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Département de Santé Publique et Environnement

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Laboratoire de Contrôle des Médicaments Vétérinaires (LACOMEV)

Trypanocide Drug Sampling Protocol for Quality Control Testing

1- Sampling period

April – May 2013

2- Sampling sites, sample number and identification

The total number of samples to be collected per country is **50 samples** (25 from legal sellers (wholesalers and retailers) and 25 samples from illegal markets):

- Two (02) wholesalers : Five (05) samples from each wholesaler;
- Three (03) retailers (Vet shops and/or pharmacies): Five (05) samples from each retailers;
- Five (05) illegal markets (livestock markets, open weekly markets, etc.): 3 to 5 samples per illegal market.

NB: At each sampling site, the commonly used trypanocide drug brands containing diminazene or isometamidium should be sampled.

2.1- Number of sachets or bottles per sample

⇒ **Granules or powder for injection**

DIMINAZENE DIACETURATE

- For the 2,36g sachet of granules/powder containing diminazene diacetate, a minimum of ten (**10**) **sachets** per sample are needed;
- For the 23,6g sachet of granules/powder containing diminazene diacetate, a minimum of five (**05**) **sachets** per sample are needed;

ISOMETAMIDIUM CHLORIDE

- For the 125 mg sachet of granules/powder containing isometamidium, a minimum of ten (**10**) **sachets** per sample are needed;
- For the 1g sachet of granules/powder containing isometamidium, a minimum of five (05) **sachets** per sample are needed.

⇒ **Liquid forms (ready to use solutions)**

- 05 (five) bottles

.2-2- Identification (see annex) and sample information required:

The following informations must be provided for each sample to allow sample recording in the laboratory and quality control testing:

- Brand name ;
- Active ingredient(s) and their respective stated amount;
- Batch number ;
- Manufacturing date ;
- Expiry date ;
- Country and place of sampling.

NB: -Please use the provided Excel Database “Drug quality batches info” to store the records.

-The number assigned should follow the following format: the first three letters of the country followed by the chronological numbers

SEN1, TAN1, TOG1, ETH1... etc...

The number is assigned to a sample: all sachets/bottles of the sample should have the same number written with a permanent marker.

3- Sample Handling and Packaging for Shipment

All the samples should be kept away from heat and humidity/moisture. Samples should be well packed in a shipping carton with tape. Each shipment should contain about 15 samples to limit loss or to meet import requirements. LACOMEV will request from the DVS of Senegal an import permit allowing the drug samples shipment to Senegal.

Shipping address

Dr Assiongbon TEK0-AGBO

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Annex: Trypanocide sample identification sheet for Quality control testing in LACOMEV, Dakar Senegal

- Brand name:
- Active ingredient(s) and their respective stated amount:
- Batch number :
- Manufacturing date:
- Expiry date :
- Country and place of sampling:
- Environment of the drug when sampling