

# Extractable & Leachable Test

Migratable compounds from the components of medical products, so called “Extractable & Leachable”, are critical for the safety of users. Analytical expertise and experience for the industrial materials are necessary for detection and determination of the chemical compounds. Additionally, biological or toxic risk assessment of each compound is inevitable. Toray Research Center provide sophisticated E&L Test services based on the long-term experience in the industrial and pharmaceutical analysis.

## What are “Extractable & Leachable(E&L)”?

### Extractables (E) :

Eluted compounds under severe conditions assuming the worst case

### Leachables (L) :

Eluted compounds under the actual use condition or under the conditions simulating actual use

Extractables

Leachables

Basically “Leachables” are included in “Extractables”, although not all of “Leachables” are detected as “Extractables”  
(In some cases, there are only detected as “Leachables”)

## Typical approach of “Extractable & Leachable Test”

\* Procedure of the examination is modified according to the acquired information and client's requests

Interview with the client about the details of composition and use conditions.

It is essential for “risk assessment” to estimate the amount of exposure to users.

### Extractable Test

Qualitative analyses of eluted compounds under severe conditions

Determination of eluted concentrations  
[Composition analyses of the elements]

LC/PDA+MS, GC/MS, HS-GC/MS and ICP-MS analyses are conducted essentially.

Organic elemental analysis, IC, MALDI-MS, Thermal desorption GC/MS, Pyrolysis GC/MS, NMR, IR etc. (Furthermore, chromatographic separation is used, if necessary.)

### Risk Assessment, Biological Safety Testing

Preliminary study of quantitative method etc.

### Leachable Test

Quantitative analyses and qualitative analyses of eluted compounds under the actual use conditions

Evaluation of products after storage and sterilization

Validation of analysis method

- ◆ It is necessary to include contents based on the latest trend of industry groups, guidelines and regulations.
- ◆ Extensive knowledge and experience of analysis and risk assessment for various products are indispensable for smooth R&D

Toray Research Center provides sophisticated “Extractable & Leachable Test” including risk assessment of medical products with wide experience in various field (industrial materials, electronic devices, medicine and biotechnology) and cutting edge analysis.