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Shaanxi Guanjie Technology Co., Ltd. (factory)

Stability Studies of Indole-3-Carbinol

Shaanxi Guanjie Technology Co., Ltd.

1. Stability Test Methods

Introduction:

The purpose of stability testing is to provide evidence on how the quality of Indole-3-Carbinol varies with time under the influences of temperature and humidity and to establish recommended storage conditions, retest periods and shelf life.

Responsibility:

QA/QC Director is responsible for the stability study program and is also responsible for the stability samples analyzed as well as the maintenance of the program records.

Procedure and Design of Stability Studies:

Long Term Studies:

The samples of Indole-3-Carbinol are closed tightly in polyethylene bags, sealed in PE bags and packaged in aluminum containers. They are stored under long-term conditions of 25 \pm 2 $^{\circ}$ C temperature and 60 \pm 5% humidity conditions according to ICH/FDA guidelines. The three consecutive process validation batches and one batch every year are sampled and placed on long term stability testing. After the initial analysis, these samples will be analyzed at intervals of 3, 6, 9, 12 and 15 months. The results to date demonstrate that Indole-3-Carbinol is stable at 25 \pm 2 $^{\circ}$ C temperature and 60 \pm 5% humidity conditions.

Accelerated Studies:

The samples of Indole-3-Carbinol are placed in polyethylene bags, sealed in PE bags, packaged in aluminum containers and stored at 40 \pm 2 $^{\circ}$ C and 75 \pm 5% humidity conditions. The three consecutive batches are taken for testing. After the initial analysis, these samples are analyzed at 1, 2, 3 and 6 months according to ICH Guidelines. The results to date demonstrate that Indole-3-Carbinol is stable at 40 \pm 2 $^{\circ}$ C temperature and 75 \pm 5% humidity conditions.

2. Stability Test Results

The following pages summarize the Accelerated and Long Term Stability Testing results available to date for three batches of Indole-3-Carbinol. As more data becomes available, we commit to forward this data so that it may be included as annual updates to the Indole-3-Carbinol Product Drug Master File.



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Shaanxi Guanjie Technology Co., Ltd.
Indole-3-Carbinol Accelerated Stability Study

Batch No: IC140910 Temperature: 40±2℃ Humidity: 75±5% Mfg. Date: 09/10/2014
Container: Duplicates commercial container (PE & PE coated Al bags in Aluminum canister)

Test Frequency	Appearance	Identity by UV	Loss on Drying	Assay (by HPLC)
Specs	To Pass	complies	≤1.0%	≥99.0%
Initial		complies	0.60	99.97
1M		complies	0.58	99.97
2M		complies	0.55	99.95
3M		complies	0.53	99.92
6M		complies	0.50	99.90



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Shaanxi Guanjie Technology Co., Ltd.
Indole-3-Carbinol Accelerated Stability Study

Batch No: IC140926 Temperature: 40±2°C Humidity: 75±5% Mfg. Date: 09/26/2014
Container: Duplicates commercial container (PE & PE coated Al bags in Aluminum canister)

Test Frequency	Appearance	Identity by UV	Loss on Drying	Assay (by HPLC)
Specs	To Pass	complies	≤1.0%	≥99.0%
Initial		complies	0.55	99.63
1M		complies	0.50	99.63
2M		complies	0.48	99.62
3M		complies	0.47	99.58
6M		complies	0.42	99.47



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Shaanxi Guanjie Technology Co., Ltd.
Indole-3-Carbinol Accelerated Stability Study

Batch No: IC140930 Temperature: 40±2°C Humidity: 75±5% Mfg. Date: 09/30/2014

Container: Duplicates commercial container (PE & PE coated Al bags in Aluminum canister)

Test Frequency	Appearance	Identity by UV	Loss on Drying	Assay (by HPLC)
Specs	To Pass	complies	≤1.0%	≥99.0%
Initial		complies	0.45	99.91
1M		complies	0.42	99.91
2M		complies	0.40	99.91
3M		complies	0.38	99.89
6M		complies	0.35	99.85

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Shaanxi Guanjie Technology Co., Ltd. (factory)

Shaanxi Guanjie Technology Co., Ltd.
Indole-3-Carbinol Long Term Stability Study

Batch No: IC140910 Temperature: 25±2℃ Humidity: 60±5% Mfg. Date: 09/10/2014
Container: Duplicates commercial container (PE & PE coated Al bags in Aluminum canister)

Test Frequency	Appearance	Identity by UV	Loss on Drying	Assay (by HPLC)
Specs	To Pass	Complies	≤1.0%	≥99.0%
Initial		Complies	0.60	99.97
3M		Complies	0.58	99.97
6M		Complies	0.55	99.95
9M		Complies	0.52	99.90
12M		Complies	0.50	99.40
15M		Complies	0.55	99.37



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Indole-3-Carbinol Long Term Stability Study

Batch No: IC140926 Temperature: 25±2°C Humidity: 60±5% Mfg. Date: 09/26/2014
Container: Duplicates commercial container (PE & PE coated Al bags in Aluminum canister)

Test Frequency	Appearance	Identity by UV	Loss on Drying	Assay (by HPLC)
Specs	To Pass	Complies	≤1.0%	≥99.0%
Initial		Complies	0.55	99.63
3M		Complies	0.50	99.60
6M		Complies	0.48	99.58
9M		Complies	0.45	99.55
12M		Complies	0.48	99.50
15M		Complies	0.43	99.45



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Shaanxi Guanjie Technology Co., Ltd.
Indole-3-Carbinol Long Term Stability Study

Batch No: IC140930 Temperature: 25±2℃ Humidity: 60±5% Mfg. Date: 30/09/2014
Container: Duplicates commercial container (PE & PE coated Al bags in Aluminum canister)

Test Frequency	Appearance	Identity by UV	Loss on Drying	Assay (by HPLC)
Specs	To Pass	Complies	≤1.0%	≥99.0%
Initial		Complies	0.45	99.91
3M		Complies	0.42	99.90
6M		Complies	0.45	99.87
9M		Complies	0.40	99.82
12M		Complies	0.36	99.76
15M		Complies	0.33	99.72



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3. Degradation Study

The purpose of the degradation study is to determine if the HPLC method used by our facility for product release and stability studies will detect impurities and as a result is stability indicating. Three lots on stability, IC140910, IC140926, IC140930 were chosen and samples from these lots were subjected to:

- a. Sodium Hydroxide, 0.00001 N
- b. Hydrochloric Acid, 0.04 N
- c. Hydrogen Peroxide, 10%
- d. Heat at 60°C
- e. Ultraviolet light

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