



# THE REGULATORY COMPASS FOR COSMETICS

Understanding Manufacturing, Import, Labeling, and Prohibitions

- COSMETICS AND COSMECEUTICALS

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### Syllabus: Cosmetics– Regulatory :

- a) Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics
- b) Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics.
- c) Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license,
- d) prohibition of manufacture and sale of certain cosmetics,
- e) loan license,
- f) offences and penalties.

### Definition of cosmetic products:

As per the regulations in place at that time, a cosmetic is defined under the Drugs and Cosmetics Act, 1940, as:

"Any article intended to be rubbed, poured, sprinkled, or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic."

Cosmetic is defined **under section 3(a) of the Drugs and Cosmetics Act, 1940** as, any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and includes any article intended for use as a component of cosmetic.

Under the provisions of Drugs and Cosmetics Act, 1940 and Rules made there under, the **manufacture of cosmetics is regulated under a system of inspection and licensing by the State Licensing Authorities appointed by the respective State Governments**, while the **import of cosmetics is regulated under a system of registration by the Central Licensing Authority appointed by the Central Government.**

The **Drugs Controller General (India) functions as the Central Licensing Authority** who grants the **Import Registration Certificate** and regulates the import of cosmetics into India vide Gazette notification G.S.R 763(E) under the provisions of Drugs and Cosmetics Act, 1940.

Any article falling within the definition of cosmetic is required to be registered along with **pack size, variant(s) and manufacturing premises before its import into the country.**

No cosmetic shall be imported into India unless the product is registered under the rules by the Central Licensing Authority appointed by the Central Government under rule 3(f) or by any person to whom such powers may be delegated under rule 5. [As per rule 12(1) of the Cosmetic Rules, 2020]

No cosmetic shall be imported or manufactured unless it complies with the specifications prescribed under the Ninth Schedule or any other standards of quality and safety, applicable to it, and other provisions under the rules. In case, the cosmetic is not included under the Ninth Schedule, it shall meet the requirements under these rules and specifications and standards applicable to it in the country of origin. [As per rule 39 of the Cosmetic Rules, 2020]

No cosmetic may purport or claim to purport or convey any idea which is false or misleading to the intending user. [As per rule 36 of the Cosmetic Rules, 2020]

**Indian regulatory requirements for labeling of cosmetics:**

The regulatory requirements for labeling of cosmetics in India are outlined under the Drugs and Cosmetics Rules, 1945. Typically, a cosmetic product would have labels on the container ("inner label"), an outer wrapper or box ("outer label"), and sometimes a leaflet containing instructions or additional information. As per the Cosmetics Rules the following declarations must appear on the label or labels specified. If the product has only a single label, all declarations must appear on that label.

**1) Mandatory Labeling Requirements****a) Both Inner and Outer Labels Must Include:**

- i) Name of the cosmetic product
- ii) Name and complete address of the manufacturer: Including the premises where the product was manufactured. If not owned by the manufacturer, include the actual manufacturer and/or country of origin (as "Made in...")
- iii) List of ingredients, present in concentration of more than one percent, shall be listed in the descending order of weight or volume at the time they are added, followed by those in concentration of less than or equal to one percent, in any order, and preceded by the words "INGREDIENTS"
- iv) Manufacturing Date: Month and year the product was manufactured, packed, or imported.

**b) Inner Label Only**

- i) List of Ingredients: In descending order of their percentage composition.
- ii) Warnings, Cautions, and Precautions: Adequate directions for safe use, including any special instructions.
- iii) Hazardous or Poisonous Ingredients: Names and quantities clearly stated.
- iv) Batch Number: Preceded by "B". (For soaps, use month and year of manufacture)
- v) Manufacturing License Number: Preceded by "M".
- vi) Additional Requirements like antidotes.

