

Method Needs and Fitness for Purpose Statement - Final

Date: January 30, 2008

Project: Determination of amprolium in animal feeding stuffs

Project Leader:

Project Team:

1.0 Needs:

Amprolium is used as an aid in the prevention of coccidiosis in turkeys, in replacement chickens intended as layers, and in broiler chickens, and in the prevention of coccidiosis caused by *Eimeria bovis* and *Eimeria zurnii* in calves.

Methodology is required to verify the levels of amprolium 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. Amprolium may be used in combination with one or more of the following drugs and antibiotics in poultry feeds: arsanilic acid, bambamycin, ethopabate, chlortetracycline hydrochloride, penicillin, 3-nitro-4-hydroxyphenylarsonic acid, bacitracin (zinc and BMD), streptomycin, virginiamycin and carbarsone.

1.1 Performance Needs (based on laboratory sample)

Accuracy: (See Recovery)

Drug premix (Type A), supplements and mineral mixes (Type B): 95 – 105 %

Medicated complete feeds (Type C): 90 – 110 %

Contamination analysis: > 80 %

Applicability:

Drug Premixes: 250 g/kg (also known as Amprol, Amprol HI-E, Amprovine 25 %)

Mineral premixes and supplements

Medicated complete feed for chickens and turkeys: 40 mg/kg (0.004 %) to 250 mg/kg (0.025 %)

Medicated complete feed for calves: 5 mg/kg (227 mg/100 lb) to 500 mg/kg (0.050 %)

Detection Limits:

Medicated products: 0.3 mg/kg

Contamination analysis: 0.03 mg/kg

Determination Limits:

Medicated products: 1.0 mg/kg

Contamination analysis: 0.1 mg/kg

Precision Repeatability:

Medicated products: $CV_r =$ or $< 5 \%$

Contamination analysis: $CV_r =$ or $< 10 \%$.

Precision Reproducibility

Medicated products: $CV_R =$ or $< 10 \%$

Contamination analysis: $CV_R =$ or $< 20 \%$.

Range: 0.1 mg/kg to 250,000 mg/kg (250 g/kg, 25 %)

Recovery:

≥ 5 mg/kg: 90 -110 %

< 5 mg/kg: > 80 %

Selectivity:

The method is to be free of interferences from matrix, other drugs, vitamins and minerals. Amprolium is compatible with the following drugs and antibiotics: arsanilic acid, bambarmycins, ethopabate, chlortetracycline hydrochloride, penicillin, 3-nitro-4-hydroxyphenylarsonic acid, bacitracin (zinc and BMD), streptomycin, virginiamycin and carbarsonne.

Linearity of standard curve:

$r \geq 0.999$, and 95 % confidence limit of the y intercept includes zero.

Special Considerations:

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:

Reference standards and acceptable sources are to be identified. Standards are to be provided with assigned purity and uncertainty value.

Method Performance:

Fitness for Purpose Review

Fitness for Purpose Statement