

CERTIFICATE OF ANALYSIS

Certificate of Analysis

Product name: Royal Brompton Heart Valve Antibiotic Solution (RBAS)
Product code(s): 04-371
Batch Number(s): 85171004
Date Manufactured: 03 Oct 17
Expiry Date: 02 Oct 18
Appearance: Red liquid

Quality Control:

	Specification	This batch result
pH	7.20-7.40	7.31
Conductivity($\mu\text{s}/\text{cm}$)	13000-15000	14600
Osmolality(mOsm/kg)	285-295	285

Preservatives used:

Antibiotics: Gentamicin sulfate, ciprofloxacin hydrochloride, cefuroxime sodium salt, vancomycin hydrochloride, colistin sulfate

Sterility: Terminally filtered with 0.2 μm filter in a grade B clean room and tested for sterility.

Storage: Store at -20°C

Country of Origin: United Kingdom

Health and Safety:

Precautionary Notes

Gentamicin sulfate is classified as 'Harmful'. While this antibiotic is dissolved in the reagent, appropriate health and safety interventions are recommended. Appropriate Personal Protective Equipment should be worn at all times whilst carrying out tests. Accidental exposure to the skin should be treated by washing with mild detergent and water for 15-20 minutes. Eyes should be washed using water or normal saline for the same duration.

Signed for Quality Control:



Date:

10 Oct 17

Author: Rafael Carlisle
Technical Reviewer: Paul Booth
QA Reviewer: Jahira Jangaria

SER-DOC-32 v1.0
Authorised Date: 06 Jul 17
Next Review Date: 06 Jul 18

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Signed for Certificate Check:

A handwritten signature in blue ink, appearing to be 'D. J. ...'.

Date:

10 Oct 17