

Unit 5: Analysis of Cosmetics, Toxicity Screening and Test Methods

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5.1 Analysis of cosmetics: what control must prove

The final unit returns the subject to the discipline it began with: a cosmetic on the market must be provably what its label says, batch after batch, and provably safe for its intended use. Quality control of cosmetics, as the syllabus frames it under the Drugs and Cosmetics Act, works at three gates, and the student should structure every answer in this unit by them. Raw material control judges every incoming material against its specification before it can enter a batch. In process control watches the manufacture at the points where faults are born, emulsion formation, dispersion, filling. Finished product control judges the packed product against its product specification and releases or rejects the batch. Around the three gates stand the supporting systems: sampling plans, retained samples, stability studies that set and defend the shelf life, complaint and recall records, and the government sampling and analysis of Section 1.4, in which the state's analyst applies the same specification logic from outside the factory.

5.2 The quality control test families

The tests themselves fall into families that follow the nature of the product, and no single list fits all classes, which is itself an examination point. Physical and organoleptic tests judge appearance, colour against standard, odour, texture and feel, and the product's physical constants: pH, viscosity, specific gravity where relevant, melting and softening behaviour for sticks, fineness and particle character for powders, foam quantity and stability for shampoos and dentifrices, and extrudability and consistency for pastes. Chemical tests judge composition where composition is the promise: assay of declared functional materials and markers for herbal products by the chromatographic methods of MPG103T, fluoride where declared, limits of heavy metals and other contaminants in colours and finished products, free alkali in soaps, and the preservative content where the system depends on it. Performance tests judge the product doing its job under defined conditions: cleansing, conditioning and moisturizing measurements, emulsion stability under centrifugation and temperature stress in the laboratory sense, and pack compatibility, since a product that reacts with its container fails in the market however good it was in the tank. Microbiological tests, treated in the next section, judge the living burden. The specification is the document that gathers the applicable tests with their limits for one product, and standardisation, the word the syllabus uses for tonics, dentifrices and the rest, means exactly this: the product is made and judged against a written specification, every batch, without exception.

Quality control: the four test families

PHYSICAL	CHEMICAL AND PERFORMANCE	MICROBIOLOGICAL
Appearance, colour, odour and texture pH and viscosity Melting behaviour Foam and fineness	Marker and declared content assays Contaminant limits Cleansing and moisturizing tests Emulsion stability	Total viable count Specified pathogens absent Preservative challenge test on the finished product

A batch is released when every applicable family passes its specification

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Figure: The four test families of cosmetic quality control. A batch is released when every applicable family passes against the written specification.

5.3 Microbiological quality and preservative efficacy

Cosmetics are applied to skin, eyes, lips and mouth, often by fingers, often kept in warm bathrooms, and their microbiological quality is therefore a first order safety matter and not a formality. Control judges the total viable count of the product, the absence of specified pathogens that must never be present in a cosmetic, and the special strictness owed to products for the eye area, for children and for use on damaged skin. The preservative efficacy or challenge test is the keystone method: the finished product is deliberately inoculated with test organisms in the laboratory and counted over time, and the preservative system passes only if the organisms fall as the method requires, proving that the product can defend itself against the contamination of real use. The herbal bearing is direct: plant materials arrive with a field and factory microbial history, water based herbal products are nutrient rich, and the natural image of a product has repeatedly tempted makers to under preserve. The test, not the image, decides, and this section should be read as the completion of Section 2.2.

5.4 Toxicity screening and test methods

Toxicity screening for cosmetics answers a different question from quality control: not is this batch correct, but is this product, correctly made, safe on the tissue it is made for, used as directed, for as long as users will use it. The standard test families, taught here as methods and purposes without protocols, are these. Skin irritation testing judges the immediate damaging action of the product or ingredient on skin. Skin sensitisation testing judges allergic potential, the delayed immune reaction that appears after repeated contact and that no single application predicts, the central long term hazard of colours, fragrances and hair dye systems. Eye irritation testing serves the products that reach the eye area or the face in use, shampoos and face products above all. Phototoxicity and photosensitisation testing serves products worn in sunlight, where an ingredient harmless in the dark may react under ultraviolet light, a risk with a real herbal history in plant materials containing light reactive constituents. Oral and mucosal tolerance serves the dentifrices, mouth washes and lip products. Systemic toxicity thinking stands behind the ingredient safety assessment itself: the permitted ingredient lists and restrictions of the rules embody it, so that the formulator's first toxicity control is to formulate only from permitted materials within their conditions.

