

Technical Data Sheet

HEIMPLATE™ R2A

Ordering number: 1.46075.0020 / 1.46075.0120

90 mm settle plates is designed for the determination of the total microbial count in water for injections in bulk, highly purified water and purified water in bulk.

General

The formulation of the basic medium (R2A Agar) is prepared according to the recommendations of the current European and Japanese Pharmacopoeia (EP, JP, Water for injections).

Mode of Action

R2A Agar (Reasoner's 2A agar) is especially designed to promote the growth of aerobic, heterotrophic micro-organisms which are adapted to low nutrient environments such as water. The low amount of nutrients in the agar allows the growth of aerobic, heterotrophic microorganisms which are adapted to a low nutrient content.

Typical Composition (g/l)

Yeast Extract	0.5 g/l
Proteose Peptone	0.5 g/l
Casein Hydrolysate	0.5 g/l
Glucose	0.5 g/l
Starch	0.5 g/l
K ₂ HPO ₄	0.3 g/l
MgSO ₄	0.024 g /l
Sodium Pyruvate	0.3 g/l
Agar	15 g/l

The appearance of the medium is clear and whitish. The pH value is in the range of 7.0-7.4. The medium can be adjusted and/or supplemented according to the performance criteria required.

Application and Interpretation

The R2A agar plates are designed for the determination of the total microbial count in water for injections in bulk, highly purified water and purified water in bulk.

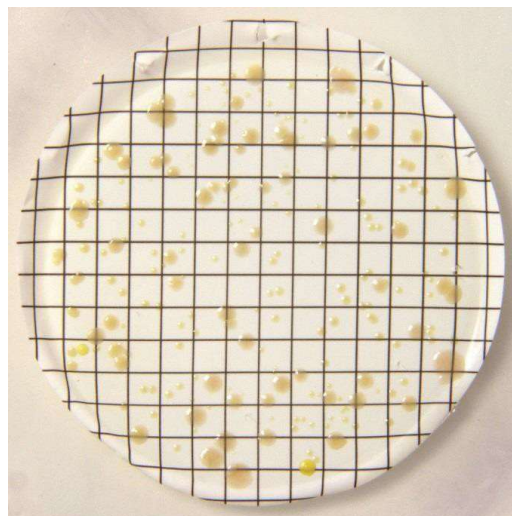
Please check each agar plate before using it on sterility and pay attention to aseptic handling in order to avoid false positive results.

For the total viable aerobic count 200 ml water

(for water for injection in bulk and for highly purified water) are filtered through a membrane ($\leq 0.45 \mu\text{m}$). The filter is subsequently incubated on R2A-Agar. The medium is incubated under aerobic conditions for 5 days at 30-35 °C.

According to the EP water for injections in bulk and highly purified water must contain less than 10 colony forming units (CFUs) per 100 ml, purified water in bulk must contain less than 100 colony forming units per ml.

Finally the number of CFU per plate is examined. Grown colonies are recommended to be identified



Mixed culture of *Pseudomonas aeruginosa*, *Ralstonia pickettii* and *Burkholderia cepacia*.

Storage and Shelf Life

The product can be used for sampling until the expiry date if stored upright, protected from light and properly sealed at +15 °C to +25 °C.

Condensation can be prevented by avoiding quick temperature shifts and mechanical stress.

The testing procedures as described on the CoA can be started up to the expiry date printed on the label.

Disposal

Please mind the respective regulations for the disposal of used culture medium (e.g. autoclave for 20 min at 121 °C, disinfect, incinerate etc.).

Quality Control

Control Strains	ATCC #	Inoculum CFU	Incubation	Expected Result Recovery in %
<i>Escherichia coli</i>	8739	10-100	24-28 h at 33-35 °C	70-200 %
<i>Pseudomonas aeruginosa</i>	9027	10-100	24-28 h at 33-35 °C	70-200 %
<i>Bacillus subtilis</i>	6633	10-100	24-28 h at 33-35 °C	70-200 %
<i>Burkholderia cepacia</i>	25416	10-100	24-28 h at 33-35 °C	70-200 %
<i>Ralstonia pickettii</i>	27511	10-100	24-28 h at 33-35 °C	70-200 %
<i>Methylobacterium extorquens</i>	15911 (NBRC #)	50-200	4-7 d at 20-25 °C	50-200 %

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<i>Pseudomonas fluorescens</i>	17386	50-200	4-7 d at 20-25 °C	50-200 %
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Please refer to the actual batch related Certificate of Analysis.

Literature

European Pharmacopoeia 8.0 (2014) Monographs: Water for injections; Water, highly purified; Water purified.

Greenberg, A.E., Clesceri L.S. and Eaton, A.D. (1992): Standard methods for the examination of water and wastewater, 18th ed. American Public Health Association, Washington, D.C.

Japanese Pharmacopoeia 16th edition (2011), Section G8 4.4.2

Reasoner, D.J. and Geldreich, E.E. (1985): A new medium for the enumeration and subculture of bacteria from potable water. Appl. Environ. Microbiol. 49: 1-7.

Ordering Information

Product	Cat. No.	Pack size
HEIMPLATE™ R2A	1.46075.0020	20 x 90 mm plates
HEIMPLATE™ R2A	1.46075.0120	120 x 90 mm plates