Veterinary Drugs Directorate (VDD)
Health Products and Food Branch (HPFB)

Veterinary Drug Experimental Studies Certificate (ESC) Application Form

Experimental Studies Certificates (ESCs) may be issued by Health Canada to approve the conduct of a variety of veterinary drug studies in Canada, such as preliminary research, immobilization procedures (e.g. for wildlife issues), and to generate data to support a veterinary drug regulatory submission. To apply for an ESC, an application form and required attachments must be submitted to Health Canada for review. This application form supports all ESC requests. The instructions for the application form explain the information required.

If the total attachments are less than 20 MB, you may send the complete application package by email to: vdd.skmd.so-dgps.dmv.cp@hc-sc.gc.ca

Important notes:

- Veterinary drugs used in experimental studies are covered by sections C.08.013-C.08.018 of the Food and Drug Regulations. Fees for ESCs are outlined in Schedule 2 of the *Fees in Respect of Drugs and Medical Devices Order* (subject to annual adjustments based on Consumer Price Index). Fees may be waived or reduced for small businesses. Note that Canadian Federal, Provincial and Territorial Government Departments and publicly funded health care institutions do not have to pay a fee for an ESC, but must submit the ESC application and all necessary accompanying documents.
- An ESC is valid for 12 months. If a date extension is required, a renewal should be filed before the end of the 12 month period.
- One site is typically permitted per ESC application; where a single protocol is to be used for multiple sites and for other situations, contact VDD for assistance: vdd.skmd.so-dgps.dmv.cp@hc-sc.gc.ca.
- For all ESCs involving aquaculture: VDD's evaluation will include considerations for environmental risk mitigation and notification of the appropriate provincial/territorial or federal departments that oversee aquaculture in each jurisdiction; and aquaculture facilities will be required to fulfill all requirements and deposit reporting under the Aquaculture Activities Regulations (AAR).
- Controlled Drugs are listed under the Schedules of the Controlled Drugs and Substances Act. For studies using controlled drugs, an ESC application must be sent to VDD, and an application exemption must be sent to the Office of Controlled Substances. For information about the application exemption, email exemption@hc-sc.gc.ca.
- Upon the coming into force of the Cannabis Act on October 17, 2018, for studies using cannabis (as defined under the Cannabis Act), an ESC application must be sent to VDD, and a research licence application must be sent to the Controlled Substances and Cannabis Branch (CSCB). For information about the research licence application, email: cannabis@hc-sc.gc.ca .

Refer to the Instructions (pages 10-14) for additional information to help you complete your application package.

Part 1 – Nature of the Proposed Experimental Study

A) Indicate which option best describes this Experimental Studies Certificate (ESC) Application:

- ◯ A new study
- ◯ A study with an **identical** protocol to that for a previously issued ESC:

  Drug Submissions Tracking System (DSTS) # of previous ESC:

  Is this application a renewal of an ESC approved within the last 12 months? Yes ◯ No ◯
- ◯ An amendment to an ESC approved within the last 12 months

  DSTS# of previous ESC:

B) Is this study intended to generate data to support a veterinary drug regulatory submission in Canada?

Yes ◯ No ◯

C) Does this study include the immobilization of wildlife?

Yes ◯ No ◯

Part 2 – Investigator & Billing Information

D) Investigator Information

Investigator Name:	
Investigator Title:	
Investigator's Company/Organization:	
Mailing Address:	
Street/Suite	
City/Town	
Province	
Postal Code	
Telephone Number	
Email	
Fax Number	
Primary contact (If different from investigator):	
Third Party authorization letter attached:	Yes ◯ No ◯
Title	
Company/Organization	
Email	
Telephone Number	

E) Billing Information

The full ESC application fee will be invoiced once the submission has been accepted into review. If the ESC application is not accepted for review, 10% of the full fee will be invoiced.

Contact Name and Title:	
Company Name:	
Mailing Address:	
Street/Suite	
City/Town	
Province/State	
Country	
Postal Code/Zip Code	
Email	
Telephone Number	
Fax Number	

Fee Mitigation Measures

The following fee mitigation measures are available. Sponsors must certify that they meet the criteria as outlined in the *Food and Drug Regulations*.

Small Business

☐ We certify that we meet the definition of small business at the time of this filing and have applied for small business status for our company with Health Canada and have received confirmation prior to submitting this submission/application. We understand that failure to hold a valid small business status with Health Canada at the time of submitting this submission/application will result in the full fee being charged.

☐ We have not previously filed an application in respect of a drug with Health Canada. We are filing our first drug application.