The modern direction of the field is part of the examination picture and should be stated: animal testing of cosmetics is prohibited in India under the Cosmetics Rules framework, and the field works by validated alternative methods, reconstructed skin and eye models, in vitro sensitisation assays, and structured safety assessment of ingredients from existing data, performed or overseen by competent safety assessors. The

student's answer should present toxicity testing as a layered assessment: ingredient data first, product tests by validated methods where the product type requires them, human compatibility and patch testing under ethical control for the final product where appropriate, and post market surveillance of complaints and reactions as the last and largest test of all.

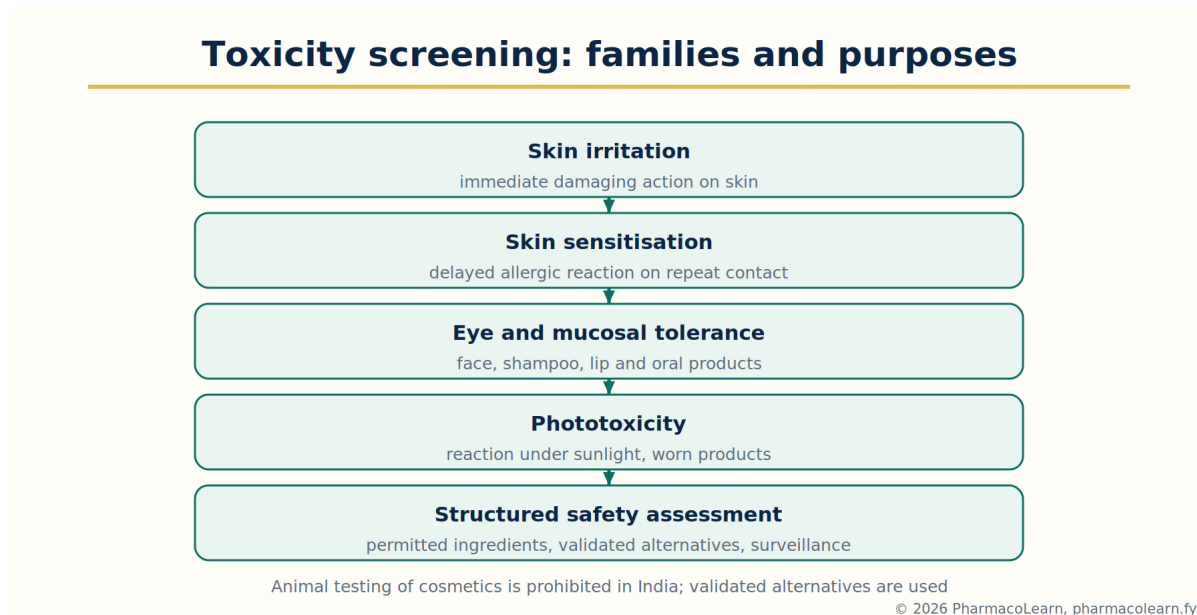
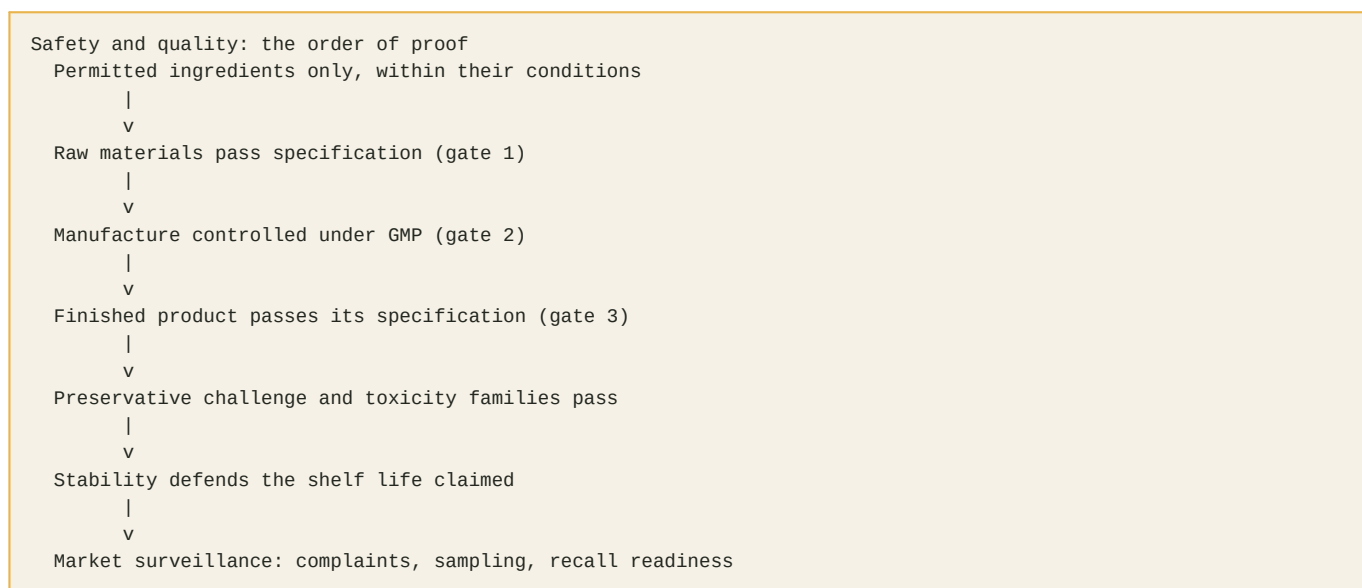


