

Unit 1: Introduction and Regulation of Herbal Cosmetics

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Herbal Cosmetics, subject code MPG204T, is the fourth core theory subject of M.Pharm Pharmacognosy, Semester 2. It carries 4 credits and 60 hours of theory, taught at 4 hours per week, for 100 marks, and its five units are of equal length at 12 hours each. Its scope, as the syllabus states it, is the study of preparation and standardization of herbal and natural cosmetics, with emphasis on the national and international standards prescribed regarding herbal cosmeceuticals. Unit 1 introduces herbal and natural cosmetics, their classification and economic aspects, and the regulatory provisions for their manufacture in India: licence, good manufacturing practice, offences and penalties, import and export, and the industries that produce them. Unit 2 studies the materials the formulator works with: raw materials, preservatives, surfactants, humectants, oils, colours and functional herbs, and then the preformulation, compatibility and interaction work by which those materials become a designed formulation. Unit 3 grounds the products in the body: the physiology and chemistry of skin and pigmentation, hair, scalp, lips and nail, and then the great product classes built on that physiology, cleansing creams, lotions, face powders, face packs, lipsticks, bath products, soaps and baby products, with the preparation and standardisation of tonics, bleaches, dentifrices, mouth washes, tooth pastes and cosmetics for nails. Unit 4 takes up cosmeceuticals of herbal and natural origin: hair growth formulations, shampoos, conditioners, colorants and hair oils, fairness formulations, vanishing and foundation creams, anti-sunburn preparations, moisturizing creams and deodorants. Unit 5 closes with control: the analysis of cosmetics, toxicity screening and test methods, and quality control and toxicity studies as per the Drugs and Cosmetics Act. One discipline runs through the whole subject and the student should hold it from the first page: a herbal cosmetic is still a cosmetic. The word herbal describes the origin of some of its ingredients; it does not exempt the product from the physiology of the skin it touches, the chemistry of the mixture it is, the licence under which it is made, or the tests by which its quality and safety are judged. These notes teach formulation at the level of class, function and principle throughout: no worked recipes, no percentage formulas, and no efficacy claims are stated, because none are in the syllabus and none belong in an examination answer.

1.1 Herbal and natural cosmetics: what the terms mean

A cosmetic, in the working definition used in Indian law and in cosmetic science alike, is an article intended to be applied to the external surfaces of the human body, or to the teeth and the mucous membranes of the oral cavity, for cleansing, beautifying, promoting attractiveness or altering the appearance, without affecting the structure or functions of the body in the manner of a drug. That last clause is the boundary of the whole subject. A preparation that claims to treat disease, to change a body function, or to act through the body rather than on its surface has crossed into drug territory and is judged by drug rules. A cosmetic works on the surface: it cleanses the surface, deposits materials on the surface, changes how the surface looks, feels or smells, and is then in large part removed or worn away.

Within cosmetics, the syllabus works with two overlapping words. A herbal cosmetic is a cosmetic in which herbs, that is plant materials and their extracts, form a significant and declared part of the formulation, as the functional ingredient, the fragrance, the colour, or the identity of the product. A natural cosmetic is the wider term: its characteristic ingredients come from natural sources generally, plant, mineral or animal in origin, as against the fully synthetic ingredient shelf. Most products examined in this subject are both: a cream carrying a plant extract in a base that also uses mineral oil or a mineral pigment is herbal in its

headline ingredient and mixed in its whole composition, The honest teaching point, repeated in Unit 5, is that natural origin is a fact about sourcing, not a proof of safety or of effect: plant materials include potent irritants and sensitisers, mineral materials include some of the most inert and safest cosmetic ingredients known, and every ingredient, of whatever origin, must pass the same quality and safety discipline.

Three consequences organise the subject. First, because the active surface is living tissue, the formulator must know that tissue: Unit 3 therefore teaches skin, hair, lips, nails and the mouth before it teaches the products used on them. Second, because a cosmetic is a manufactured mixture held stable for months on a shelf and hours on skin, its science is the science of mixtures: emulsions, suspensions, surfactant systems and preservation, which Unit 2 builds from the ingredient classes. Third, because cosmetics are made for sale to the public in very large numbers, they are a licensed, inspected and tested industry, and Unit 1 now turns to that regulation after classification and economics have set the scene.

