



# Biological Evaluation of Medical Devices

## ISO 10993 - 18 Chemical Characterization of Materials

*AppTec provides qualitative and quantitative analysis of materials and toxicological assessment according to ISO 10993 Part 18 guidelines.*

### VENDOR/SUPPLIER RESEARCH

Determine type of polymer or material to be tested.  
Review MSDS for compound specific information.

### ANALYTIC SCAN FOR LEACHABLES

Screen samples using various extraction and headspace methods utilizing GCMS, ICPMS, and FTIR for organic compounds. Perform USP Physiochemical testing where applicable. Perform extractions and analyze extracts by ICPMS to scan for inorganic compounds. Other test methods can include TOC, conductivity, pH, or any other USP test method requested. Library will be developed per material for future testing.

### ANALYTICAL STUDIES FOR ANALYSIS OF TARGET COMPOUNDS

When compounds of concern have been detected, a validated method will be developed for that compound. Instrumentation that may be utilized: HPLC, LCMS, LCMSMS, GCMS, FTIR, UV-Vis.

### LITERATURE SEARCH FOR COMPOUND TOXICITY

All appropriate databases will be queried and relevant data reviewed.

### TOXICOLOGICAL RISK ASSESSMENT OF EXTRACTABLE TARGET COMPOUNDS

Perform comparative analysis of analytical data, literature data, and potential human exposure.

GLP/cGMP Testing Services  
USP/EP/JP Compendium Methods

For more information on AppTec's testing and manufacturing services, contact an AppTec Account Manager at 888.794.0077.  
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