**2) Additional Requirements:**

- i) **Import Registration Certificate (IRC):** All imported cosmetics require an IRC issued by the Central Drugs Standard Control Organisation (CDSCO). The IRC number must be on the label.
  - ii) **India-Specific Labeling:** Any specific labeling requirements mandated by Indian authorities must be applied, potentially on stickers placed at bonded warehouses.
  - iii) **Language:** Labels can be in English or Hindi.
- 3) **Relaxations for Small Containers:** Containers of  $\leq 60$  ml (liquid) or  $\leq 30$  gm (solid/semi-solid) can omit:
- a) Manufacturer address (pin code and principal place of manufacture are sufficient )
  - b) Batch number
  - c) Ingredients list

**Components of cosmetic label:**

- **Name and Address of the Manufacturer/Importer:** The label must include the name and address of the manufacturer or the person or company responsible for placing the cosmetic product in the market.
- **Generic Name of the Product:** The label should contain the generic or common name of the cosmetic product. The use of misleading names or claims is typically prohibited.
- **List of Ingredients:** Cosmetics should have a list of ingredients used in their formulation. Ingredients must be listed in descending order of quantity. Fragrance and flavor may be listed as "perfume" or "flavor" without disclosing individual components.
- **Net Quantity:** The label must specify the net quantity of the product, usually in metric units (grams, milliliters, etc.).
- **Batch Number/Code:** A batch number or code should be provided to facilitate traceability in case of quality issues or recalls.
- **Manufacturing and Expiry Date:** The manufacturing date and the expiry date of the product should be mentioned. The shelf life is typically expressed in terms of months or years.
- **Instructions for Use:** If necessary, clear instructions for the safe and effective use of the product should be provided.
- **Precautions:** Any necessary precautions or warnings for use, storage, or handling of the product should be mentioned on the label.
- **Country of Origin:** The country of origin of the product should be mentioned.
- **Testing Information:** Information related to testing, such as "not tested on animals" or other relevant claims, should comply with applicable regulations.

**Regulatory Provisions for Importing Cosmetics into India:**

Importing cosmetics into India is governed by a comprehensive legal framework designed to ensure product safety, quality, and compliance with national standards. The primary legislations governing cosmetic imports are the **Drugs and Cosmetics Act, 1940** and the

**Cosmetics Rules, 2020.** These laws ensure that all cosmetic products entering the Indian market are safe for human use and meet stringent regulatory criteria.

Under Rule 12 of the Cosmetics Rules, 2020, **no cosmetic shall be imported into India unless it is registered** with the Central Licensing Authority (CLA), which functions under the **Central Drugs Standard Control Organisation (CDSCO)**. The CLA may also delegate its powers to any authorized officer under Rule 5(1) for the purpose of regulating cosmetic imports.

### 1. Registration of Imported Cosmetics

#### a) Mandatory Registration

All cosmetic products intended for import and sale in India must be registered with CDSCO. This registration is **mandatory** and applies regardless of the product's origin, whether from multinational brands or small-scale manufacturers. Each variant, shade, or formulation of a cosmetic product requires **individual registration**.

#### b) Application Procedure

To initiate the registration process, the importer or the authorized agent must submit **Form COS-1 (earlier known as Form 42)** to the CDSCO. This form must be accompanied by a set of detailed documents, including:

- A copy of the **Free Sale Certificate (FSC)** issued by the regulatory authority of the country of origin.
- Product details, including **ingredient list**, specifications, intended use, and shelf life.
- Packaging and **label samples**.
- Undertaking regarding **compliance with Indian cosmetic regulations**.
- **Power of Attorney** from the manufacturer, if the applicant is an authorized agent.

The applicant must also provide a **Product Information File (PIF)** containing safety and efficacy data, wherever applicable.

#### c) Registration Fees

The CDSCO charges registration fees based on the number and category of products. Typically, the fee structure includes:

- **USD 250 per brand**
- **USD 1,000 per variant** (such as different shades or formulations)

The fees are subject to change as per government notifications and must be submitted via authorized payment channels.

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## 2. Import Requirements

### a) Import Authorization

While a specific import license is not required for general cosmetic products, **product registration itself acts as the primary authorization** for import. Once registered, the product can be imported through any authorized port, provided all accompanying documentation is in place.