Publicly Funded Health Care Institution

☐ We certify that our institution is funded by the Government of Canada or the government of a province or territory and that it is
a) licensed, approved or designated by a province in accordance with the laws of the province to provide care or treatment to persons or animals suffering from any form of disease or illness; or
b) owned or operated by the Government of Canada or the government of a province and that provides health services.

Government Organization

☐ We certify that our organization is a branch or agency of the Government of Canada or of a province or territory.

Part 3 – Drug and Supplier Information

Drug 1- Information

F) Brand Name (or identifying name or code)	
G) Proper or Common Name	
H) Dosage Form	
I) Route of Administration	
J) Chemical Structure – diagram attached (if known):	Yes ◯ No ◯
K) Package / Vial Size	

L) Formulation

Medicinal (Active) Ingredient(s)

Active Ingredient Name (Include CAS # if known)	Standard	Strength	Units	Per	Calculated as Base (Y/N)
					Yes ◯ No ◯
					Yes ◯ No ◯
					Yes ◯ No ◯
					Yes ◯ No ◯

Non-medicinal Ingredient(s) (including preservatives, colouring agents)

Non-medicinal Ingredients (Include CAS # if known)	Standard	Strength	Units	Per	Calculated as Base (Y/N)
					Yes ◯ No ◯
					Yes ◯ No ◯
					Yes ◯ No ◯
					Yes ◯ No ◯
					Yes ◯ No ◯

M) List any other drugs to be used in the study
To add additional lines, choose [Tab] to create a new line.

Drug Name	DIN (if approved)

N) Indicate how the other drugs will be obtained (select all that apply):

- ☐ Available Over-the-counter
- ☐ Veterinarian or Veterinary Prescription
- ☐ Supplier using this Experimental Studies Certificate (all products outlined on these forms)
- ☐ Other (specify):

O) Drug 1 - Supplier Information

Company Name:	
Contact Name:	
Mailing Address:	
Street/Suite	
City/Town	
Province/State	
Country	
Postal/Zip Code	
Email	
Telephone Number	
Fax Number	

Drug 2 - Information (if more than one drug is part of this ESC application)

F) Brand Name (or identifying name or code)	
G) Proper or Common Name	
H) Dosage Form	
I) Route of Administration	
J) Chemical Structure – diagram attached (if known):	Yes ◯ No ◯
K) Package / Vial Size	

L) Formulation

Medicinal (Active) Ingredient(s)

Active Ingredient Name (Include CAS # if known)	Standard	Strength	Units	Per	Calculated as
					Yes ◯ No ◯
					Yes ◯ No ◯
					Yes ◯ No ◯
					Yes ◯ No ◯

Non-medicinal Ingredients (Including preservatives, colouring agents)

Non-medicinal Ingredients (Include CAS # if known)	Standard	Strength	Units	Per	Calculated as Base (Y/N)
					Yes ◯ No ◯
					Yes ◯ No ◯
					Yes ◯ No ◯
					Yes ◯ No ◯
					Yes ◯ No ◯

O) Drug 2 - Supplier Information (if more than one drug is part of this ESC application)

Company Name:	
Contact Name:	
Mailing Address:	
Street/Suite	
City/Town	
Province/State	
Country	
Postal/Zip Code	
Telephone Number	
Email	
Fax Number	

Part 4 – Proposed Experimental Study Information

P) Study Site Location or Facility Name	
Q) Mailing Address:	
Street/Suite	
City/Town	
Province	
Postal/Zip Code	
R) Study Animal Description:	
Species	
Production Type	
Number of Study Animals	
S) Study Duration	
T) Quantity of Drug Required for the Experimental Study	Total quantity of each product: Total amount of active ingredient for each product:
U) Fate & Disposition of Animals Included in the Protocol	
V) Proposed Withdrawal Period for Food Producing Animals or Wildlife that may be Consumed	Meat: Milk: Eggs: Other:

Part 5 – Required Attachments Checklist

Prior to the submission of the ESC application form, complete the checklist below to ensure that all documents listed have been included. For instructions on the required content of each attachment, refer to the Part 5 Instructions (pages 13-14).

- ☐ Cover letter
- ☐ Name and Qualifications of Primary Investigator and other key study personnel
- ☐ Facility Description(s)
- ☐ Proposed Experimental Study Information, including Study Title and Study Number
- ☐ Rationale and/or Calculation for the Drug Quantity requested
- ☐ Summary of evidence that the drug and proposed study do not cause undue foreseeable risk to animals or humans
- ☐ Commercial/Approved Drug label (if available)
- ☐ Experimental Drug label (as per C.08.016 of the Food and Drug Regulations)
- ☐ If an ESC was previously issued:A summary of results from the previous study period, if available and include any safety information and adverse events involving humans or animals; and a log outlining drug usage
- ☐ If the ESC is for food-producing animals: toxicity and residue data for determination of withdrawal period.

