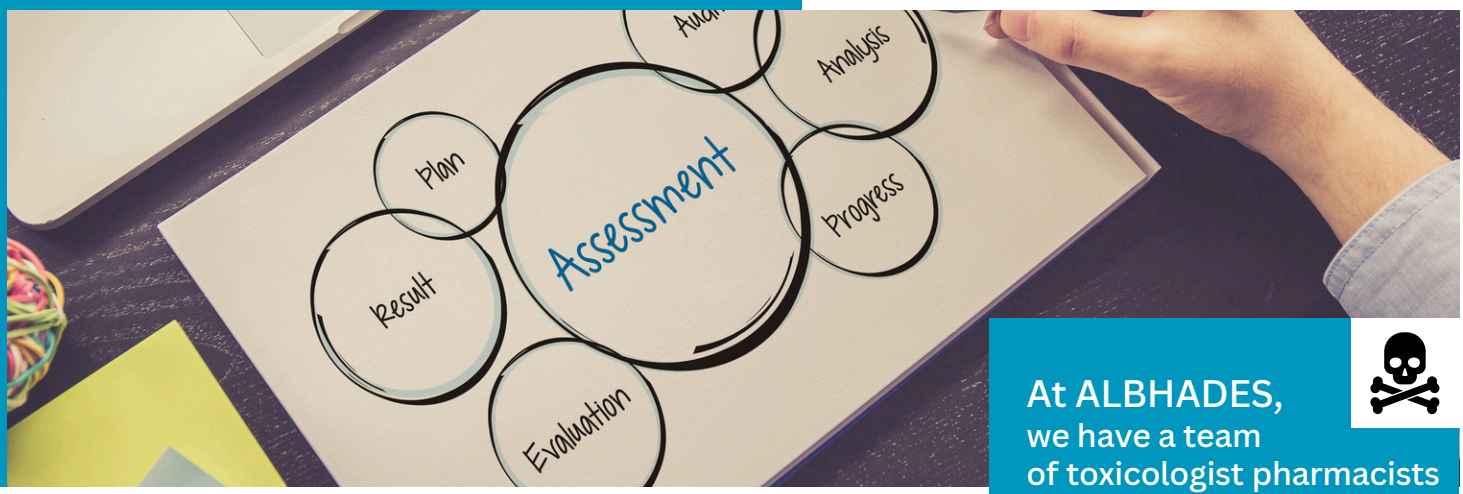
albhades
Analytical Solutions for Health Products

a WORMS SAFETY company

OUR CONSULTING SERVICE: ANALYTICAL AND INTELLECTUAL SERVICES AT YOUR SERVICE!



At ALBHADES, we have a team of toxicologist pharmacists to assist you with your toxicological needs, whether for analytical or intellectual services (for products intended for humans and animals): for the cosmetics, medical device, or pharmaceutical industries, etc.

Cosmetics:

- Safety Report (RSPC) – Regulation (EC) No. 1223/2009
- Equivalence assessment and reformulation justification
- Complete Product Information File (PIF)
- Toxicological pre-assessment of formulas or ingredients
- Control and compliance of raw materials (PE, PVC, PET, etc.)
- Verification and justification of claims (e.g., rPET, marketing claims)

Medical devices:

- Biological evaluation plan (BEP) – ISO 10993-1, ISO 14971
- Chemical characterization – ISO 10993-12, ISO 10993-18
- Toxicological risk assessment (TRA) – ISO 10993-17
- Biological evaluation report (BER) – ISO 10993-1
- Biocompatibility packaging
- Definition of cleaning specifications and process validation
- Regulatory support on safety aspects of your projects (strategy, gap analysis, exchanges with ON/ANSM)
- Specific toxicological evaluations (irritation, sensitization, genotoxicity, reprotoxicity)

Pharmaceutical:

- Toxicological assessment of excipients and impurities
- Extractables/releasables studies (E&L – ICH Q3E) and interpretation of results
- Packaging: toxicological assessment according to ICH Q3D and EMA/FDA guidelines
- Literature review and scientific justification (additives, NIAS)

Our+

Our services are provided in accordance with quality standards: cGMP, GMP, ISO 17025, ISO 9001, etc.
Our pharmaceutical facility for human and veterinary medicines has been inspected by the FDA and is CIR-approved.