**Improved Creatine Stability and pH Profile for Kre-Alkalyn**

Jeff Golini, PhD.
All American Pharmaceutical, Billings Montana
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**Background**

Creatine (N-(aminoiminomethyl)-N-methyl glycine) is an important energy producing amino acid base metabolite produced in the liver, kidneys, and pancreas. It is found in large concentrations around skeletal muscles and is absolutely essential for the health and function of every muscle cell in the body. Creatine is pivotally important in delaying ATP depletion during anoxia or ischemia through the creatine-phosphocreatine system.

Creatine in various forms is used as a supplement to increase athletic performance. Yet its stored shelf life and half-life in the stomach play a role in its bioavailability after ingestion. Previous reports suggest that the degradation of creatine results from pH changes. At normal physiological pH, 10% of creatine has been suggested to convert to creatinine, it's most common byproduct.

Various modifications to creatine intended to increase its bioavailability and stability have been attempted.

**Study Objective**

The objective of this study was to assess the stability of a unique sodium bicarbonate buffered creatine sold under the brand name Kre-Alkalyn® under various conditions.

**Materials and Method**

**Real Time and Accelerated Stability Testing**

Kre-Alkalyn® powder was assayed for purity and stability. Two samples of the same lot of Kre-Alkalyn powder were used. A total of 1.5 grams of powder was added to 4 oz of water and stored in the lab for real time testing. A total of 1.5 grams of Kre-Alkalyn powder was added to 4 oz of water and put into an incubator for accelerated testing. Both groups of products were tested at thirty-day intervals.

**HPLC Analysis**

Analysis performed by HPLC using Intersil ODS-2 5 µm (250 × 4.6 mm) 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.

**FTNIR**

Identification was performed by FTNIR, against in-house external library standards which were obtained from Sigma and produced by HPLC. Quantification was accomplished by FTNIR against external library standards obtained from Sigma and produced by HPLC (Bran and Luebbe InfraProver II FTNIR).

**Stomacher**

Previously described by Golini, it consists of a glass vessel and liquid acid to mimic the acidic environment of the stomach. Creatine or Kre-Alkalyn was first added to water then added to the acid and pH was assessed over time.

**pH Analysis**

Creatine and Kre-alkalyn solutions were tested for changes in pH using a standard calibrated pH meter (ATLAS Bioscience; Tuscon, AZ). Three solutions were added to Kre-Alkalyn: hydrochloric acid (0.1 ml-1M), sodium hydrogen carbonate/sodium carbonate (11.7/13.7 (ml-1M)), and ethanolamine/ethanolamine hydrochloride (18.6/6.3 (ml-1M)).

**Results**

Kre-Alkalyn is shown to have a good 6 year stability and shelf life under accelerated testing. It maintains a high pH over time compared to normal creatine and can be augmented with additional stabilizing buffers. This stability and buffering profile may serve useful in providing continued creatine availability.