1.2 Classification of cosmetics

Cosmetics are classified in several useful ways at once, and the examination expects the student to move between them. The first classification is by site of application, which is the classification the syllabus itself follows in Units 3 and 4: cosmetics for the skin (creams, lotions, powders, packs, foundations), cosmetics for the hair and scalp (shampoos, conditioners, oils, colorants), cosmetics for the face and lips in the decorative sense (lipsticks, face powders, foundations), cosmetics for the nails (lacquers, removers, creams), cosmetics for the mouth (dentifrices, tooth pastes, mouth washes), bath and cleansing preparations (soaps, bath products), and preparations for fragrance and odour control (deodorants and perfumes in the wider trade). The second classification is by function: cleansing, conditioning and protecting, moisturizing, colouring and decorating, fragrancing, and the borderline functional class the syllabus calls cosmeceuticals, taken up in Unit 4. The third classification is by physical form: emulsions (creams and lotions), suspensions and pastes (tooth pastes, face packs), powders (face powders, talc type products), sticks (lipsticks, deodorant sticks), solutions and lotions proper, gels, aerosols in the wider industry, and solid cakes (soaps). A single product sits in all three classifications at once: a lipstick is a lip product by site, a colouring product by function and a stick by form, and each classification predicts something different about it, its safety tests from its site, its performance tests from its function, and its manufacture from its form.

Herbal and natural cosmetics cut across the same grid. A herbal variant can exist in almost every cell of it: herbal soaps and herbal shampoos in the cleansing class, herbal creams and oils in the conditioning class, plant colours in the decorative class, and herbal dentifrices in the oral class. What makes the variant herbal is the ingredient story of Unit 2, not a separate physical science: a herbal cream is still an emulsion and fails in the same ways an emulsion fails. The classification table below gathers the scheme the rest of these notes use.

Classification basis	Principal classes	What the class predicts
Site of application	Skin, hair and scalp, lips and face, nails, oral cavity, whole body bathing	The tissue involved, the safety tests, the regulatory care level
Function	Cleansing, conditioning, moisturizing, colouring, fragrancing, odour control	The performance the user judges, the claims that may honestly be made
Physical form	Emulsion, suspension, powder, stick, solution, gel, cake	The manufacturing process, the stability faults, the packaging
Ingredient character	Herbal, natural, mixed, synthetic	The sourcing, standardisation and interaction questions of Unit 2

Cosmetics classified three ways at once

BY SITE	BY FUNCTION	BY FORM
Skin: creams, lotions, powders and packs Hair and scalp: washes, oils and colorants Lips, nails and mouth: sticks, lacquers, pastes	Cleansing Conditioning Moisturizing Colouring Fragrancing Odour control	Emulsions: creams and lotions Suspensions and pastes Powders and sticks Solutions and gels Solid cakes: soaps

Site predicts safety care, function predicts the test, form predicts manufacture

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Figure: Three classifications at once. Site predicts the safety care, function predicts the performance test, and form predicts the manufacture and the stability faults.

1.3 Economic aspects and the industries involved

The syllabus joins classification to economic aspects in one breath, because the herbal cosmetics trade is a large industry and the pharmacognosist will work in it, regulate it or supply it. The economic facts to hold are structural rather than numerical, since market figures age quickly and none are printed in the syllabus. Cosmetics are high volume, repeat purchase consumer goods: the same household buys soap, tooth paste and shampoo continuously, so the industry rewards reliable quality at controlled cost far more than novelty. Herbal and natural products occupy a large and long established segment of the Indian market in particular, where plant based personal care connects with the Ayurvedic tradition taught in MPG203T, and where manufacturers range from very large national companies with full research and quality departments, through medium firms making a narrow range well, to small and cottage scale units making soaps, oils and powders for local sale. International trade runs in both directions: India exports herbal cosmetics and the raw materials and extracts behind them, and imports finished cosmetics, speciality ingredients and fragrances, which is why import and export control appears in this unit beside the manufacturing licence.

