Veterinary Medicine Product Data Sheet Guideline

ACVM guideline (March 2018)

Introduction

Use this guideline to help you complete the Veterinary Medicine Product Data Sheet (PDS) for registration of a veterinary medicine. The PDS form (ACVM 1-2) is available on our website.

The completed and MPI-approved PDS is part of the "product and manufacturing specifications" referred to in the conditions of registration for your product.

The following information from the PDS and application form will appear on the Public Register:

- trade name of product
- registration number
- registrant's name and address
- New Zealand agent's name and address (if applicable)
- product type(s)
- the nominal content of the active ingredient(s), not including overages.

Identification Table

At the bottom of each page (except the last) you will find a product identification table that includes date and electronic signature, which can be a hand-written signature that has been scanned. Complete the footer on page 1. All other footers should then fill automatically. (If double clicking does not open the footer, put your mouse over the footer and right click on edit when it appears.)

If you have any questions, contact us (approvals@mpi.govt.nz).

Part A: General Information

A1 Trade Name of the Veterinary Medicine

The wording of the trade name **must be identical** on the PDS and the label you supply. The registration number will be assigned by MPI (if not previously assigned).

Prohibited substances
Some New Zealand trading partners prohibit the use of certain substances in food-producing animals. Consequently, MPI will not approve the registration of products containing these substances with label claims for use in cattle, deer, goats, sheep, llamas, ostriches, emus or fish unless agreed tagging and tracking programmes are instituted. The following substances are considered prohibited:

17ß-oestradiol and its esters

Arsenilic acid

Chloramphenicol

Chloroform

Chlorpromazine

Colchichine

Dapsone

Nandrolone

Nitrofurans (including, but not limited to, nitrofurazone, nihydrazone, furazolidone, furaltodone)

Nitroimidazoles (including, but not limited to, dimetridazole, ronidazole, metronidazole, carnidazole)

Substances with the pyrazolidone moiety within the chemical makeup (for example, but not restricted to, phenylbutazone, ramifenazone, dipyrone).

A2 Registrant Information

The registrant is the person/company who applies to register a trade name product or the person to whom a registration is transferred.

In the Full Legal Name box, put the registered company name or partnership names (including the trading name) or individual name.

If you are an overseas company applying to be a product registrant, you must be registered as an overseas company under section 334 of the New Zealand Companies Act 1993 to carry out business in New Zealand. You must also provide a New Zealand contact (name, address and phone number) on your product label.

A3 Product Type

Select the product type from the table below.

Product type	Definition
Anaesthetic	Any drug or agent administered to bring about partial or complete loss of sensation.
Analgesic	Any drug or agent administered to relieve the sensation of pain.
Antibiotic	Any drug or agent based on a chemical substance produced by a micro-organism that has the capacity to kill, or inhibit growth of other micro-organisms (includes sulphonamides).
Anticonvulsant	Any drug or agent that inhibits convulsions by depressing the central nervous system. (This can include specific motor depressants, or narcotics and sedatives.)
Antidote	Any agent that counteracts the effect of a poisonous substance or drug. These can be chemical, physiological, mechanical or universal agents. (This class will include anti-toxins, anti-sera and reversal agents.)
Antifungal	Any agent administered to destroy or suppress the growth of fungi.
Anti-inflammatory	Any agent administered to reduce the inflammatory response to infection, trauma, surgery or musculoskeletal disease.
Antimicrobial	Any agent (usually chemical) administered to destroy micro-organisms, or suppress their multiplication and growth.
Antiprotozoal	Any agent administered to destroy protozoa, or suppress their multiplication and growth.
Behaviour modifier	Any agent administered to regulate behaviour patterns (includes psychotropic/tricyclics).
Bloat remedy	Any agent administered to alleviate tympany of the rumen, abomasum, stomach or caecum.
Cardiovascular agent	Any agent administered to alter or enhance the activity of the cardiovascular system (includes ionotropes, vasodilators).
Coccidiostat	Any agent administered to destroy coccidia or suppress their multiplication and growth (usually in the form of a feed additive).
Ectoparasiticide	Any agent administered to destroy external parasites or suppress their multiplication and growth.
Endocrine agent (hormone)	Any agent administered to regulate or enhance the activity of the endocrine system.
Endoparasiticide	Any agent administered to destroy internal parasites or suppress their multiplication and growth.

