

Method Needs and Fitness for Purpose Statement – Final Draft

Date: August 3, 2007

Project: Determination of Pyrantel Tartrate in animal feeding stuffs

Project Leader:

Project Team:

1.0 Needs:

Pyrantel tartrate is used in swine feed and supplements for the following: for the removal and control of large round-worm (*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections in swine; aid in the prevention of migration and establishment of large roundworm (*A. suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections in swine; for the removal and control of large roundworm (*A. suum*) infections in swine.

Methodology is also required to determine contamination levels to verify clean out of manufacturing equipment for the prevention of cross contamination. Pyrantel Tartrate may be used in combination with one or more of the following drugs and antibiotics in swine feeds: carbadox, tylosin and lincomycin.

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: 10.6% (48 g/lb) known as Banminth® 48

Protein Supplements: 4.8 g/lb

Medicated complete feed for swine: 0.0106% (106.0 mg/kg) to 0.881% (8810 mg/kg)

Detection Limits:

Medicated products: 3.0 mg/kg

Contamination analysis: 0.3 mg/kg

Determination Limits:

Medicated products: 10.0 mg/kg

Contamination analysis: 1.0 mg/kg

Precision Repeatability:

Medicated products: $CV_r = \text{or} < 5\%$

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

Precision Reproducibility

Medicated products: $CV_R = \text{or} < 10\%$

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

Range: 1.0 mg/kg to 106,000 mg/kg (10.6 %)

Recovery:

$\geq 10 \text{ mg/kg}$: 90 -110 %
 $< 10 \text{ mg/kg}$: > 80 %

Selectivity:

The method is to be free of interferences from matrix, other drugs, vitamins and minerals. Pyrantel tartrate is compatible with the following products: carbadox, tylosin phosphate, lincomycin.

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.

A single method that combines the analysis of pyrantel tartrate with carbadox would be highly desirable since these two analytes are often used in combination.

Traceability:

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