Figure: The toxicity test families. Each family answers for one tissue and one pattern of harm, and together they stand behind the safety of the finished product.



5.5 Stability studies

Stability work defends the time dimension of quality: the product must remain within specification, safe, effective in its cosmetic function and acceptable in appearance for the whole of its labelled life. The method follows the pattern of MPG203T and the wider degree: batches are stored under defined conditions of temperature and humidity, including accelerated conditions that predict ageing, and examined at intervals by the test families of Section 5.2, with the herbal products watched in particular for colour darkening, odour change from oxidising oils and extracts, emulsion separation, preservative failure over time, and pack interaction. The output is the shelf life and the storage instruction on the label, both earned by data. A herbal cosmetic with no stability record has an asserted shelf life, and the distinction between earned and asserted runs through this whole subject.

5.6 Quality control and toxicity studies as per the Drugs and Cosmetics Act

The unit closes by placing the laboratory work inside the legal frame of Unit 1, which is the syllabus's own closing phrase. Under the Drugs and Cosmetics Act and the Cosmetics Rules, the manufacturer's licence obliges the quality system these sections describe: manufacture under GMP, testing against standards, correct labelling, and records that prove all three. The state enforces from outside by inspection of premises, by sampling of products from manufacture and from the market, and by analysis in government laboratories, whose reports ground prosecution where a sample is found misbranded, spurious or not of standard quality. Imported cosmetics meet the same standards at the border gate. The student's closing synthesis is now available, and it is the synthesis of the whole subject: Unit 1 built the licence and the law, Unit 2 built the materials and the method of design, Unit 3 built the tissues and the product classes on them, Unit 4 carried the classes into functional cosmeceutical territory without crossing the claim boundary, and Unit 5 proves, batch by batch and test by test, that what the law licensed and the formulator designed is what the user actually receives. A graduate who can hold all five together can formulate, manufacture, regulate or examine herbal cosmetics anywhere in the Indian industry.