Euthanasia agent	Any agent administered to cause humane death by cessation of cardiac and central nervous system activity.
Gastrointestinal tract modifier	Any agent administered to alter or enhance the activity, motility or secretions of the gastrointestinal tract (includes probiotics).
Hormonal growth promotant	Any hormone administered to influence protein, carbohydrate and lipid metabolism to control or alter the rate of skeletal and visceral growth.
Musculoskeletal modifier	Any agent administered to influence the activity of the musculoskeletal system (includes polysulphated aminoglycans).
Oral nutritional compound	Any substance ingested by an animal as feed, or a nutritional preparation intended for oral administration to an animal to achieve a nutritional benefit.
Parenteral nutrient/electrolyte	Any substance containing ions which are essential to the normal function of cells, or that provides nourishment from minerals, vitamins, fats, protein, carbohydrates and water administered in an injectable formulation.
Renal and urinary tract modifier	Any agent administered to alter or enhance the function of the kidneys or urinary tract (includes pH modifiers).
Respiratory tract modifier	Any agent administered to alter or enhance the function of the respiratory tract (includes bronchodilators, antitussives).
Sedative	Any agent administered to depress the activity of the central nervous system to calm nervousness, irritability and excitement (includes pre-anaesthetic agents).
Skin/coat conditioner	Any agent administered solely to improve or enhance condition of the skin and coat.
Vaccine	Any suspension of attenuated live or killed micro-organisms (bacteria, viruses or rickettsiae) administered for prevention, amelioration or treatment of infectious diseases.
Other	Please specify.

A4 Formulation Type

Select the formulation type from the table below.

Formulation type	Definition
Aqueous solution	A formulation of particles dissolved in water.
Aqueous suspension	A formulation of particles suspended in water.
Block (salt lick)	A prepared mixture of salt and minerals formed into blocks for oral consumption by groups of animals as a feed supplement.
Bolus	A rounded concentrated mass of pharmaceutical or nutritional preparation ready to be swallowed.
Capsule	A soluble structure containing a dose of a pharmaceutical preparation.
Cerate	A pharmaceutical preparation of wax-like consistency, usually for topical intramammary use.
Cream	An oil in water emulsion generally used topically in the treatment of skin disease.
Gel	A colloid of firm consistency, although containing much liquid.
Granule	Solid formulation comprising small particles usually for administration without further dilution.
Impregnated material	Any solid pharmaceutical preparation inserted into intact tissues or body cavity (includes HGPs and CIDRs). Also includes collars.
Non-aqueous solution	A formulation of particles dissolved in a solution other than water (such as benzene, alcohol, ether, carbon, disulphide, carbon tetrachloride, acetone).
Non-aqueous suspension	A formulation of particles suspended in a solution other than water (such as benzene, alcohol, ether, carbon, disulphide, carbon tetrachloride, acetone).
Oily solution	A formulation of particles dissolved in oil.
Oily suspension	A colloid mixture of two immiscible liquids, one dispersed throughout the other in small droplets.
Ointment	A semi-solid pharmaceutical preparation usually for topical application.

Paste	A highly viscous pharmaceutical preparation containing a large amount of powder.
Powder	An aggregation of fine particles usually obtained by grinding.
Syrup	A viscous concentrated solution of a sugar used as a vehicle for medications.
Tablet/pellet	A small solid pharmaceutical preparation usually for oral administration.
Vapour releasing product	A formulated product containing one or more volatile ingredients, the vapours of which are released into the air. Evaporation rate normally is controlled by using suitable formulations and/or dispensers.
Other	Please specify.

A5 Overseas Regulatory Status

List the countries where the identical trade name product is already registered. This information is used if there is an urgent product recall.

General Information that is Part of the Product and Manufacturing Specifications

The product and manufacturing specifications are the collective description of the characteristics of the product and how it is to be manufactured, as proposed by the applicant, detailed in the PDS and approved as part of the registration. In effect, they include:

- all of the chemistry and manufacturing details, including labelling, that specify what the product is (formulation and specific detailing regarding packaging)
- how the product is made and handled from sourcing materials through to the point at which the registrant is no longer responsible
- the approved ACVM label content, including all specifically approved use claims and contraindications (if applicable).

A6 Label Information

You must provide an electronic copy of the label as part of your application. The label information, including all claims, warnings, contraindications, and application methods, is considered part of the product and manufacturing specifications.

A7 Shelf Life of the Formulated Product

For new registrations state the proposed shelf life. Include in-use shelf life if appropriate.

