**Certificate no. 1652403146031**

# CERTIFICATE OF MANUFACTURE (APPROVED GMP)

Issued under section 70 of
the *Agricultural and Veterinary Chemicals (Administration) Act 1992*

I, **Nerida Jacobs**, an officer of the Australian Pesticides and Veterinary Medicines Authority (APVMA) authorised pursuant to subparagraph 70(1)(a)(iii) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (the 'Admin Act') hereby state for the purposes of subparagraph 70(1)(b)(i) of the Admin Act that:

1) the APVMA has issued **Eagle Vet. Tech Co., Ltd.** with a GMP Compliance letter, to manufacture veterinary chemical products:

   a. the GMP Compliance letter issued **30 September 2021**and remains in force as of the date of this certificate; [i]

   b. the letter authorises the manufacture of the following types of veterinary chemical products:

      **Category 1 – (*Sterile and/or immunobiological products*) – sterile products for injection and sterile powder for injection; specifically:**

      - **Eagle Catofull Injection 100mL**
      - **Tulshot Injection 100mL**
      - **Oxyvet 10% Injection 250mL**
      - **E-mectin -one 100mL**

      *Note: The products listed above are not currently registered with the APVMA; however, the manufacturer has indicated that these products are expected to be registered in the near future. These products were all assessed as GMP compliant during the 2021 remote GMP audit.*

      - **Aseptic injectables containing: non-beta lactam antibiotics, parasiticides, and nutritionals.**

      *Note: New aseptic injectable products (not listed in the 4 above) will need to be assessed by MQL as part of an application*

      at **235 – 34, Chusa-ro, Sinam-Myeon, Yesan-gun, Chungcheongnam Do, 32417 Korea**; and

   c. the GMP Compliance letter authorises the following steps of manufacture only:

**Quality assurance (QA) of raw materials, formulation including blending, filling, aseptic filling, sterilisation (heat and filtration), microbiological reduction treatment (heat, chemical), analysis and testing (physical, chemical, endotoxin testing, chemical antibiotic assay, microbiological, sterility test), packaging, labelling, storage, and release from supply.**; and

**Authorised person's signature:** N. Jacobs **Date:** 20 July 2022

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2) the APVMA has authorised Good Manufacturing Practice (GMP) auditors to regularly inspect and audit this manufacturing facility for compliance with the *Agricultural and Veterinary Chemicals (Manufacturing Principles) Determination 2014* and *The Australian Code of Good Manufacturing Practice for Veterinary Chemical Products*, 2007; and

3) based on the latest audit/inspection for the company, which was conducted on **08-11 June 2021,** the APVMA has formed the opinion that the manufacturer complies with the APVMA's GMP requirements.

Dated this 20 July 2022

N. J R

**Nerida Jacobs**
**A/g Assistant Director, Manufacturing Quality & Licensing**
**Veterinary Medicines**
Australian Pesticides and Veterinary Medicines Authority

[i] Licences issued by the APVMA for the manufacture of veterinary chemical products do not contain an expiry date. Once a licence is issued it remains in force unless suspended or cancelled, or replaced by a more recent, amended version of the licence.