
Appearance - prepared medium	Clear to slightly opalescent pale yellow solution.
Storage	10-30°C in a dry place, tightly closed, protected from moisture and light.
Shelf life	Refer to label; use prepared medium promptly or according to validated in-house holding conditions.

Quality notes

- Prepared medium should be used within validated in-house hold times.
- Laboratories should verify suitability against the current compendial method and their validated procedure.
- Actual COA values must be completed from batch-specific release testing.