For variations to registrations state the approved shelf life. If a variation application is submitted to amend the currently approved shelf life, list both the approved and proposed shelf life on the application form (ACVM 1V).

A8 Pack Sizes and Ranges

For new registrations state the requested pack sizes.

For variations to registrations list each individual pack size currently approved, or the range of sizes/volumes (such as 1L to 20L) if applicable. The currently approved pack sizes for a product must be listed by volume per package or number of solid dose forms (such as tablets, capsules) per package. If a variation application is submitted to amend the currently approved pack sizes, list both the approved and proposed pack sizes on the application form (ACVM 1V).

Indicate which pack sizes will be/are marketed (use an X or a tick or **bold** type or any other clear identifier).

Part B: Product and Manufacturing Specifications-- Commercially Sensitive Information

Note: If you cross-reference another product, you still must provide the relevant information in the PDS. For information that is confidential to another party, you cannot put "refer to AXXX".

B1 Active Ingredient Manufacturer

For each active ingredient list the details for each manufacturer and each manufacturing site if there is more than one. Attach additional page if more space needed.

B2 Active Ingredient Minimum Purity and Impurities

State for each manufacturer. List all impurities present at levels:

- greater than or equal to 10 g/kg (1%) regardless of toxicity/ecotoxicity
- less than 10 g/kg (1%) for toxic/ecotoxic impurities
- any level where toxicity/ecotoxicity is unknown.

The following is an example only.

Active Ingredient	Manufacturer	Grade	% Minimum Purity	Impurity and Amount
Copper Gluconate	XYZ Ltd	USP	98%	Arsenic: ≤3ppm Lead: ≤0.0025%

If registering a new product or updating specifications, provide a copy of the pharmacopoeial grade specified for each active ingredient as per the Chemistry and Manufacturing Information Requirements. If a manufacturer's specification (MS) is used, provide a copy of that specification and any associated validation.

Attach additional page if needed.

B3 Formulation Details

Provide details of the full composition of the final formulated trade name product. Use the information below to complete the table.

Ingredient name
Enter the accepted ISO common name or IUPAC name for the active ingredient or, where this has not been established, provide the chemical name. **If trade name products are**

used as an ingredient, provide full formulations of all trade name products used, or arrange to have complete formulations sent directly to MPI by the supplier in confidence.

CAS number
Enter the CAS registry or colour index number if assigned.

Standard
Put relevant abbreviation here if ingredient meets pharmacopeia standard or internal manufacturer's specification (MS).

Quantity
The concentration of all ingredients must be provided.

Chemical-based formulations are to be expressed in **g/L for liquids** and **g/kg for solids**. Do not list ingredient quantities in amount per unit of product (that is, mg/tablet or g/bolus).

Biological-based formulations are to be expressed in appropriate international units ensuring consistency.

Function
Describe the purpose for each of the ingredients. Refer to table below.

For the purposes of formulation function, ingredients intended for nutritional benefit, such as minerals intended for dietary supplementation, are considered active ingredients even if there are no specific claims made.

For new registrations, state the proposed formulation.

For variations to registrations state the approved formulation. If a variation application is submitted to amend the currently approved formulation, list both the approved and proposed formulations on the application form (ACVM 1V).

Include the amount of active ingredient *added* to the formulation and also the amount of active *in* the formulation if this is different. For example, include the amount of sodium selenate in g/L and the amount of selenium in g/L.

Use the following table to complete the questions on purpose/function of each ingredient.

Function	Definition
Active ingredient	The substance or substances in a formulated product that is/are primarily responsible for the biological or other effects that make the product a veterinary medicine.
Adjuvant	A substance added to a formulation to assist the action of the principal ingredient or base.
Buffer	A weak acid and its conjugate base that is used to maintain the pH at a desired level.
Diluent	A chemically inert substance added to a solution to increase the volume and reduce the concentration; a soluble structure containing a dose of a pharmaceutical preparation.
Emulsifier	A surface active agent used to enable the dispersion of one liquid in another when one is not dissolvable in the other.
Filler	An inert bulking agent used to assist in measurement or distribution of an end use product.
Preservative	Any chemical additive that prevents or retards spoilage (such as sodium benzoate).

Surfactant	A substance that aids or enhances the surface modifying properties of a formulation (also known as wetting agent).
Suspending agent	A substance that evenly disperses solid or liquid material in a liquid or gas phase.
Other	Please specify.