Frequently Asked Questions

Q: What is a herbal cosmetic, and how is it different from a natural cosmetic? A herbal cosmetic is a cosmetic in which herbs, plant materials and their extracts, form a significant and declared part of the formulation. Natural cosmetic is the wider term, covering characteristic ingredients from natural sources generally, plant, mineral or animal. Most herbal products are also mixed products in their whole composition, and both stand fully inside the Drugs and Cosmetics Act frame with no lighter licence for being herbal. See Sections 1.1 and 1.4.

Q: How are cosmetics classified in MPG204T? By site of application (skin, hair and scalp, lips and face, nails, oral cavity, bathing), by function (cleansing, conditioning, moisturizing, colouring, fragrancings, odour control), and by physical form (emulsion, suspension, powder, stick, solution, gel, cake). Each basis predicts something different: safety care, performance testing, and manufacture and stability respectively. See Section 1.2.

Q: What does the manufacturing licence for cosmetics require, and what is a loan licence? The licence, granted by the state licensing authority, requires suitable premises and plant, manufacturing and testing facilities or approved testing arrangements, technically qualified supervision, and GMP compliance, for the categories of cosmetics named. A loan licence covers a firm whose products are made for it in another manufacturer's licensed premises, with manufacture under the host licence and marketing responsibility on the loan licensee. See Sections 1.5 and 1.6.

Q: What is the difference between a misbranded and a spurious cosmetic? A misbranded cosmetic deceives by its label or presentation: false claims, imitation, or missing and incorrect particulars. A spurious cosmetic is false in its very identity: it purports to be a product it is not or bears a name and mark it has no right to. Both are offences under the Drugs and Cosmetics Act, as is manufacture without a valid licence. See Section 1.7.

Q: What are the main ingredient families in a herbal cosmetic formulation? The aqueous phase materials, oils, fats and waxes, surfactants, humectants, preservatives, colours, fragrances and volatile oils, thickeners and structuring agents, and the functional herbs and extracts that give the product its herbal identity. Every material enters against a specification, and a herbal extract is standardised like any other raw material. See Sections 2.1 to 2.7.

Q: How are surfactants classified, and what does each class do in cosmetics? By the charge of the head group. Anionic surfactants are the primary cleansers of shampoos, washes and dentifrices. Cationic surfactants condition hair by adsorbing to the damaged shaft. Nonionic surfactants emulsify and solubilise mildly across creams and lotions. Amphoteric surfactants soften anionic systems in shampoos and baby products. See Section 2.3.

Q: Why are preformulation and compatibility studies essential for herbal cosmetics? Because plant extracts bring colour, odour, pH, load and reactive constituents into a base system they can break, precipitate, discolour or inactivate. Preformulation characterises herb and base before they meet, compatibility studies prove the chosen combination over time and stress, and together they convert formulation from assembly into design. See Sections 2.8 to 2.10.

Q: Describe the structure of skin and say where cosmetics act. The epidermis produces keratinised cells that form the stratum corneum, corneocytes in a lipid mortar, which is the skin barrier; below it the dermis carries collagen, elastin, vessels, nerves, sweat and sebaceous glands and follicles; below that the hypodermis insulates. Cosmetics act in and on the stratum corneum and the surface film; action in the dermis would be drug action. See Section 3.1.

Q: What is a cosmeceutical, and what boundary must its claims respect? Cosmeceutical is a trade and teaching word, not an Indian legal category, for cosmetics built around functional ingredients and positioned for a defined surface condition. The product remains a cosmetic in law, acts on the surface, and may make appearance claims only; claims to treat disease or change body function cross into drug territory. See Section 4.1.

Q: What quality control and toxicity testing must a herbal cosmetic pass? Quality control works at raw material, in process and finished product gates against a written specification, across physical and organoleptic, chemical, performance and microbiological test families, including the preservative challenge test, defended over shelf life by stability studies. Toxicity screening covers irritation, sensitisation, eye and mucosal tolerance and phototoxicity by validated methods, within the Drugs and Cosmetics Act frame that also provides inspection, sampling and government analysis. See Sections 5.1 to 5.6.

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