Australian Government
Australian Pesticides and Veterinary Medicines Authority

LICENCE TO MANUFACTURE VETERINARY CHEMICAL PRODUCTS

Licence Holder: **Eurofins ams Laboratories Pty Limited** **Licence No:** **6241**
ACN 075 467 757

The APVMA hereby issues a licence under section 123 of the Agricultural and Veterinary Chemicals Code (Agvet Code) to the above named person (the Licence Holder) to carry out the following step(s) of manufacture:

Analysis and testing (antibiotic bioassay, microbiological, chemical, physical, sterility and endotoxin).

This licence authorises the manufacture of the following type(s) of veterinary chemical products only:

Category 6 **(*Single-step manufacture*) – all dosage forms, unless otherwise specified**

—at the following premises:

179 Magowar Road
GIRRAWEEN NSW 2145

This licence is subject to the conditions set out in subsection 126(4) of the Agvet Code, regulations 60, 61 and 62 of the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Agvet Code Regulations) and the **additional conditions in the attached Schedule.**

This licence comes into force on the date of issue. This licence remains in force unless otherwise suspended or cancelled by the APVMA.

Dated this 28th **day of June 2022**

N. J

Nerida Jacobs
A/g Assistant Director
Delegate of the Australian Pesticides and Veterinary Medicines Authority

This licence remains the property of the APVMA and must be returned on request

SCHEDULE OF ADDITIONAL LICENCE CONDITIONS

The following additional conditions apply to and form part of Licence No. **6241** issued to the Licence Holder:

Eurofins ams Laboratories Pty Limited

ACN 075 467 757

S1.1 This Licence authorises only those steps of manufacture, product type(s) and premises listed.

S1.2 The Licence Holder must provide the original signed copy of the audit report together with details of all corrective actions they propose to take with respect to the identified non-conformances and the timeframe for their implementation. This documentation must be received by the APVMA within 25 working days of the audit in accordance with Regulation 61(8C)(a)(i).

S2.1 The Licence Holder must perform all aspects of veterinary chemical manufacture, including analysis and testing, in accordance with Good Manufacturing Practice using the same:

a) premises,
b) plant and equipment,
c) processes and procedures,
d) documentation, and
e) personnel (including those persons responsible for Production and Quality)

that are used in the manufacture of human therapeutics, as inspected and licensed by the Therapeutic Goods Administration (TGA Licence No. **MI-2021-LI-08995-1**).

S2.2 Prior to each TGA inspection, the Licence Holder must arrange for the TGA inspector to verify during the inspection that all aspects of veterinary chemical manufacture are carried out within the scope of that TGA licence.

S2.3 The Licence Holder must maintain their TGA licence and advise the APVMA in writing within 10 working days, of any changes in the scope of that licence. The Licence Holder must also provide the APVMA with copies of all TGA inspection reports and correspondence related to the conduct and closure of such inspections, within 10 working days of receipt of those reports or correspondence.

S2.4 The authorisation for chemical testing it restricted to the testing of Ethylene oxide residues by gas-liquid chromatography.

S2.5 The authorisation for physical testing it restricted to the testing of sub-visible particles.

S2.6 The licence also authorises the disinfectant testing.

Dated this 28th **day of June 2022**

N. [signature]

Nerida Jacobs
A/g Assistant Director
Delegate of the Australian Pesticides and Veterinary Medicines Authority

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