The industries involved, as the syllabus names them, form a chain rather than a single factory type. Growers and collectors supply the crude herbs; extractors and distillers convert them into the standardised extracts and volatile oils of commerce; ingredient manufacturers supply the surfactants, oils, waxes, colours and preservatives; cosmetic manufacturers formulate and pack the finished product; and packers, distributors and retailers carry it to the user. Loan licence and third party manufacture are established features of this chain in India: a marketing firm may have its product made in another firm's licensed premises, which is why the examination asks about loan licensing, and why Unit 5 insists that responsibility for quality follows the licence and the label, not the size of the firm.

1.4 Regulatory provisions: the legal frame

Cosmetics in India are regulated under the Drugs and Cosmetics Act, 1940 and the rules made under it, with the cosmetics provisions now carried in the Cosmetics Rules, 2020, administered through the Central Drugs Standard Control Organization at the centre and the state licensing authorities in the states. The frame has the same architecture as the drug frame the student already knows, fitted to the lower risk and higher volume of cosmetics: manufacture is licensed, premises and practice are controlled by good manufacturing practice requirements, products must meet the standards and labelling the rules prescribe, misbranded and spurious cosmetics are offences, imports are controlled at registration and the border, and samples may be taken and analysed by government analysts, with penalties on conviction. Herbal and

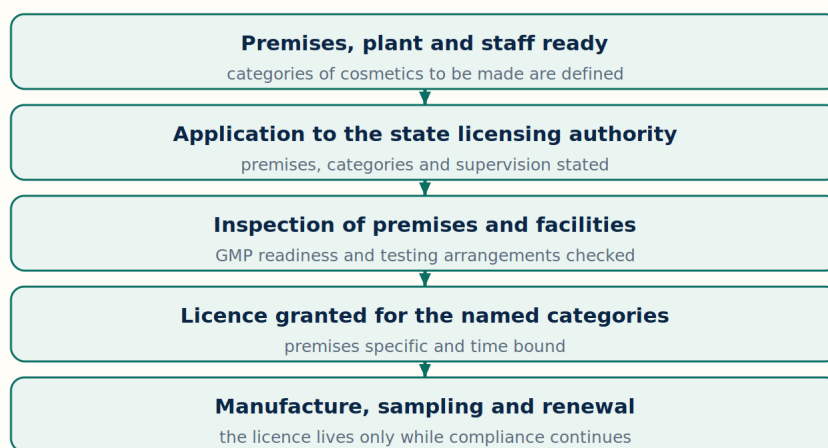
natural cosmetics stand fully inside this frame. No separate, lighter licence exists for a product because it is herbal, and a product that makes drug claims may be treated as a drug, or as a misbranded cosmetic, according to the claim it makes. Ayurvedic cosmetics occupy a boundary the student should state carefully: a preparation manufactured as an Ayurvedic medicine under the Ayurvedic licensing provisions of the Act follows that route, while a preparation sold as a cosmetic follows the cosmetics route, and the route is decided by the product's intended use, claims and composition, not by the manufacturer's preference.

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The cosmetics control frame in outline
  Drugs and Cosmetics Act, 1940 and Cosmetics Rules, 2020
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    v
  Manufacture only in licensed premises, under GMP
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    v
  Standards, labelling and prohibited claims applied
    |
    v
  Market sampling and analysis by government analysts
    |
    v
  Misbranded or spurious findings: offences and penalties
    |
    v
  Imports controlled in parallel: registration and border checks
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1.5 The manufacturing licence

The licence is the permission to manufacture cosmetics for sale, granted by the state licensing authority for premises that satisfy the rules: suitable premises and plant, the required manufacturing and testing facilities or approved arrangements for testing, technically qualified supervision, and compliance with good manufacturing practice. The application states the categories of cosmetics to be made, because a licence for creams does not by itself authorise every other class, and the licence is premises specific and time bound, renewed on continued compliance and liable to suspension or cancellation when conditions fail. The own premises licence covers the manufacturer making products in its own factory, one of two licence forms that matter for the examination. The loan licence covers the firm that markets products made for it in another manufacturer's licensed premises: the actual manufacture happens under the host premises' licence and supervision, while the loan licensee carries the marketing responsibility the rules assign, and the label must tell the truth about who made the product and who markets it. The licensing flow diagram below shows the sequence every applicant follows in outline, whatever the category.