Part 6 – Statement(s) of Owner/Manager (Food-Producing Animals Only)

W) Statement of Owner or Manager of Animals (for livestock or aquaculture)

I agree not to sell the animal(s) used in the Experimental Study, or any products from it (them) without prior written authorization from the Experimental Studies Investigator.

Name of investigator:	
Owner/Manager Name:	
Owner/Manager Address:	
Street/Suite	
City/Town	
Province/State	
Country	
Postal/Zip Code	
Signature	Date:

Part 7– Statement(s) of Investigator

For all ESCs:

As the primary investigator, I attest to:

1. Use the drug only in accordance with the outline of the experimental study.
2. Report immediately to the Veterinary Drugs Directorate all serious adverse reactions associated with the use of the new drug.
3. Report promptly to the Veterinary Drugs Directorate, on request, the results of the experimental study.
4. Return to the manufacturer, on request, all quantities of the new drug not used in the experimental study.
5. Maintain all records of the experimental study for a period of at least two years after the conclusion of the study and, on request, make such records available to the Veterinary Drugs Directorate.
6. Report promptly to the Veterinary Drugs Directorate any known disposition of animals involved in the study or of any products from the animals that is contrary to the terms of the agreement referred to in subsection C.08.014 (2) (Food and Drugs Regulations).
7. Account to the Veterinary Drugs Directorate, on request, for all quantities of the new drug received.
8. Be responsible for the health and welfare of study animals and ensure the maintenance of adequate study facilities.

X) Signature of Investigator	Date:

For ESCs pertaining to Food-Producing Animals (only):

In addition to the above statements, I attest to:

1. Use a federally inspected abattoir or federal fish processing facility for the slaughter of any animals which were used in this Experimental Study.
2. Notify the veterinarian-in-charge of this abattoir or fish processor in advance of the slaughter date.
3. Notify the Canadian Food Inspection Agency at least ten (10) days before an anticipated slaughter date of any animals which were used in this Experimental Study, providing the Agency the name and address of the abattoir or federal fish processing facility which will be used for this slaughter.

Y) Signature of Investigator	Date:

For ESCs pertaining to Race Horses (only):

I agree that I am responsible for ensuring that this drug is used in compliance with the Pari-Mutuel Betting Supervision Regulations administered by the Canadian Pari-Mutuel Agency (CPMA).

Z) Signature of Investigator	Date:

Instructions

Part 1– Nature of the Experimental Study

Section A)

Indicate whether the study requiring an ESC has been the subject of a previously issued ESC with an **identical** protocol, and indicate if that ESC was issued within the last 12 months or longer.

A study Amendment may be filed if **minor changes** are required to a protocol that was approved within the previous12 months. When filing an amendment ensure that the submitted ESC application form contains, at minimum, thecontact information of the applicant, the DSTS number and study name of the already approved ESC, any informationcontained within the form that would have changed from the initial application, all required signatures under Parts 6 &7 of the application form and all supporting documents related to the proposed changes. An amendment can include,for example, any minor changes to procedure, the number of animals required, or an unexpected change in theamount of drug required. The addition of a new site, new drug or any major protocol change would be considered anew study and requires a new ESC application. Provide a rationale explaining all proposed changes. If you have anyquestions about filing an amendment, contact VDD for further advice: vdd.skmd.so-dgps.dmv.cp@hc-sc.gc.ca.

Section B)

Indicate if the data from this study is intended to support a pivotal safety or efficacy trial for a veterinary drug regulatory submission in Canada (called a New Drug Submission (NDS), Abbreviated New Drug Submission (ANDS), or Supplemental New Drug Submission (SNDS)). If you are unsure if your study would be considered pivotal, contact VDD for further advice: vdd.skmd.so-dgps.dmv.cp@hc-sc.gc.ca .

ESC applications that indicate that the data is intended to support a veterinary drug submission ((S)NDS) will have a more detailed review of the study protocol. The review will include some evaluation of the suitability of the study design. This is not a formal protocol review, but is intended to highlight any major study flaws to avoid the conduct of a study that is unlikely to support its intended purpose.

Section C)

Indicate if the study contains any aspects related to wildlife immobilization/sedation.

Part 2 – Investigator & Billing Information

Section D)

Provide complete contact information regarding the Principal Investigator for the Experimental Studies Certificate. This should be the same person who signs in block X. (Regulation C.08.014(1)(g)).