### b) Special Import Licenses

Although most cosmetics do not require a separate import license, certain **cosmetic ingredients listed in Schedule M** of the Drugs and Cosmetics Rules, 1945 may fall under restricted categories. In such cases, a specific import license may be needed.

### c) Import Duties and Taxes

Imported cosmetics are subject to **customs duties and taxes** under the **Customs Tariff Act**.

The applicable duty varies based on:

- HS code (Harmonized System code)
- fProduct category (e.g., skincare, haircare, color cosmetics)
- Material composition (e.g., alcohol-based, water-based)

In addition to **Basic Customs Duty (BCD)**, other applicable levies may include **Integrated GST (IGST)**, **Social Welfare Surcharge**, and **Countervailing Duty**, if applicable.

## 3. Labeling Requirements

### a) Regulatory Compliance

Imported cosmetics must strictly adhere to the **labeling guidelines as per the Cosmetics Rules, 2020**. Non-compliance can lead to refusal of import, seizure of goods, or legal penalties.

### b) Mandatory Labeling Information

Each cosmetic product must bear the following information on its label:

- Name of the product
- **Name and address of the manufacturer**
- **Net contents** (weight/volume)
- Batch number and **manufacture/expiry date**
- **List of ingredients** in descending order of concentration
- **Directions for use**
- **Any necessary warnings or precautions**

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For imported products, the label must also include:

- Name and address of the **importer**
- **Import Registration Certificate (IRC) number** issued by CDSCO
- Country of origin

If the original label does not contain this information, an **additional label (sticker)** with compliant details must be affixed before import clearance.

#### 4. Other Regulatory Provisions

##### a) Animal Testing Ban

India has imposed a complete **ban on animal testing for cosmetics**, both for domestic production and imported goods. As per the guidelines issued by CDSCO, any cosmetic tested on animals after a specific cut-off date is **not allowed** to be sold or imported into India.

Importers must provide declarations and evidence to show that the products are **cruelty-free** and comply with India's **ethical sourcing policies**.

##### b) Quality and Safety Standards

All imported cosmetics must meet the **quality standards specified by the Bureau of Indian Standards (BIS)**, where applicable. While not all cosmetic categories currently have mandatory BIS standards, many critical products such as **sunscreens, skin creams, and hair dyes** are required to conform to **specific BIS guidelines**.

The CLA may also inspect products post-import and test random samples to ensure quality, consistency, and safety.

#### 5. Post-Market Surveillance and Penalties

Even after successful import and sale, cosmetics remain under the purview of regulatory surveillance. CDSCO conducts **random testing**, market checks, and compliance verification.

Non-compliant products may be recalled, banned, or penalized.

Violations may attract penalties including:

- Cancellation of registration certificate
- Confiscation of stock
- Fines and prosecution under the Drugs and Cosmetics Act

### CHAPTER III IMPORT AND REGISTRATION

- 12. Import of cosmetics.**— (1) No cosmetic shall be imported into India unless the product has been registered in accordance with these rules by the Central Licensing Authority or by any officer to whom such powers may be delegated under sub-rule (1) of rule 5.
- (2) An application for registration of a cosmetic product intended to be imported into India shall be made through the online portal of the Central Government in Form COS-1 either by the manufacturer himself or by his authorised agent or the importer in India or by the subsidiary in India authorised by the manufacturer.
- (3) An authorisation by the manufacturer to his agent in India shall be duly authenticated either in India before a first class Magistrate or in the country of origin before the authority competent under the laws of that country or by an authority specified in the First Schedule.
- (4) The applicant referred to sub-rule (2) above shall furnish along with the application such other information and documents as specified in Part I of the Second Schedule:
- Provided also that in the event of application for import of bulk finished formulation ready to fill, the following additional documents shall also required to be furnished:
- a valid manufacturing license for the finished formulation of the cosmetic ready to fill in finished form from the State Licensing Authority; and
  - details of registered brand owner of the finished product in India;
- (5) The application for registration in accordance with sub-rule (2) shall be accompanied by a copy of the receipt of fee having been deposited as specified in Third Schedule.
- (6) The fee shall be such for each category of cosmetic along with each manufacturing site with additional fee for each category of cosmetic and variant specified in the Fourth Schedule.
- (7) Till such time, the online portal becomes operational for this purpose, offline application in Form COS- 1 may be made either by the manufacturer himself or by his authorised agent or by the importer in India or by the subsidiary in India authorised by the manufacturer for registration of a cosmetic referred to in sub-rule (1).
- (8) The applicant shall be liable to pay testing fees directly to the testing Laboratory approved by the Central Government referred in rule 11, for examination, test and analysis of imported cosmetics in respect of cosmetics identified for such examination as specified in the Fifth Schedule.
- (9) The applicant shall pay the fee as specified in the Third Schedule in connection with the expenditure to be incurred for inspecting or visiting the manufacturing premises of cosmetics approved in the foreign countries by officers authorised by Central Licensing Authority, as considered necessary.