Specific gravity
If the formulation is a liquid, state its specific gravity.

Other information
Include any other physicochemical parameters or information that is important to the identity of the product, manufacturing consistent of the product, or areas of ACVM concern. If there is an active ingredient overage included in the formulation, state the amount of overage per active ingredient and the reason for its inclusion (for example, manufacturing loss or degradation of the active in product storage).

B4 Manufacturer(s) of the Formulated Product

Provide the name, site address and function of all facilities involved in any step of manufacture. This includes but is not limited to the following: bulk product formulation, filling, packaging and labelling, contract sterilisation, external analytical laboratory testing, re-packing/re-labelling* (secondary packaging), release for supply.

The manufacturer(s) listed must be approved. In the last column of the table, put A, B or C to indicate which of the following forms of evidence of GMP approval is provided for each manufacturer listed:
A. International Manufacturer GMP certificate (Provide as clearly named electronic attachment)

B. Other form of MPI recognised evidence (Provide as clearly named electronic attachment)

C. MPI GMP approval (Evidence of approval not required)

For new registrations, list all proposed manufacturers.

For variations to registrations state the approved manufacturers. If a variation application is submitted to amend the currently approved manufacturer information, list both the approved and proposed manufacturers on the application form (ACVM 1V).

For veterinary medicines, all manufacturers of the formulated product must have a current GMP approval appropriate to the formulation type before it can be considered approved by MPI. The GMP approval must be issued by MPI or a competent authority recognised by MPI. If a manufacturer does not meet approval requirements, it is unlikely that the Director-General would have sufficient confidence in the manufacturer's risk management capabilities to register the product.

*Repacker(s)/relabeller(s) are restricted to activities that do not breach the primary packaging (that is, packaging in direct contact with the product).

Quality control function
The quality control function, whether it is in house and/or external, must be listed.

Products imported unfinished
Products imported unfinished for repacking or relabelling include any formulations, bulk products, unlabelled products or products labelled with foreign labels that require a change in the market packaging in New Zealand to complete them for sale as a New Zealand registered product. These products require an import certificate issued by MPI.

'Release for supply'
Provide the name of the main company responsible for conducting the final product checks and ensuring the product meets the registration conditions before it is released for supply.

B5 Manufacturing Process

Explained on form.

B6 Specifications of the Formulated Product

Release specifications are those parameters that are tested before the product is to be released for sale. They are intended to confirm the quality of the product and batch-to-batch consistency.

Expiry specifications (sometimes called 'stability specifications') are those parameters that the product must meet at the end of its shelf life to remain fit for purpose. These parameters may be identical to the release specifications, with adjustments to acceptable values if appropriate.

The following is an example only. Refer to the Chemistry and Manufacturing Information Requirements for a more comprehensive list of relevant chemical and physical characteristics that should be covered in the specifications.

Parameter	Range (include units if appropriate)	Method
Appearance	Description of acceptable parameters	Pharmacopeial or manufacturer standard as appropriate.
pH	5.0 – 7.0	EP
Identification of active ingredient	Complies with BP	Retention time of the sample and standard solutions in the HPLC assay correspond.
Active Ingredient concentration	47.5 – 52.5g/kg (95 – 105%)	MS (state)
Sterility	Complies with requirements	EP

As in the example above, include a volume or weight for quantifiable parameters wherever possible. The acceptable percentage range can also be included.

B7 Packaging Details

Give details of the exact packaging for each pack size in which the formulated product is distributed and marketed. Include composition (such as PP, HDPE) and construction of the container(s), and details of stoppers and closures.

Include material and thickness. If the packaging material is formed from layers, all layers should be included and it should be clear which layer is in direct contact with the product.

If packaging is recycled*, provide details about the recycling process and explain the verification methods to ensure the packaging is fit for purpose.

If more space is required, attach additional sheet.

*Recycled packaging includes:
1. reused existing packaging
2. containers with single use liners
3. packaging made from recycled materials.

B8 Distribution Process (if applicable)

Complete this section if there are special requirements to ensure the integrity of the product through the distribution chain. This would include restrictions on who may purchase the product (such as restricted veterinary medicines [RVMs] requiring sellers/purchasers to have an MPI-approved Operating Plan) or if defined transport conditions are required (such as cold chain for vaccines).

Note: the registrant is not responsible for compliance with the distribution process beyond the point of market release.

Part C: Statement and Notices

Explained on form.