

BioCeuticals Research & Development Laboratory

3039 Grand Avenue, Suite B

Billings, MT 59102

Start Date: June 10th, 2000
Completion Date: June 10th, 2001
Study: Kre-Alkalyn^R in water study

Purpose of Study: To measure the stability of Kre-Alkalyn[®] in water

Procedures: 1.5 grams of Kre-Alkalyn[®] was mixed in water. Real Time and Accelerated testing was performed

Same lot was used for both test

Step 1:

- a. Kre-Alkalyn[®] powder was assayed for purity
- b. 1.5 grams of Kre-Alkalyn powder was added to 4 oz of water and stored in lab for real time testing
- c. 1.5 grams of Kre-Alkalyn powder was added to 4 oz of water and put into incubator for accelerated testing

Testing Method:

FTNIR Analysis by:

Identification performed by FTNIR, against in-house external library standards obtained from Sigma & produced by HPLC. / Quantification by FTNIR against external library standards obtained from Sigma & produced by HPLC

Testing Equipment:

Bran & Luebbe InfraProver II FTNIR

HPLC Analysis by:

Analysis performed by HPLC using Intersil ODS-2 5.μm (250x4.6mm) and 25 min. gradient elution with 0.1% phosphoric acid buffer in H₂O and 0.1% phosphoric acid in acetonitrile. External reference standards obtained from Sigma-Aldrich.

Step 2:

Both groups of products were tested at 30 day segments.

Results:

Product	Time	Kre-Alkalyn converted to creatinine
Accelerated Test	30 days equal to one years	0 %
	60 days equal to two years	0 %
	90 days equal to three years	0 %
	120 days equal to four years	0.0%
	150 days equal to five years	.05 %
	180 days equal to six years	.10 %
	Real Time Test	30 days
60 days		0 %
90 days		0 %
120 days		0.0%
150 days		0 %
180 days		0 %
210 days		0 %
240 days		0 %
270 days		0 %
300 days		0.0%
330 days		0 %
360 days		0 %

Conclusions: Kre-Alkalyn® was completely stable in real time testing up to one year.

Kre-Alkalyn® was completely stable in accelerated testing for up to six years. A small conversion took place after five years but at a rate of only .05%.

Kre-Alkalyn® is completely stable if left in water for a period of 6 years.