Method Needs and Fitness for Purpose Statement – DRAFTv2

Date: January 17, 2005

Project: Determination of virginiamycin in animal feeding stuffs

Project Leader:

Project Team:

1.0 Needs:
Virginiamycin is used for an increased rate of gain in weight in swine and broiler chickens, for improved feed efficiency in broiler chickens, as an aid in the treatment and control of dysentery in swine, and as an aid in the prevention of Necrotic enteritis in broiler chickens caused by Clostridium perfringens susceptible to virginiamycin.

Methodology is required to verify the levels of virginiamycin in various feeds, supplements and premixes. Methodology is also required to determine contamination levels to verify clean out of manufacturing equipment for the prevention of cross contamination. Due to potential residues in tissues and animal products for use in food, withdrawal periods are required.

Presently a biological assay is available for the determination, however, a method is required which is more specific and has better reproducibility. It would be preferable if the methodology is based on another principle such as HPLC or GC with appropriate detection such as UV, fluorescence or mass spectroscopy.

1.1 Performance Needs (based on laboratory sample)
Accuracy: (See Recovery)
       Type A & Type B Medicated/Additive/Premix/Mineral Mix, 95 – 105%,
       Type C Medicated Feed, 90 – 110 %
       Contamination, > 80%
Applicability:
For use in meal or pellet feeds for broiler chickens and swine which include starter, grower and finisher feeds.
       Premixes: 22 - 500 g//kg
       Medicated/Additive Complete Feed for broiler chickens: 11 - 22 mg/kg
       Medicated/Additive Complete Feed for swine: 11 - 110 mg/kg
Detection Limits:
       Medicated/Additive/Premix/Mineral Mix: 3 mg/kg
       Contamination: 0.5 mg/kg
Determination Limits:
       Medicated/Additive/Premix/Mineral Mix: 5 mg/kg
       Contamination: 2 mg/kg
Precision Repeatability:
       Medicated/Additive/Premix/Mineral Mix: CV_r = or < 5 %
       Contamination: CV_r = or < 15 %.
Precision Reproducibility:
       Medicated/Additive/Premix/Mineral Mix: CV_R = or < 8 %
       Contamination: CV_R = or < 30 %.

Range:

2 mg/kg to 600 g/kg

Recovery:

Medicated/Additive/Premixes/Mineral Mixes: 95 – 105 %

Contamination: > 80%

Selectivity:

The method is to be free of interferences from matrix, other drugs, vitamins, minerals. Virginiamcyin is compatible with the following drug/drug combinations: semduramicin sodium, lasalocid sodium, maduramicin ammonium, monensin sodium, narasin, salinomycin sodium, and halofuginone hydrobromide (broiler chickens, swine).

Pellet binding agents other than Bentonite, Lignosol, Agri-Colloid or Pel-Aid may affect the analysis.

Linearity of standard curve:

r ≥ 0.999, and 95% confidence limit of the y intercept includes zero.

Special Considerations:

Performance of this method should be comparable to or exceed the plate assay method based on Method # AM/V012D-1, James A. Miller, SmithKline Beecham.

The method is to be rugged/robust and critical parameters are to be identified and controlled.

Method performance criteria are to be defined. Familiarization plan is to be suggested which will demonstrate that the laboratory analyst can capably perform the method prior to analyzing samples.

Quality control plan is to be suggested along with warning and out of control limits.

Traceability:

Standards and acceptable sources are to be identified. Standards are to provide activities and uncertainty.

Regulatory:

Canadian regulations allow an analytical tolerance of ± 20% for the label claim for medicated feeds.

1.2   Method Performance:

1.3   Fitness for Purpose Review

1.4   Fitness for Purpose Statement