Method Needs and Fitness for Purpose Statement – Final

Date: February 21, 2008

Project: Determination of chlortetracycline hydrochloride in animal feeding stuffs

Project Leader:

Project Team:

1.0 Needs:

Chlortetracycline hydrochloride is used as an aid in stimulating growth rate and improving efficiency in chickens, turkeys, swine, calves, lambs and mink. It is also used as an aid in stimulating appetite, maintaining weight gains, feed efficiency, egg production, hatchability, and eggshell quality in the blood during periods of stress and/or bacterial infections or potential infections in broiler, replacement and laying chickens, turkeys, pigs, swine and beef cattle. It is used as an aid in the prevention, treatment and reduction of losses due to bacterial infections in turkeys, lambs, pigs, swine, cattle and calves.

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

1.1 Performance Needs (based on laboratory sample)

Accuracy: (See Recovery)

Type A & Type B Medicated/Additive/Premix/Mineral Mix, 95 – 10 5%,
Type C Medicated Feed, 90 – 110 %
Contamination, 80 – 120 %

Applicability:

For use in broiler, layer and replacement chicken, turkey, pig, swine, beef cattle, calves, calf milk replacers, lambs, and mink.

Premix: 44 – 220 g//kg
Medicated/Additive Complete Feed for broiler chickens: 5.5 - 220 mg/kg
Medicated/Additive Complete Feed for laying chickens: 5.5 - 110 mg/kg
Medicated/Additive Complete Feed for replacement chickens: 5.5 - 220 mg/kg
Medicated/Additive Complete Feed for turkeys: 5.5 - 220 mg/kg
Medicated/Additive Complete Feed for beef cattle and non-lactating dairy cattle: 36 mg/kg
Medicated/Additive Complete Feed for lambs: 11 - 22 mg/kg
Medicated/Additive Complete Feed for pigs/swine: 5.5 - 110 mg/kg
Medicated/Additive Complete Feed for mink: 27 mg/kg
Medicated/Additive Complete Feed for calves: 11 – 55 mg/kg
Medicated/Additive Complete Feed for beef and non-lactating dairy cattle: 11 mg/kg

Detection Limits:

Medicated/Additive/Premix/Mineral Mix: 0.6 mg/kg

Contamination: 0.06 mg/kg

Determination Limits:

Medicated/Additive/Premix/Mineral Mix: 2 mg/kg

Contamination: 0.2 mg/kg

Precision Repeatability:

Medicated/Additive/Premix/Mineral Mix: CV_r = or < 5 %

Note: at the 5 mg/kg level 7.5 % CV would be acceptable

Contamination: CV_r = or < 10 %.

Precision Reproducibility

Medicated/Additive/Premix/Mineral Mix: CV = or < 10 %

Contamination: CV_R = or < 15 %.

Range: 0.2 mg/kg to 220 g/kg

Recovery:

Medicated/Additive/Premixes/Mineral Mixes: 90 – 110 %

Contamination: > 80%

Selectivity:

The method is to be free of interferences from matrix, other drugs, vitamins, minerals. Chlortetracycline hydrochloride is compatible with the following drug/drug combinations: amprolium (broiler chickens, replacement chickens, turkeys), arsanilic acid (broiler chickens, replacement chickens, turkeys, swine), decoquinate (broiler chickens) hygromycin B (broiler chickens, replacement chickens, swine), 3-nitro-4-hydroxyphenylasonic acid (broiler chickens, replacement chickens, turkeys), penicillin (swine), piperazine (broiler chickens, replacement chickens, turkeys), robenidine hydrochloride (broiler chickens), sulphamethazine (cattle, swine), tiamulin (swine), zoalene (broiler chickens, replacement chickens, turkeys).

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

Special Considerations:

Performance of this method should be comparable to or exceed plate assay AOACI OMA 967.39 and turbidimetric assay 977.37.

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.

Method Performance:

Fitness for Purpose Review

Fitness for Purpose Statement