



LEACHABLE AND EXTRACTABLE TESTING, CONTACT STUDIES

GEO Analytical engages in a wide range of projects involving the evaluation of packaging components of drug products and materials. Some of these studies have included developing extractable and leachable testing protocols on various products to evaluate potential organic contaminants from adhesive or ink migration related to labeling. Other studies have involved the evaluation of products for inorganic contaminants such as trace metals that may have resulted from contact of the material with the glass container or components of the stoppers used. We have also developed contact studies to evaluate the interaction of drug product with the stainless steel used in the manufacturing process along with tubing and other components used in the fill process. We utilize a broad spectrum of analytical capabilities in conjunction with these studies. Some examples of these projects include:

- Study to determine if any residual components of adhesive or ink formulation from labeling migrate through plastic vials and concentrate in a drug product. Step 1 is to induce potential volatile or semi-volatile leachables by extracting labels in a number of solvent types and qualitatively identifying any peaks not produced in the control sample by mass spectrometry. Step 2 is to analyze vials of labeled drug product under accelerated conditions and analyze for any compounds found in the extractable study and quantify those results.



- Examination of leachables from PVC and Non-PVC IV bags. Samples of ethanol extracts were submitted for analysis and comparison to qualify type and quantity of PVC related contaminants potentially produced during the study. The samples were analyzed by GC-MS.
- A contact study was conducted in conjunction with an ANDA submission. The client provided a stainless steel coupon along with various tubing components that would be used in the manufacture and filling of the product. These materials were immersed in drug product for a specified time and analyzed by HPLC to determine whether impurities were present.
- Leachable tubing study to determine whether Teflon or Silicon was present in stability samples. The residual monomer most expected from Teflon or Polytetrafluoroethylene (PTFE) is Tetrafluoroethylene. The extract and control samples submitted were analyzed by GC-MS and chromatographic profiles were compared to the reference standard. The silicon analysis was determined by ICP-AES.

