

# Stability Study for Vitamin E 50% Powder

## 1. Stability summary and conclusions

In accordance with ICH Guidance for Industry: ICH Q1A (R2) Stability Testing of New Drug Substances and Products, and Q1E Evaluation of Stability Data, the stability studies performed in support of this application include lots of Vitamin E 50% Powder.

### 1.1 Recommended shelf-life

Based on the data obtained from the long-term stability study for Climate Zone IVB, the product is stable for at least 3 years. Therefore, we recommend an expiry period of 3 years (36 months).

### 1.2 Advice on storage

Preserve in a well ventilated dry place, protected from light.

## 2. Post-approval stability protocol and stability commitment

### 2.1 Long-term stability study

Samples used for stability study are taken from commercial batches. Samples are taken from the first three batches over the first year, and from at least one batch over the year thereafter.

If any major changes are made in the manufacturing process and/or the equipment, the first three batches after the change should be put into stability study.

<b>Test frequency</b>	0, 3, 6, 9, 12, 18, 24 and 36 months.
<b>Packaging</b>	The same as the actual packaging used for storage and distribution, i.e. polyethylene bags / fiber carton system.
<b>Storage conditions</b>	Temperature $30 \pm 2$ °C; relative humidity $75\% \pm 5\%$ .
<b>Test performed</b>	As listed below.

Test	Specification	Method
Appearance	Almost white to yellowish powder or granular powder	Visual observation
Identification	Meet the requirements	National standard
Loss on drying	NMT 5.0%	National standard
Assay	NLT 50.0%	National standard

**Tabulated Long-Term Stability Study Data for Vitamin E 50% Powder -1**

Batch No. TP150701

Date of Initial test: Jul 8, 2015

30±2 °C, 75±5%RH

Test	Specification, GB/T 7293-2006	Test frequency, month							
		0	3	6	9	12	18	24	36
Appearance	Almost white to yellowish powder or granular powder	Almost white granular powder							
Identification	Meet the requirements	Comply	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Loss on drying	NMT 5.0%	2.26%	2.49%	1.94%	1.76%	1.52%	1.85%	1.76%	1.95%
Assay	NLT 50.0%	50.3%	50.0%	50.1%	50.1%	50.6%	50.1%	50.1%	50.3%

**Tabulated Long-Term Stability Study Data for Vitamin E 50% Powder -2**

Batch No. TP150702

Date of Initial test: Jul 8, 2015

30±2 °C, 75±5%RH

Test	Specification, GB/T 7293-2006	Test frequency, month							
		0	3	6	9	12	18	24	36
Appearance	Almost white to yellowish powder or granular powder	Almost white granular powder							
Identification	Meet the requirements	Comply	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Loss on drying	NMT 5.0%	1.92%	2.25%	2.09%	1.84%	1.76%	2.08%	1.92%	1.97%
Assay	NLT 50.0%	50.5%	50.0%	50.0%	50.0%	50.4%	50.1%	50.2%	50.2%

**Tabulated Long-Term Stability Study Data for Vitamin E 50% Powder -3**

Batch No. TP150703

Date of Initial test: Jul 8, 2015

30±2 °C, 75±5%RH

Test	Specification, GB/T 7293-2006	Test frequency, month							
		0	3	6	9	12	18	24	36
Appearance	Almost white to yellowish powder or granular powder	Almost white granular powder							
Identification	Meet the requirements	Comply	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Loss on drying	NMT 5.0%	1.94%	2.35%	1.86%	1.62%	1.42%	1.79%	1.69%	1.96%
Assay	NLT 50.0%	50.6%	50.2%	50.8%	50.4%	50.5%	50.3%	50.1%	50.2%

