

Method Needs and Fitness for Purpose Statement – Final

Date: July 31, 2011

Project: Determination of vitamin E in animal feeding stuffs containing supplemental vitamin E.

Project Leader:

Project Team:

1.0 Needs:

Vitamin E is a fat-soluble vitamin and an essential nutrient required for fertility and reproduction. Vitamin E supplement is added to animal feeds for both farmed animals and companion animals.

The term vitamin E applies to all tocol and tocotrienol derivatives qualitatively exhibiting biological activity of α -tocopherol. Tocopherols are methyl tocols, and not synonymous with “vitamin E”. 5,7,8-trimethyltolcol, or α -tocopheryl, is a trivial term and should not be used without stereospecific designation. The compound which is isolated from natural sources is 2*R*,4'*R*,8'*R*- α -tocopherol and should be designated ***RRR*- α -tocopherol**. Totally synthetic α -tocopherol obtained from totally synthetic phytol or isophytol as starting material is a mixture of 8 diastereoisomers as 4 racemates or pairs of enantiomers in unspecified proportions and should be designated ***all-rac*- α -tocopherol**. A mixture of ***RRR*- α -tocopherol** and 2-*epi*- α -tocopherol is obtained by synthesis using natural phytol and should be designated 2-*ambo*- α -tocopherol.

The method should produce results comparable to the current AOACI OMA (971.30) and be able to separate α -tocopherol and its esters from other tocopherols (beta, gamma, and delta). The developed methodology should cover a large range of vitamin E levels and should be applicable to feeds for a wide variety of animal species, including farm and companion animals. Other desirable characteristics of the method include improved throughput and ease-of-use and the ability to separate various sources of vitamin E activity listed in the title. A method determining multiple fat soluble vitamins would be preferred.

Vitamin E (mg) is calculated on the basis of the following:

1 mg *RRR*-alpha tocopherol = 1.36 IU vitamin E
1 mg *all rac*-alpha-tocopherol = 1.00 IU vitamin E

1.1 Performance Needs:

Accuracy: (See Recovery)

Feed premixes: 90 – 110 %

Feeds and feed ingredients: 70 – 130 %

Applicability:

- Complete feeds: 10 to 100 IU/lb (22 to 220 IU/kg)

- Premixes: 10,000 to 100,000 IU/lb (22,000 to 220,000 IU/kg)
- Base Mixes: 50 to 10,000 IU/lb (110 to 22,000 IU/kg)
- Concentrates: 20 to 5,000 IU/lb (44 to 11,000 IU/kg)
- Dairy/beef supplements: 20 to 100,000 IU/lb (44 to 220,000 IU/kg)
- As straight vitamin E supplements: up to 250,000 IU/lb (550,000 IU/kg)

Detection Limits:

Feeds, feed premixes, and feed ingredients: 0.30 IU/lb (0.66 IU/kg)

Determination Limits:

Feeds, feed premixes, and feed ingredients: 1.0 IU/lb (2.2 IU/kg)

Precision Repeatability:

> 1,000 IU/lb (> 2,200 IU/kg): $CV_r =$ or < 5 %
 ≤ 1,000 IU/lb (≤ 2,200 IU/kg): $CV_r =$ or < 8 %.

Precision Reproducibility:

> 1,000 IU/lb (> 2,200 IU/kg): $CV_R =$ or < 10 %
 ≤ 1,000 IU/lb (≤ 2,200 IU/kg): $CV_R =$ or < 15 %.

Range:

10 to 500,000 IU/lb (22 to 1,100,000 IU/kg)

Recovery:

Feed premixes and supplements: 92 – 105 %
 Feeds and feed ingredients: 80 – 115 %

Selectivity:

The method is to be free of interferences from the matrix, other drugs, vitamins, and minerals.

Linearity of standard curve:

$r \geq 0.999$ and 95% confidence limits of the y-intercept must include zero.

Special Considerations:

The method is to be rugged/robust and critical parameters are to be identified and controlled.

Vitamin E is not encapsulated but adsorbed on silica so the analyte should be able to free itself from the silica carrier.

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:

Acceptable analytical standard material is available from U.S. Pharmacopeia (USP).

Method Performance:

Fitness for Purpose Review

Fitness for Purpose Statement