A third party may be authorized to support the application, including in the communication and/or provision of confidential information on behalf of a manufacturer or supplier. In this case, attach a signed letter indicating the contact information for the person to be authorized to communicate on behalf of the manufacturer or supplier.

Section E)

The full ESC application fee will be invoiced once the submission has been accepted into review. If the ESC application is not accepted for review, 10% of the full fee will be invoiced.

Note that Canadian Federal, Provincial and Territorial Government Departments and publicly funded health care institutions are not charged a fee for an ESC.

Part 3 – Drug & Supplier Information

Drug Information - If the proposed study includes more than 2 drugs, attach an extra sheet with all of the information required in sections F)-O).

Section F)

The **brand name** is the name assigned by the manufacturer to distinguish the drug, and under which the drug is to be sold/advertised. The brand name is used to identify the product in all correspondence related to the submission and on the product labelling. If the brand name has not yet been determined, the proper or common name of the drug or the research code may be used. (Regulation C.08.014(1)(a)).

Section G)

The **proper name for an ingredient** is considered to be the name:

- assigned to that ingredient in section C.01.002 of the Regulations;
- that appears in boldface type in other sections of the Regulations;
- or assigned to the ingredient in the titles of monographs of Schedule B publications.

Where a proper name for an ingredient appears both in the Regulations and in one or more Schedule B publications, the name appearing in the Regulations takes precedence.

The **proper name for a drug product** includes the dosage form and is the name assigned to that final product in one of the Schedule B publications (e.g., Azithromycin Capsules).

If there is no proper name and the drug is comprised of more than one medicinal ingredient, leave G blank.

A **common name** is used in the case where there is no proper name. The common name of a drug substance is a name chosen by a respected body responsible for drug nomenclature, often with international recognition (e.g. International Non-proprietary Name [INN], United States Adopted Name [USAN], and British Approved Name [BAN]). The common name of a drug product consists of the common name of the drug substance and the dosage form.

Section H)

Identify the proposed dosage form (pharmaceutical form) of the drug product (e.g. tablet, solution for injection, cream).

Section I)

Indicate the proposed route(s) of administration (e.g. oral, intravenous, topical).

Section J)

Attach a diagram of the chemical structure of the drug (if known). (Regulation C.08.014(1)(h)).

Section K)

Indicate how the drug will be supplied (e.g. number of tablets in a package, volume of drug in a vial). The package or vial size is important to determine how much product will be required and will help specify quantities on the ESC letter.

Section L)

Provide the complete drug formulation if possible, including the CAS# (if known).

List the medicinal (active) ingredients using the proper or common name(s) and the strength of the active ingredient(s) and the standard (e.g. USP, BP, etc).

List the non-medicinal ingredients separately; these include preservatives and colouring agents, if applicable. (Regulation C.08.014(1)(h)).

If there is insufficient space on the ESC application form, attach a separate sheet with the additional information in the same format.

Section M)

Indicate all the drugs (over-the-counter and prescription) that will be used during the treatment period. Although approved drug products may not require an ESC, they are important to record and should be included in the study details.

Section N)

Indicate how all other drugs in the study will be obtained (if applicable).

Section O)

Provide a contact name and address for the supplier of the drug(s), which is/are the subject of the ESC application.

Part 4 – Proposed Experimental Study Information

Section P)

Provide the name of the facility or location where the study will take place. (Regulation C.08.014(1)(e)).

Section Q)

Provide the address of the facility or location where the study will take place. (Regulation C.08.014(1)(e)).

Note: There are some circumstances where a study may include multiple sites. These should be discussed with VDD before an application is made. Email: vdd.skmd.so-dgps.dmv.cp@hc-sc.gc.ca.

Section R)

Animal to be studied: Species, total number of study animals (experimental, control) and production type, if relevant. (Regulation C.08.014(1)(c)). Where more than one species is included, list all species.

Section S)

Provide the anticipated time-frame to conduct the Experimental Study. The maximum time an ESC is issued for is 12 months. If the study duration will be greater than 12 months, a renewal ESC application must be filed prior to the expiration of the initial ESC.

Section T)

State the total amount of the experimental drug required to complete up to 12 months of the proposed study or purpose (Regulation C.08.014(1)(l)), both in terms of the amount of active ingredient and the amount of drug product. If only one is known, be sure to input the information in the appropriate box.

Section U)

Indicate the fate of the study animals at the end of the study, and the disposition of study animals.

