Stability Test of Niacin

1 Stability summary and conclusion

Stability test on active substance

We carried out the long term, accelerated stability tests and intermediate condition stability test on two typical industrial batches.

A specification sheet has been established for stability test. Some of items are omitted as compared with our specification for practical reasons.

A. Specification page

Specification page for long-term, accelerated and intermediate condition stability studies are same, as shown in the following table:

Specification sheet for Re-test of Niacin

Determination	Specifications
Appearance	White Granule
Moisture	≤0.5%
Assay	≥99%

The long term stability test results indicate that Niacin exhibits excellent stability within the first 24 months under the described storage (Temperature: 30℃±2℃; Relative humidity: 65%±5%). This long-term stability test is being continued.

The accelerated and intermediate condition stability test results indicate that Niacin remains unchanged under the accelerated and intermediate condition stability test conditions, respectively.

B. Long term stability test protocol

Long-term stability information the test conditions are as follows:

Storage condition of sample:

Temperature: 30℃(±2℃)

Relative humidity: 65% (±5%) RH

Selection of batches:

No. of batches selected: 2009070201 2009070302

Container and closure system: with simulate to commercial packing

Testing frequency: Every three month over the first year, six month over the second year and then annually

Testing methods: GB/T 7300-2006

Re-test specification: Specification sheet for re-test of Niacin

C. Accelerated stability test protocol

Accelerated information the test condition is as follows:

Storage condition of sample:

Temperature: 40℃ (±2℃)

Relative humidity: 75% (±5%)

Selection of batches:

No. of batches selected: 2009070201 2009070302

Container and closure system: with simulate to commercial packing

Testing frequency: Every month over six months.

Testing method: GB/T 7300-2006

Re-test specification: Specification sheet for re-test of Niacin

Retest period

In the light of all the results we have obtained from the stability test, Niacin is extremely stable in those stability tests. Meanwhile, we propose a re-test period of 24 months at present for the product stored in a well-closed contain and place in a cool and dry place.

2 Stability data

Long Term Stability Testing Report

CANAVIT
Canadian Feed Additives Inc.
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Sample Name: Niacin Batch No.: 2010051101

Storage Condition: 30±2℃, 65%±5%RH

Analysis date	Storage (Month)	Description (White Granule)	Moisture (≤0.5%)	Assay (≥99%)
May. 12, 2010	0	White Granule	0.31%	99.48%
Aug. 12, 2010	3	White Granule	0.31%	99.45%
Nov. 12, 2010	6	White Granule	0.30%	99.46%
Feb 12, 2011	9	White Granule	0.29%	99.39%
May. 12, 2011	12	White Granule	0.30%	99.37%
Nov 12, 2011	18	White Granule	0.28%	99.22%
May 12, 2012	24	White Granule	0.28%	99.15%

Batch No.: 2010051402

Analysis date	Storage (Month)	Description (White Granule)	Moisture (≤0.5%)	Assay (≥99%)
May 14, 2010	0	White Granule	0.27%	99.56%
Oct. 14, 2010	3	White Granule	0.26%	99.54%
Nov. 14, 2010	6	White Granule	0.23%	99.46%
Feb 14, 2011	9	White Granule	0.23%	99.47%
May. 14, 2011	12	White Granule	0.23%	99.38%
Nov 14, 2012	18	White Granule	0.24%	99.31%
May 03, 2011	24	White Granule	0.24%	99.25%

Accelerated Stability Testing Report

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CANAVIT
Canadian Feed Additives Inc.
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Sample Name: Niacin

Batch No.: 2011041101

Storage Condition: 40±2℃, 75%±5%RH

Analysis date	Storage (Month)	Description (White Granule)	Moisture (≤0.5%)	Assay (≥99%)
Apr. 11, 2011	0	White Granule	0.36%	99.27%
May. 11, 2011	1	White Granule	0.35%	99.26%
June 11, 2011	2	White Granule	0.36%	99.26%
July. 11, 2011	3	White Granule	0.33%	99.21%
Aug 11, 2011	4	White Granule	0.32%	99.16%
Sep 11, 2011	5	White Granule	0.33%	99.13%
Oct 11,2011	6	White Granule	0.33%	99.08%

Batch No.: 2011041302

Analysis date	Storage (Month)	Description (White Granule)	Moisture (≤0.5%)	Assay (≥99%)
Apr. 13, 2011	0	White Granule	0.28%	99.53%
May. 13, 2011	1	White Granule	0.29%	99.46%
June 13 2011	2	White Granule	0.29%	99.38%
July. 13, 2011	3	White Granule	0.30%	99.37%
Aug 13, 2011	4	White Granule	0.29%	99.27%
Sep 13, 2011	5	White Granule	0.31%	99.26%
Oct 13, 2011	6	White Granule	0.31%	99.14%

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