vela Laboratories
A Tentamus Company

GMP-certified GCLP-compliant

LET´S TALK ABOUT...

Extractable and Leachable Studies

Extractable and leachable (E&L) studies are an essential part of the pharmaceutical drug development process. Depending on the phase of product development and regulatory expectations, classical and accelerated approaches for E&L studies can be carried out at VelaLabs.

Classical E&L approach:

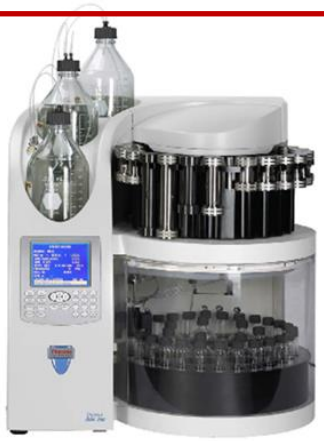
Gather information → Set AET → Extraction studies → Develop/validate leachable method → Leachable study → Report leachable above AET → Toxicology assessment

Accelerated E&L approach:

Gather information → Set SCT and/or AET → Extraction studies with leachable simulation → Report leachable above AET → Toxicology assessment

Both approaches are based on Quality by Design (QbD) principles. Depending on the information available, a risk analysis is carried out and a study plan is developed. The correct safety concern threshold (SCT) is selected and an analytical evaluation threshold (AET) is calculated from the SCT, the container parameters and the dosing regimen. Potential leachables are reported if they are above the AET. In the accelerated study design several steps are combined.

Automated solvent extractor (ASE) for extraction studies



VelaLabs GmbH
Brunner Straße 69 / Obj. 3, A-1230 Vienna / Austria
Phone: +43 1 890 5979 11, Fax: +43 1 890 5979 10
E-Mail: office@vela-labs.at