

Unit 1: Cosmetics, Regulatory

Free notes at pharmacolearn.fyi

Cosmetic and Cosmeceuticals, subject code MPH204T, is a core Semester 2 subject of M.Pharm Pharmaceutics. It carries 4 credits and 60 hours of theory, taught at 4 hours per week, for 100 marks. A cosmetic is the only pharmaceutical product class that a healthy person applies every day for years, so its science sits at the meeting point of law, biology and formulation. This subject follows that order. The first unit is regulatory: what a cosmetic legally is in India, what its label must say, and the licensing, import and offence provisions of the Drugs and Cosmetics framework that govern its manufacture and sale. The second unit is the biology the products act on: the structure of skin read through the problems it presents (dry skin, acne, pigmentation, prickly heat, wrinkles, body odor), the structure and growth cycle of hair, the common problems of the oral cavity, and the cleansing and care needs of each body site. The third unit is the formulator's toolbox: surfactants, emollients, rheology additives and antimicrobial preservatives, the building blocks of a moisturizing cream, a vanishing cream, a cold cream, a shampoo and a toothpaste, soaps and syndet bars, perfumes and their regulated allergens, and the controversial ingredients that every formulator must be able to discuss honestly. The fourth unit turns the toolbox onto the problems: sunscreen design and its regulation, then a cosmeceutical formulation strategy for each condition of Unit 2, extended to dandruff and the oral problems. The fifth unit covers herbal cosmetics: the herbal ingredients of hair, skin and oral care, the private standards such as COSMOS that govern natural claims, and the real challenges of formulating with plant materials.

1.1 What a cosmetic is: the Indian legal definition

Every regulatory question in this unit starts from one definition. Under the Drugs and Cosmetics Act, 1940, a cosmetic is any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part of it, for cleansing, beautifying, promoting attractiveness or altering the appearance. Three features of this definition matter. First, it is defined by intended use and site of application, not by composition: the same cream base is a cosmetic if sold to beautify and a drug if sold to treat. Second, the list of purposes is cosmetic in the plain sense, cleansing and appearance, so a product that claims to cure, mitigate or prevent a disease steps outside the cosmetic definition and into the drug definition, with the much heavier drug licensing and evidence requirements that follow. Third, soaps are expressly included within the Indian cosmetic definition, unlike the position in the United States, which is why Unit 3 can treat soaps and syndet bars as cosmetics. The word cosmeceutical, used throughout this subject, has no legal status in India or in most jurisdictions: it is a professional term for a cosmetic positioned on the borderline, carrying an active ingredient with a biologically plausible benefit beyond appearance. A cosmeceutical is regulated as a cosmetic, and its claims must stay within what a cosmetic may claim, however active its formulation feels.

Feature	Cosmetic (India)	Drug (India)
Legal basis	Drugs and Cosmetics Act 1940 definition of cosmetic	Drugs and Cosmetics Act 1940 definition of drug
Intended purpose	Cleansing, beautifying, promoting attractiveness, altering appearance	Diagnosis, treatment, mitigation or prevention of disease
Claims allowed	Appearance and hygiene claims	Therapeutic claims, with evidence

Feature	Cosmetic (India)	Drug (India)
Examples	Face cream, shampoo, toothpaste for cleaning, lipstick	Antifungal cream, medicated anti dandruff preparation with drug claims, fluoride toothpaste positioned against caries as a disease claim in some markets

1.2 The regulatory framework: Act, Rules and the administering authority

Cosmetics in India are regulated under the same statute as drugs, the Drugs and Cosmetics Act, 1940, and the rules made under it, principally the Drugs and Cosmetics Rules, 1945 for manufacture and sale, and the Cosmetics Rules, 2020, which separated out and modernised the provisions for import and registration of cosmetics. The Central Drugs Standard Control Organization (CDSCO), headed by the Drugs Controller General of India, is the central authority; manufacture licensing is administered through the state licensing authorities, and import registration is handled centrally. This split, central control of what enters the country and state licensing of what is made in it, explains the shape of the rest of this unit: import provisions are registration based and uniform, while manufacturing licences are granted by the state in which the factory sits. India also maintains a list approach through the Bureau of Indian Standards for certain specification matters and restricts or prohibits specific ingredients from time to time by notification, so a formulator's duty is to check the current position rather than memorise a frozen list. The framework's logic is consistent: cosmetics are lower risk than drugs but are applied widely, repeatedly and to children, so the law controls identity, labelling honesty, manufacturing hygiene and prohibited products rather than pre market proof of efficacy.

