Australian Government

Australian Pesticides and Veterinary Medicines Authority

LICENCE TO MANUFACTURE VETERINARY CHEMICAL PRODUCTS

Licence Holder: **Delta Laboratories Pty Limited**
ACN 050 324 742

Licence No: **1056**

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:

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

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

Category 1 ***(Sterile and/or Immunobiological products)*** **– Sterile products for injection**

Category 2 ***(Non-sterile veterinary preparations excluding Ectoparasiticides, Premixes and Supplements)*** **– Creams / lotions, ointments, pastes, sprays, liquids and gels.**

—at the following premises:

8 Warringah Close
SOMERSBY NSW 2250

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 and replaces the previous licence issued on 11 March 2020. This licence remains in force unless otherwise suspended or cancelled by the APVMA.

Dated this 18th **day of June 2021**

Mr Vishal Kaushik
Manager, Manufacturing Quality and Licensing
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. **1056** issued to the Licence Holder:

Delta Laboratories Pty Limited

ACN 050 324 742

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-25102004-LI-000050-1**):

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 This licence does not authorise the manufacture of veterinary chemical products containing:
(i) penicillins, cephalosporins, antineoplastic drugs; or
(ii) hormones, except adrenocorticotrophic drugs; or
(iii) steroids, except semi-solid preparations for topical use containing 1% or less hydrocortisone or 1% of less prednisolone.

S2.5 Analysis and testing (microbiological) is only authorised for Category 2 (*Non-sterile veterinary preparations excluding Ectoparasiticides, Premixes and Supplements)* products in the following dosage forms: creams / lotions, ointments, pastes, sprays, liquids and gels.

Dated this 18th day of June 2021

Mr Vishal Kaushik
Manager, Manufacturing Quality and Licensing
Delegate of the Australian Pesticides and
Veterinary Medicines Authority

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LICENCE TO MANUFACTURE VETERINARY CHEMICAL PRODUCTS

Licence Holder: **Delta Laboratories Pty Limited**
ACN 050 324 742

Licence No: **6234**

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:

Quality assurance (QA) of raw materials, sampling, dispensing, secondary packaging, secondary labelling, analysis and testing (physical and chemical), and storage.

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

Category 6 (*Single step manufacture)* – all dosage forms

—at the following premises:

9 Chivers Road
SOMERSBY NSW 2250

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 and replaces the previous licence issued on 24 July 2020. This licence remains in force unless otherwise suspended or cancelled by the APVMA.

Dated this 19 **day of May 2022**

Dr John Owusu
Director, Manufacturing Quality and Licensing
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. **6234** issued to the Licence Holder:

Delta Laboratories Pty Limited

ACN 050 324 742

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-2017-LI-11602-1**):

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 Quality assurance (QA) of raw materials, sampling and dispensing of starting materials is authorised for the production of non-sterile and sterile veterinary chemical products; excluding ectoparasiticides, premixes and supplements.

S2.5 This licence does not authorise the manufacture of preparations containing:
(a) penicillins, cephalosporins, antineoplastic drugs; or
(b) steroids, except semi-solid preparations for topical use containing <1% hydrocortisone or <1% prednisolone; or
(c) hormones, excepting preparations containing steroid hormones permitted in (b) and adrenocorticotrophic hormone

Dated this 19 **day of May 2022**

Dr John Owusu
Director, Manufacturing Quality and Licensing
Delegate of the Australian Pesticides and Veterinary Medicines Authority

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