

USP <232> <233> Analysis

Case Study

Background

A pharmaceutical company was in need of class 1 and 2A elements testing on their API per USP methods <232> and <233>. In order to break organometallic bonds, samples are typically digested in a strong acid such as HCl or HNO₃ at approximately 100 °C prior to analysis. The sample was unique in that the API was classified by USP as a rare “direct aqueous solution”, a water soluble compound containing no metals; therefore, digestion was not required. However, as Avomeen’s elemental analysis team analyzed the sample, they observed unexpected repeated instability issues with mercury (Hg).



Approach

During their investigation of observed instability issues, our scientists discovered that Hg analysis in the absence of stabilizers can become troublesome due to Hg²⁺ depositing on active sites of high density polyurethane (HDPE) and reducing to Hg. The increased volatility of Hg in its elemental form can cause it to adhere to the container, dissipate through the walls, or release into the surrounding atmosphere if the cap is not properly tightened.

Solution

Our team overcame this problem by adding trace quantities of Au in a dilute solution of HCl.

Although the exact mechanism of this approach is not thoroughly understood, it has been found to stabilize Hg²⁺, thus preventing the loss of Hg throughout the course of the analysis.

The methods were verified for recovery, precision, specificity, and system suitability. All analyzed elements, including Hg, passed respective acceptance criteria.



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