



Packaging Qualification Studies

One of the most important factors involved in guaranteeing maintenance of the intrinsic characteristics of a pharmaceutical product, an active substance, or a health care product is undoubtedly the primary packaging. This makes it necessary to carry out complete studies on packaging and its components in order to be able to guarantee product suitability

Eurofins professionals have an extensive knowledge of the behaviour of packaging materials (glass, elastomer materials, polymeric materials, metals, etc.), and can prepare protocols for specific studies to evaluate the suitability of the materials used, the final packaging chosen, and the interaction between packaging and contents.

Services for packaging qualification include:

- Global migration
- Colour migration
- Specific migrations (depending on the nature of the materials)
- Identification studies with different techniques: FT-IR, pyrolysis, GC-MS, NMR, elemental analysis
- Determination of generic, inorganic, organometallic and organic additives
- Determination of phenolic and non-phenolic antioxidants
- Determination of the distribution of molecular weights
- Determination of residual monomers
- Determination of heavy metals
- Determination of specific contaminants (nitrosamines, organostannic compounds, etc.)
- Evaluation studies on packaging integrity
- Evaluation studies on impermeability to bacteria

The analysis are performed according to customized protocols that consider the specificities of each product and packaging material in the selection and definition of:

- Critical components of the packaging
- Storage conditions tested (t, T, R.H.)
- Extraction and simulation procedures