

What's the difference between Extractables and Leachables - HPLC Primer

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Extractables and **Leachables** are both chemical species that migrate from packaging or container materials into the sample or other contents, but the difference is the conditions under how they are acquired.

Extractables: These are compounds that can be extracted from a packaging component, delivery system, or manufacturing surfaces via laboratory manipulation, such as exposure to solvents or heat. **Extractables are obtained under exaggerated or forcing conditions using solvents or simulation media.** This provides an effective worst-case scenario in terms of what can migrate from a component.

Leachables: These are compounds that leach from a container / closure system into the finished drug products **under normal storage conditions.** Leachables are obtained under normal application or storage conditions. They are generally a subset of the extractables, although interaction with product components may produce leachables not seen as extractables.

In short: **extractable** studies are designed to obtain a fingerprint of chemical components that **can be extracted under exaggerated conditions**, while **leachable** studies aim to identify what compounds **might migrate into the product under normal conditions.**

If the manufacturer has changed their resin or mold release agents, it could potentially introduce new leachables or contaminants. Therefore, it's important to conduct an E&L study to confirm if any new leachables or contaminants have been introduced.