1.3 Labelling of cosmetics: Indian requirements

The label is the consumer's only contract with the product, and Indian rules prescribe what a cosmetic label must carry. The inner and outer labels together must state the name of the cosmetic, the name and address of the manufacturer (and, for imported products, of the importer), the net contents, the batch or lot number, the manufacturing licence number, the month and year of manufacture and the expiry or best before date, and the list of ingredients. Ingredients are declared in descending order of concentration by weight or volume at the time of manufacture, following the convention used internationally, so the first named ingredient is the largest component, usually water. Directions for safe use and any warnings or cautions the product requires must be printed where the product needs them, and special precautions apply to particular categories, for example hair dyes containing certain dye intermediates carry prescribed caution statements about skin sensitivity testing. Two principles run through the detail. The label must not make false or misleading claims, because a misleading label makes the product misbranded (section 1.5), and the particulars must be legible and indelible under normal conditions of storage and use. For the formulator, labelling is not an afterthought: the ingredient list is written in the INCI style naming used by the industry, and every claim on the pack must be supportable by the formulation as filed.

1.4 Regulatory provisions relating to import of cosmetics

Because a large share of cosmetics sold in India is imported, the import provisions are registration based. Under the Cosmetics Rules, 2020, a cosmetic may be imported only if it is registered with the central licensing authority and the importer holds the registration certificate for the product and its overseas manufacturing site; the application is made by the manufacturer or its authorised agent or importer in India. No cosmetic may be imported if it is prohibited in its country of origin for safety reasons, if it contains a prohibited ingredient, or if it is misbranded or spurious. Imported products must carry the registration number and the importer's particulars on the label in addition to the standard labelling. Consignments enter through notified ports and are liable to sampling and testing by the port officers, and the central authority may prohibit the import of any cosmetic whose quality or safety is in doubt. The practical effect for the

industry is that market entry for a foreign brand is a dossier exercise: product composition, free sale status in the origin country, manufacturing site credentials and labelling artwork are examined before the first consignment ships, rather than the product being judged at the border alone.

1.5 Misbranded and spurious cosmetics

The Act grades defective cosmetics by the kind of deception involved, and the distinction matters in examinations and in enforcement. A cosmetic is **misbranded** if it is not labelled in the prescribed manner, if its label or container bears a statement, design or device that makes a false claim or is misleading, or if it is coloured or coated in a way that conceals damage or makes it appear of better or greater therapeutic value than it is. Misbranding is therefore about information: the product may be perfectly safe, yet it deceives the buyer. A cosmetic is **spurious** if it is manufactured under a name that belongs to another cosmetic, if it imitates or substitutes for another cosmetic in a manner likely to deceive, or if it falsely claims to be the product of a manufacturer of whom it is not truly a product. Spuriousness is about identity and origin: the product pretends to be something or someone else's. Adulteration, the drug side concept of a product rendered injurious or substandard, has its cosmetic analogue in products contaminated with harmful substances or made under insanitary conditions, which the manufacture and prohibition provisions of this unit address. Enforcement proceeds by sampling by drugs inspectors, testing in government laboratories, and prosecution or administrative action proportionate to the grade of offence.

Defect	Core idea	Typical example
Misbranded	The information deceives	A cream labelled with a false claim of curing eczema; a label missing the manufacturer address
Spurious	The identity deceives	A counterfeit of a well known brand, packed to imitate it
Prohibited or substandard	The product itself is the problem	A cosmetic containing a prohibited ingredient, or made in insanitary premises

Misbranded versus Spurious Cosmetics

MISBRANDED The information deceives	SPURIOUS The identity deceives
<ul style="list-style-type: none"> Not labelled in the prescribed manner False or misleading claim on the label Colouring conceals damage or defect Example: a cream claiming to cure eczema 	<ul style="list-style-type: none"> Manufactured under another product's name Imitates or substitutes another cosmetic False claim about who manufactured it Example: a counterfeit of a known brand

Both are prohibited from manufacture and sale; offences are graded by seriousness, with spurious products punished most severely

© 2026 PharmacoLearn, pharmacolearn.fyi

Figure: The two ways a cosmetic deceives. Misbranding corrupts the information; spuriousness corrupts the identity.

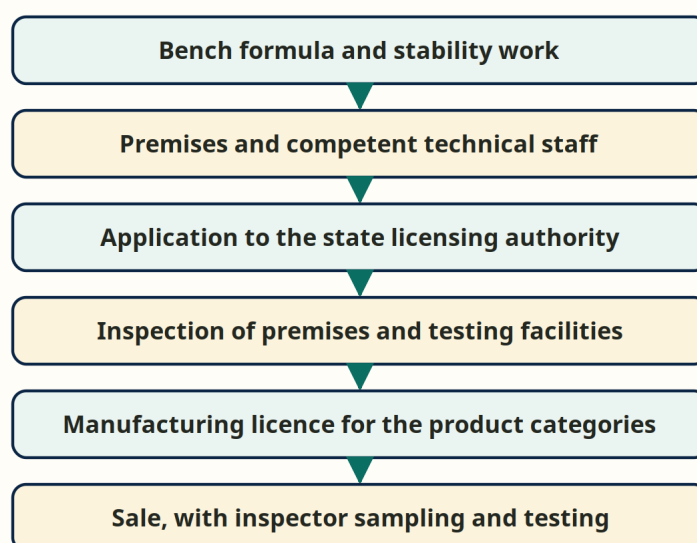
1.6 Manufacture of cosmetics: conditions for obtaining a licence