Section V)

Provide the **proposed** withdrawal period for any applicable uses of the animal(s) or products. The withdrawal period to be used will be determined by the Human Safety Division, Veterinary Drugs Directorate.

Part 5 – Required Attachments Checklist

Complete the checklist to confirm that the required attachments have been included in your application package. The following provides additional instructions for each attachment:

- ☐ **Cover letter** indicating at minimum: the study name, the drug and amount requested, the primary investigator and the location of the study. If this is an amendment, highlight the main study changes in the cover letter.
- ☐ **Name and Qualifications of Primary Investigator** (Regulation C.08.014.(1)(g)) and other co-Investigators, including relevant qualifications (e.g. Curriculum Vitae, academic degrees, professional experience, CAZWV or equivalent certificate for the immobilization of wildlife by non-veterinarians).
- ☐ **Facility Description** (Regulation C.08.014.(1)(f)): include a description of the study facilities or location where the study will occur, and a description of animal husbandry practices and any facility accreditations, such as Canadian Council on Animal Care (CCAC) or Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).
- ☐ **Proposed Experimental Study Information** (Regulation C.08.014.(1)(b)), including:
  - Study objective(s), and if there are more than one, indicate the primary and secondary objectives
  - Study Design
  - Outline of all pertinent experimental study parameters being assessed and study procedures (including immobilization and monitoring under sedation, if applicable)
  - Species, number and production type of animals. Animal description should include the sex, age and relative weight
  - Fate and disposition of animals included in the study
  - If a previous ESC was issued for the same protocol, highlight any changes from the last approval
- ☐ **Rationale and/or Calculation of Drug Quantity** (Regulation C.08.014.(1)(i)):
  - Proposed quantity of drug to be used for the experimental study
  - Calculation including the consideration for the number of animals and approximate weight of the animal(s), drug dosage to be used and number of doses required
  - Amount included as overage or wastage should be highlighted and explained
  - For in-feed or in-water medications, include any assumptions made in terms of feed or water intake
  - Manufacturing information should be provided for all in-feed medication
  - Provide drug shipping information including contact and address for Ship From and Ship To locations
  - If a previous ESC for a similar protocol was issued, include the amount of product obtained from the previous ESC, the amount of product remaining, and the expiry date on the remaining product. A drug log accounting for the drug used and notes regarding results should also be submitted
- ☐ **Summary of evidence that the product(s) and proposed study would not cause undue foreseeable risk to animals or humans:** This information may include toxicology, pharmacology, product or product class history of use, approved labelling, proof of efficacy, etc. If there are associated risks, outline the risk mitigation procedures incorporated in the above summary. (Regulation C.08.014.(1)(j))
- ☐ **Commercial/Approved Drug label (if available)**
  - Attach a copy of all labelling for the drug, including package insert (if available)
- ☐ **Experimental Drug label** (Regulation C.08.016), including:
  - The brand name of the drug or the identifying name or code proposed for the drug
  - A warning statement to the effect that the drug is for use only in an experimental study in animals
  - The lot number of the drug
  - The name and address of the manufacturer of the drug
  - The name of the person to whom the drug has been supplied

If an ESC was issued for the same protocol previously:

- **A summary of results from the previous study period** (if possible), including any safety information and adverse events involving humans or animals (Regulation C.08.017(b)(c))
- **A log of drug usage** (Regulation C.08.017(g)), including the amount of drug obtained, drug used, drug wasted, drug returned to the manufacturer or drug destroyed.

☐ **If the ESC is for food-producing animals: toxicity and residue data** for determination of withdrawal period

- Provide any available information pertaining to the toxicity and residue depletion of the drug for use by VDD's Human Safety Division in their evaluation. (Regulation C.08.014.(1)(j)).

Part 6 – Statement(s) of Owner/Manager (Food-Producing Animals Only)

Section W)

The owner of livestock and/or aquaculture animal(s) to be used in the study must complete and sign the attestation. (Regulation C.08.014.(1)(k)).

Part 7 – Statement(s) of Investigator

Section X)

The investigator must sign the attestation.

Section Y)

The investigator of food-producing animals must sign the attestation in section Y, as well as section X. The Veterinary Drugs Directorate will inform the appropriate provincial Milk Marketing board of the issuance of an ESC for dairy cattle by copy of the ESC letter.

Section Z)

The investigator of race horses must sign the attestation in section Z, as well as section W. The investigator is responsible for ensuring that the drug is used in compliance with the Pari-Mutuel Betting Supervision Regulations administered by the Canadian Pari-Mutuel Agency (CPMA). The Veterinary Drugs Directorate will advise the CPMA by copy of the ESC letter.