

Method Needs and Fitness for Purpose Statement – DRAFT

Date: May 9, 2007

Project: Determination of Carbadox in animal feeding stuffs

Project Leader:

Project Team:

1.0 Needs:

Carbadox is used in the U.S. in swine feed and supplements for the following: control of swine dysentery (vibriotic dysentery, bloody scours or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); increased rate of weight gain and improved feed efficiency in swine. Methodology is also required to determine contamination levels to verify clean out of manufacturing equipment for the prevention of cross contamination. Carbadox may be used in combination with one or more of the following drugs and antibiotics in swine feeds: pyrantel tartrate and oxytetracycline. The use of Carbadox is banned in Canada. **How about the E.U.?**

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: 2.2% (10 g/lb) also known as Mecadox® 10

Protein Supplements: up to 5,500 mg/Kg (5,000 g/ton)

Medicated complete feed for swine: 11 to 55 mg/Kg (10 to 50 g/ton)

Detection Limits:

Medicated products: 1.7 mg/kg

Contamination analysis: 0.3 mg/kg

Determination Limits:

Medicated products: 5.0 mg/kg

Contamination analysis: 1.0 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: 1.0 mg/kg to 22,000 mg/kg (2.2 %)

Recovery:

≥ 10 mg/kg: 90 -110 %

< 10 mg/kg: > 80 %

Selectivity:

The method is to be free of interferences from matrix, other drugs, vitamins and minerals. Carbadox is compatible with the following products: pyrantel tartrate and oxytetracycline.

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 carbadox with pyrantel tartrate 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.