



Ref: M-7692

30 September 2021

Mr Seung-Ho
Regulatory Affairs Director
Eagle Vet Tech Co Ltd
235-34, Chusa-ro
Sinam-Myeon, Yesan-gun
Chungcheongnam-Do, Yesan-gun, 32417 Korea

Dear Mr Seung-Ho,

CONFIRMATION: OVERSEAS SITE GMP COMPLIANCE

The APVMA is satisfied that this manufacturer meets the requirements for the manufacture of the products nominated in your most recent Pre-Audit Notification form (FM_MQL45) dated 14 May 2021.

The following site was last remotely inspected for GMP compliance by an APVMA-
authorised auditor on 08-11 June 2021. Provided no further contrary evidence is received,
the APVMA will recognise the GMP compliance of this site, for the steps and/or products
specified, for a period of **30 months** from the date of the last inspection.

Therefore, provided no further contrary evidence is received, the following site will be
recognised until **08 December 2023** for the following steps and product types:

Manufacturing site name:

Eagle Vet Tech Co Ltd

Manufacturing site address:

235-34, Chusa-ro
Sinam-Myeon, Yesan-gun
Chungcheongnam-Do, Yesan-gun, 32417 Korea

Steps of Manufacture:

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



Products / Types:

Category 1 – (Sterile and/or immunobiological products) – sterile products 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

The next **GMP audit** for renewal of this confirmation should be conducted by **08 September 2023** well in advance of the expiry date.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Nerida Jacobs'.

Ms Nerida Jacobs
GMP Reviewer
Manufacturing Quality and Licensing

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