Central Administration for Pharmaceutical Products
General Administration of Veterinary Pharmaceuticals

Notice to Applicant

Procedures for Participating in The Pilot Phase of Submitting Bioequivalence Studies for Veterinary Pharmaceuticals Year 2026

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Procedures for participating in the pilot phase of submitting bioequivalence studies for veterinary pharmaceuticals:

1.Submitting request to Participate in the Pilot Phase:

a. The company submits a request specifying the following:

- The name of the product, its dosage form, and the concentration of the active ingredients, along with the date of approval to proceed with the registration process (for products under registration) or the registration number (for registered products).
- The type of study proposed (supported by references).
- The reference product (supported by references).

The company also submits the following attachments:

- Approval to proceed with the registration procedures (for products under registration)
- Registration certificate with all its attachments (for registered products)
- Sample withdrawal report for bioequivalence studies issued by the Central Administration of Inspection on Pharmaceutical institutions accompanied by a composition statement of the (pilot/production) batch, signed by the responsible inspector, specifying the animal housing location and the bioequivalence center.

b - The request and all its attachments are received and reviewed; the company will be notified of the technical requirements and completions that need to be fulfilled. Completed request is then presented to the relevant committee for evaluation and appropriate decision.

2. Submission of the Study Protocol:

a. The company shall submit the following:

- The study protocol, dated and signed by the officials of the center responsible for the study and representatives of the company that owns the product, including the mechanism for transporting samples from the animals' housing location to the bioequivalence center.
- A contract between the bioequivalence center and animal housing where the study is conducted (a research center affiliated with a public university or a public research institute), the contract must specify the veterinarian responsible for monitoring the study.
- Approval of the study protocol by the Research Ethics Committee.

b. The protocol will be received, reviewed, and the company will be notified of the technical requirements and completions needed. It will then be presented to the relevant committee for evaluation and appropriate decision

c- The center shall notify the Egyptian Drug Authority (General Administration of Veterinary Pharmaceuticals) of the study date with sufficient notice, not less than five working days and not more than two weeks.

3-Submitting the Study Results:

a. The center shall notify the Egyptian Drug Authority (General Administration of Veterinary Pharmaceuticals) of the date for conducting the analysis of the collected samples within a period of no less than five working days.

b. The company shall submit the following:

- The study results.
- An assessment of the animals' health status signed by the veterinarian responsible for monitoring the study.
- The analysis results on the original laboratory paper from which the analyses were conducted, signed and stamped by the laboratory responsible person.

c. The study shall be presented to the specialized committee for evaluation and approval.

General Rules:

*All applications for bioequivalence studies must be submitted via the following link:

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*Companies are required to submit their applications to the Central Administration of Pharmaceutical institutions Licensing within three months of the study submission date, to regularize their status and take the necessary actions in accordance with the approved regulatory requirements.

*In vivo studies are conducted in research centers affiliated with public universities or public research institutes.

*Laboratory analyses are conducted in laboratories affiliated with public research institutes and faculties of veterinary medicine at Egyptian universities.

The benefits granted to companies participating in this phase include:

- Granting an additional six months for the validity of the product's approval to proceed with the registration procedures

- Review of the final registration file for the product under the fast-track pathway.

Pre-Study Animals Health Evaluation

A comprehensive health screening is performed on all animals selected for a bioequivalence study 2 weeks before dosing; It generally includes the following checks in addition to any diagnostics that are particularly relevant to certain species if needed:

Physical Examination:

1. Eyes, Ears, and Nose
2. Coat, Skin, fur and Feathers
3. Mouth and Teeth.
4. Free Movement.
5. Urine and Faeces.
6. Legs, Feet & joint.
7. Weight and Body Condition.

Behavioural Examination:

1. Attitude& activity.
2. Appetite (Feeding)
3. Sleeping and resting.
4. Urination
5. Defecation

Clinical Examination:

1. Respiratory rate.
2. Pulse Rate.
3. Temperature.
4. Capillary refill time
5. Examination of mucous membrane.

Diagnostic Testing:

1.CBC
2.Liver function tests (ALT/AST)
3.Kidney function tests (BUN/ Creatinine)
4.Glucose (Random blood sugar)
5.Lipid profile (cholesterol/Triglycerides)
6.Serology (canine Parvo Ag/Feline Panleukopenia Ag)

Parasite screening:

-Internal parasite examination
-External parasite examination

Housing and Acclimation:

- Proper housing and acclimation of animals are very important for ensuring the validity of study results. Before the study begins, animals require a period to acclimate to new surroundings, which involves providing appropriate housing that minimizes stress, ensuring access to food and water, and gradually introducing changes to diet and gentle handling of animals, as well as controlling environment (maintain appropriate temperature, humidity, and light cycles for the specific species.).

- A minimum of 72 hours is a standard recommendation before experimental use to allow for physiological, psychological, and nutritional stabilization. A longer acclimation period of up to 12 days may be recommended for certain procedures, or animals that have undergone long-distance travel, to reduce stress and improve outcomes.

- The animals should not receive any medication prior to testing for a period of two weeks or more, depending upon the biological half-life of the ancillary drug.

Chickens & Turkeys:

Should be from SPF (Specific -Pathogen-Free) flocks to ensure accurate and reliable results.

*SPF flocks are raised in a controlled environment to be free from specific pathogens that could interfere with the study results.