Method Needs and Fitness for Purpose Statement – DRAFT #

Please fill in the yellow highlighted sections

Date:

Project:

Project Leader and/or Team:

1.0 Needs:

List the application or consequence of the compound in animal feed.
What is it used for and why? What will it do to animals that consume the feed?
List any methodology requirements here, eg. cross contaminants and/or compatibilities, isomers present and biopotency factors.
Will the method be used for contaminant level analysis?

1.1 Performance Needs (based on laboratory sample)

Applicability:

List the types of feed (premixes and medicated) in which the product is found along with the applicable concentration ranges, e.g.:
Premixes: 30 g/lb (66 g/kg) and 50 g/lb (110 g/kg)
Medicated complete feed for chickens: 4-50 g/ton (4.4-55 mg/kg)
Medicated complete feed for feedlot beef cattle: 70 or 250 mg/head/day

Range:

List the analytical range over which the method should apply.

Accuracy (Recovery):

The recommended recoveries will vary depending on the quantitation level. The AOAC's Single Lab Validation document recommends general recovery limits of 75 – 120% at levels below 1 mg/kg, 80 – 115% at levels of 10 mg/kg, 85 – 110% at 100 mg/kg, 90 – 108% at 1000 mg/kg, and 92% – 105% at 1% (see Figure 1). It notes, however, that "These limits may be modified as needed in view of the variability of individual results or which set of regulatory requirements are referenced.

Concentration	Recovery limits
100 %	98-101%
10 %	95-102%
1 %	92-105%
1000 µg/g (ppm)	90-108%
100 µg/g (ppm)	85-110%
10 µg/g (ppm)	80-115%
1 µg/g	75-120%
10 µg/kg (ppb)	70-125%

List (if relevant) the recovery values for each of the following feed types or relevant cateories:

Drug premix (Type A):
Medicated feeds (Type B):
Medicated feeds (Type C):
Contaminated Feeds:

Precision Repeatability and Reproducibility:

The coefficient of variation will depend upon the target quantitation level. The repeatability and reproducibility coefficient of variation will vary depending on the concentration of the analyte in feed matrix. The following table can be used as a guide.

Concentration	CV_r (HCV)	CV_R (2*HCV)
10%	<3	<6
5%	<3	<6
1 %	<4	<8
5000 mg/kg	<5	<10
1000 mg/kg	< 6	<12
500 mg/kg	<7	<14
100 mg/kg	<8	<16
50 mg/kg	<9	<18
10 mg/kg	<12	<24
5 mg/kg	<13	<26
1 mg/kg	<16	<32
0.5 mg/kg	<18	<36
0.1 mg/kg	<22	<44
0.05 mg/kg	<25	<50
0.01 mg/kg	<32	<64

Quantitation / Determination Limits:

This is typically 10% - 20% of the lowest applicable amount found in feed. If the method is to be used for residue analyses, the limit can be 1% - 5% of the lowest applicable amount found in feed. Note that the above levels are guidelines and that other relevant regulations or limits should be considered.

Detection Limits:

This is typically 1/3 to 1/5 the value of the above determination limits.

Selectivity:

A statement outlining how selective the method needs to be, e.g. “The method is to be

free of interferences from matrix, other drugs, vitamins, minerals."

Linearity of standard curve:

A statement outlining the linearity requirements of the method, e.g. "$r \geq 0.999$, and 95 % confidence limit of the y-intercept includes zero."

Special Considerations:

List any other aspects that need to be considered for the method, e.g.

- Does the method need to be comparable to an existing methodology?
- Are there any preferred/avoidable methodologies that exist?
- Are any critical control parameters known?

A statement should be included indicating that the method must be rugged/robust and that critical parameters and method performance criteria must be identified.

In addition, a statement should be included indicating that a familiarization and quality control plan must be present in any method.

Traceability:

A statement outlining the traceability requirements of the method, e.g. "Standards and acceptable sources are to be identified. Standards are to be provided with assigned purity or potency and uncertainty value (if possible)."