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# CHEMICAL-PHYSICAL ANALYSIS FOR QUALITY CONTROL

• **Instrumental analysis** by HPLC and UHPLC with UV/DAD/RID detector.

• **Instrumental analysis** by GC-FID, GC-MS, ICP-OES, FT-IR/UATR, UV-VIS.

• **Quantification** of active ingredients and preservatives in cosmetics and medical devices.

• **Analysis** of multiresidal impurities and of trace contaminants in finished products and ingredients, like for example: phtalates, nitrosamines, VOC, substances listed in annex II of regulation (CE) 1223/2009.

• **Chemical characterization of medical devices** according to ISO 10993-18: extractables and leachables

• **"Paraben free":** ultra-traces analysis to support the claim "Paraben-Free" in finished coasmetic products, control of preservatives residure on manufacturing plants and « cleaning validation".

• **Allergenes:** analysis of allergenes in cosmetic finished products and ingredients from natural sources.

• **"Nickel Tested":** control on product batches and intermediates bulks to support the claim "Nickel Tested".

• **Metals:** analysis of inorganic contaminants in finished products and raw materials; toxic metals like Hg, Cd, As, Pb and sensitising metals like Ni, Cd, Co, Cr. Cosmetic relevant metals: As, Sb, Cd, Hg, Ni, Co, Cr, Pb e Cr VI.

• **Metals:** ICH guideline Q3D (R2) on elemental impurities - Table 5.1: elements to be considered in the risk assessment – oral, parenteral and inhalation exposure.

• **Release test in artificial sweat or saliva** for the detection of sensitising metals in cosmetic anhydrous and solid products; Release test in artificial sweat or saliva according to ISO 10993-12 for substances or impurities in medical devices.

• **Validation of analytical methods** according to ICH Guidelines for medical devices and for products to be marketed on the USA and European market.

• **Test and analysis to support specific claims**, customized according to the sponsor's needs.

• **Test and analysis** to support "cleaning validation" processes.

• **Percutaneous and permucosal** absorption test through Franz cells (OECD 428 and FDA methods): many epithelial and epidermis human models as well as synthetic membranes.

• **Stability assays** according to ICH for medical devices, to CIPAC for PMC e Biocides, to ASTM or PCPC for cosmetics. Chemical-physical and microbiological analysis.

• **Packaging compatibility.**

• **Photostability of sun products** with SUN TEST – sunscreens analysis and evaluation of decay before and after Uv exposure.

• **E-cigarettes and aromes:** safety and toxicity analysis.

• **Botanical extracts analysis.**

• **Control of manufacturing** for batches of PMC and Biocides.

• **Quality control:** analysis of osmolarity, surface tension, viscosity, density, drop point, softening point etc. on ingredients, bulks and manufacturing product batches.


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# CHEMICAL-PHYSICAL ANALYSIS AND ASSAYS TO SUPPORT PRODUCT DEVELOPMENT

• **Stability assays** according to ICH for medical devices, to CIPAC for PMC e Biocides, to ASTM or PCPC for cosmetics. Chemical-physical and microbiological analysis.

• **Compatibility with packaging,** analysis of impurities and contaminants released or absorbed by the packaging components.

• **Photostability of sun products** with SUN TEST – sunscreens analysis and evaluation of decay before and after Uv exposure.

• **Chmical characterization of medical devices** and components of for BEP/BER (Biological Evaluation Plan and Report).

• **Metals:** ICH guideline Q3D (R2) on elemental impurities - Table 5.1: elements to be considered in the risk assessment – oral, parenteral and inhalation exposure.

• **Release test in artificial sweat or saliva** for the detection of sensitising metals in cosmetic anhydrous and solid products; Release test in artificial sweat or saliva according to ISO 10993-12 for substances or impurities in medical devices.

• **Validation of analytical methods** according to ICH Guidelines for medical devices and for products to be marketed on the USA and European market.

• **Test and analysis to support specific claims,** customized according to the sponsor's needs.

• **Test and analysis** to support "cleaning validation" processes development.

• **Percutaneous and permucosal absorption test through Franz cells** (OECD 428 and FDA methods): many epithelial and epidermal human models available as well as synthetic membranes to select according to the product destination and use. Identification and development of the analytical method.

• **E-cigarettes and aromes:** safety evaluation and toxicological analysis for components and ingredients with in-use simulation.

• **Characterisation of botanical extracts** and development of the extraction method for the industrial scale-up.

• **Mucoadhesion assay:** adhesiveness test to verify nd compare the physical adhesion properties of medical devices and products aimed to be used on mucosae.

• **Compatibility** with condoms according to ASTM D6771 o ISO 19671 standards through traction and explosion tests.

• **In vitro UVA pf and broad spectrum UV** protection according to ISO 24443: and to Boots Star Rating; in vitro water resistance and variants.

• **In vitro blue light protection** and far UVA protection evaluations.

• **Trichological tests in vitro on human hair** locks to support customized cosmetic claims Test like for example: resistance to break, combability, color strenght and many others.

• **Customized tests on hair treatments** according to the sponsor's needs.

• **UV protection test for Medical adhesive** and Textiles according to EN 13758.

**Certificazioni e sistemi di qualità: BPL (Ministero Salute), ISO 17025, ISO 13485, ISO 9001.**

## *CONTACT*


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