The cosmetic licensing sequence



A loan licence places manufacture in another firm's licensed premises

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Figure: The licensing sequence in outline. The licence certifies premises, categories and supervision, and it stays alive only while inspection and sampling keep passing.

1.6 Good manufacturing practice for cosmetics

Good manufacturing practice, GMP, is the discipline that makes a licensed factory produce the same acceptable product on the hundredth batch as on the first, and the syllabus places it inside the regulatory unit because compliance is a licence condition, not a voluntary extra. Its components, stated at the level of principle the syllabus requires, are: premises designed and maintained so that operations do not contaminate each other, with washing, water and waste systems fit for cosmetic manufacture; equipment suited to the products, cleaned and maintained on a recorded schedule; raw materials received against specification, tested or certified, stored so that identity is never in doubt, and issued by recorded procedure; a defined manufacturing process for each product, written as a master formula and process record at the level of operations, followed batch by batch and signed as performed; in process and finished product quality control against the product specification, with retained samples; personnel who are trained, medically fit for the work and held to hygiene rules, since cosmetics are made for direct skin contact; documentation complete enough that any batch on the market can be traced to its materials, its process record and its test results; and a complaints and recall procedure that can find and withdraw a defective batch. None of this is peculiar to herbal products, but two points are: herbal raw materials vary as agricultural materials vary, so raw material control carries extra weight, and the natural image of the product tempts weak firms to treat GMP as optional, which is exactly the failure the licence system exists to catch.

1.7 Offences and penalties: misbranded and spurious cosmetics

The Act's enforcement vocabulary for cosmetics turns on two words the student must be able to distinguish. A cosmetic is misbranded when its label or presentation deceives: false or misleading claims, imitation of another product, missing or incorrect particulars such as the manufacturer, licence number, batch, ingredients where required, or directions and warnings the rules prescribe. A cosmetic is spurious when its very identity is false: it purports to be a product it is not, bears a name or mark it has no right to, or is manufactured or imported in a way that counterfeits a genuine article. Manufacture for sale, sale, stocking or import of misbranded or spurious cosmetics, and manufacture without a valid licence, are offences under the Act, punishable on conviction with the imprisonment and fine the Act prescribes for the class of offence, with enhanced consequences for repeat offences, and with forfeiture and licence action beside the prosecution. These notes state the structure of the liability and not penalty figures, because the syllabus

names offences and penalties as a head and prints no figures, and an examination answer earns its marks by the distinctions, misbranded against spurious, unlicensed against licensed but non compliant, and cosmetic claim against drug claim, rather than by recited numbers.

1.8 Import and export of herbal and natural cosmetics

Imports are controlled so that a foreign cosmetic cannot enter the Indian market on weaker terms than a domestic one. In outline, cosmetics imported for sale require registration of the product and the manufacturer with the central authority under the Cosmetics Rules, import through permitted routes with the documents the rules require, compliance with the same standards, labelling and prohibited ingredient provisions as domestic products, and liability to sampling and refusal where a consignment fails. Prohibited and restricted ingredients, and cosmetics tested on animals in the manner the Indian rules prohibit, stand outside the permitted trade, and the student's answer should present import control as the border arm of the same system as the factory licence: one standard, two gates. Export runs the other way: the Indian manufacturer exporting herbal and natural cosmetics must meet the importing country's rules, which differ in their ingredient lists, labelling languages and claim rules, and must support the consignment with the certificates and documents the trade requires, commonly including evidence of lawful manufacture at home. The economic point of Section 1.3 completes itself here: India's strength in this trade rests on its plant wealth and its traditional formulations, and both are exportable only from licensed, documented, testable manufacture.

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