Manufacture of cosmetics for sale requires a licence from the state licensing authority, granted for specified premises and product categories. The conditions for obtaining the licence define the floor of cosmetic

manufacturing practice. The applicant must provide premises that meet the factory requirements of the Rules: a clean, hygienic site with adequate space for manufacture, quality control and storage, with provision against contamination. Competent technical staff must supervise manufacture and testing, persons with prescribed qualifications in pharmacy, science or cosmetic technology as the Rules require. The manufacturer must maintain adequate facilities for quality control testing of raw materials and finished products, or have access to approved testing arrangements, and must keep records of manufacture and testing. The licence is granted for the categories applied for, so a unit licensed for creams cannot automatically make every other cosmetic class. Conditions continue after grant: the licensee must allow inspection, maintain the premises and staff standards, and manufacture according to good manufacturing practice expectations, with the licence liable to suspension or cancellation for breach. These conditions are the regulatory counterpart of the formulation work in Unit 3: the licence is what converts a bench formula into a product that may lawfully be sold.

```
From formula to market: the Indian cosmetic licence path
Bench formula and stability work (Unit 3)
|
v
Premises and competent technical staff in place
|
v
Application to the state licensing authority
|
v
Inspection of premises, staff and testing facilities
|
v
Manufacturing licence for the product categories
|
v
Manufacture under licence conditions, labelled as prescribed
|
v
Sale, with inspector sampling and testing in the market
```

From Formula to Market: The Indian Cosmetic Licence Path



© 2026 PharmacoLearn, pharmacolearn.fyi

Figure: The licence path of an Indian cosmetic, from bench formula to a marketed product under inspector sampling.

1.7 Prohibition of manufacture and sale of certain cosmetics

The licence system is balanced by explicit prohibitions. Manufacture and sale are prohibited for cosmetics that are misbranded or spurious, that contain a prohibited ingredient, that are not of standard quality where standards apply, or that contain a prescribed colour or substance beyond its permitted conditions. No cosmetic may be manufactured or sold if it has been imported in violation of the import provisions, and the central and state governments may, by notification in the public interest, prohibit the manufacture, sale or distribution of a cosmetic that involves risk to human beings. Prohibition is the framework's emergency brake and its routine filter at once: routine, because inspectors sample and withdraw non complying products continuously; emergency, because a notification can remove a whole ingredient or product class from the market when evidence of harm accumulates. For formulators the lesson is to design against the prohibition logic from the start: avoid borderline ingredients with a known safety cloud (Unit 3's controversial ingredients), respect claim limits, and keep the dossier evidence that a product is what its label says.

1.8 Loan licence

A loan licence is a distinctive Indian provision that separates the right to manufacture from the ownership of the factory. Under it, an applicant who does not own manufacturing premises may be granted a licence to manufacture cosmetics using the premises and facilities of another manufacturer who already holds a licence for those premises. The loan licensee markets the product under its own name and licence number, while the actual manufacture happens at the approved site under the site licensee's systems. The provision exists to let brands and small companies bring products to market without building factories, while keeping every product tied to an inspected premises and an accountable licensee. It carries the same conditions as an ordinary licence in respect of the product: qualified technical supervision at the manufacturing site, quality control arrangements, and liability for the product's compliance rests with those the rules make responsible, so a loan licence is a regulated arrangement, not a shortcut around the licensing conditions of section 1.6. Examiners test the contrast: an ordinary licence authorises manufacture on the licensee's own premises; a loan licence authorises manufacture on another licensee's premises.

1.9 Offences and penalties

The Act enforces the cosmetics provisions through offences graded by seriousness. Manufacturing, selling, stocking or exhibiting for sale a spurious cosmetic, manufacturing without a licence, and obstructing an inspector are offences under the Act, and offences concerning cosmetics are punishable with imprisonment and fines as prescribed, with enhanced punishment for repeat offences. The grading reflects harm: offences involving spurious products and unlicensed manufacture attract the severest treatment because they remove the product from every safeguard at once, while labelling and record offences are treated more leniently. Two features deserve note. The Act provides for the liability of companies and the persons in charge of their business, so offences are not deflected onto junior staff, and it provides for confiscation of the offending stock. Penalties interact with the licence system as well: conviction and breach of licence conditions can each end a business, one through the courts and one through the licensing authority, and a manufacturer must satisfy both regimes at all times. Because the precise penalty amounts and imprisonment terms are amended from time to time, they are stated here in structure rather than figures; the examinable point is the grading logic, which offences exist, and that repeat offences are punished more severely.

*More free M.Pharm notes and unit wise PDFs at pharmacolearn.fyi
Free video lectures on the PharmacoLearn YouTube channel*