

Method Needs and Fitness for Purpose Statement - FINAL

Date: January 30, 2008

Project: Determination of Melengestrol Acetate in animal feeding stuffs

Project Leader:

Project Team:

1.0 Needs:

Melengestrol Acetate is used in beef cattle (heifers) feed and supplements for increased rate of weight gain, improved feed efficiency and suppression of estrus (heat) in heifers fed for slaughter, or for suppression of estrus (heat) in heifers intended for reproduction, and reduced incidence of liver abscessed fed in confinement. Methodology is also required to determine contamination levels to verify clean out of manufacturing equipment for the prevention of cross contamination. Melengestrol acetate may be used in combination with one or more of the following drugs and antibiotic in beef cattle feeds monensin, tylosin, lasalocid, oxytetracycline. (as of 2002 Feed additive compendium). While a method for measuring contamination levels is desirable, at this time priority will be given to a method that addresses the needs at medicating levels.

1.1 Performance Needs (based on laboratory sample)

Accuracy: (See Recovery)

Drug premix (Type A), supplements and mineral mixes (Type B): 92 – 105 %

Medicated complete feeds (Type C): 80 – 115 %

Contamination analysis: > 70 %

Applicability:

Drug Premixes: 220 mg/kg, 440 mg/kg, 1100 mg/kg.

Medicated complete feed for beef cattle (heifers): 0.275 mg/kg – 2.20 mg/kg (or 0.125 mg/lb - 1.0 mg/lb).

Detection Limits:

Medicated products: 0.03 mg/kg

Contamination analysis: 0.003 mg/kg

Determination Limits:

Medicated products: 0.10 mg/kg

Contamination analysis: 0.01 mg/kg

Precision Repeatability:

Medicated products: $CV_r =$ or $< 8 \%$

Contamination analysis: $CV_r =$ or $< 15 \%$.

Precision Reproducibility

Medicated products: $CV_R =$ or $< 15 \%$

Contamination analysis: $CV_R =$ or $< 25 \%$.

Range: Medicated products: 0.10 mg/kg to 1100 mg/kg (0.5 g/lb)

Contamination analysis: quantify down to 0.01 mg/kg

Recovery:

≥ 10 mg/kg: 90 -110 %

0.1 to < 10 mg/kg: 80 – 115%

< 0.1 mg/kg: > 70%

Selectivity:

The method is to be free of interferences from matrix, other drugs, vitamins and minerals. Melengestrol Acetate is compatible with the following products: monensin, tylosin, lasalocid, 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.

Traceability:

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