### Regulatory Provisions Relating to Misbranded and Spurious Cosmetics in India:

The Indian regulations classify both misbranded and spurious cosmetics as adulterated under the Drugs and Cosmetics Act, 1940 (DCA) and the Cosmetics Rules, 2020.

### Misbranded Cosmetics:







### Spurious Cosmetics:

**Definition:** A cosmetic is considered spurious under Section 17D of the DCA if it:

- Is an imitation of a genuine cosmetic that bears a false trade mark or brand name.
- Does not contain the ingredients mentioned on the label.
- Uses contaminated or inferior quality ingredients.

Spurious cosmetics are products that are falsely manufactured or deliberately mislabelled to mislead consumers. These products are often presented as popular, high-end brands or local herbal solutions, but in reality, they contain harmful, substandard, or banned ingredients. Unlike genuine cosmetic products, which undergo rigorous safety, stability, and quality checks, spurious cosmetics are produced without any regulatory oversight, putting users at risk of severe health consequences.



In India, the issue of spurious cosmetics is growing at an alarming rate. With the rise of e-commerce platforms, social media marketplaces, and unregulated local vendors, counterfeit and unauthorized cosmetic products have found easy access to consumers. These products are often attractively packaged to mimic internationally reputed brands like MAC, Huda Beauty, or Kylie Cosmetics, and sold at unbelievably low prices to lure unsuspecting buyers. Additionally, fairness creams, whitening products, and herbal formulations such as Faiza

Beauty Cream and Golden Pearl Whitening Cream are circulated without proper testing and often contain banned substances like mercury, hydroquinone, or high-potency corticosteroids. The health risks posed by such cosmetics are serious and often irreversible. Users may experience allergic reactions, skin burns, pigmentation, hormonal imbalances, or even systemic toxicity due to long-term use. In some cases, ingredients like mercury can accumulate in the body and affect the kidneys and nervous system. The use of steroid-based creams without medical supervision can cause skin thinning, redness, acne, and permanent damage to the skin barrier.

From a regulatory and industry perspective, spurious cosmetics damage the reputation of authentic brands, erode consumer trust, and create unfair competition in the market. Small-scale manufacturers that comply with safety norms find it difficult to compete with the low-cost, low-quality products that flood the market. Furthermore, the presence of such counterfeit goods violates multiple sections of the Drugs and Cosmetics Act, 1940, and the Bureau of Indian Standards (BIS) norms.

Authorities such as the Central Drugs Standard Control Organization (CDSCO) and state-level Food and Drug Administrations (FDAs) routinely conduct raids and seize counterfeit cosmetic products. However, the enforcement is often limited due to the widespread nature of this problem and the rapid evolution of illegal manufacturing practices. Greater public awareness, stricter digital platform regulation, and consumer vigilance are essential to curb this menace. Consumers must be cautious while purchasing cosmetic products. Buying only from authorized dealers, checking for proper labeling, manufacturing details, batch numbers, expiry dates, and ISI marks can help avoid the use of spurious items. If the price of a branded product seems too good to be true, it probably is.

**Examples:**

- Counterfeit products that mimic the packaging and brand names of established brands.
- Cosmetics containing unlisted hazardous ingredients that could pose health risks.

Manufacturing, selling, or distributing misbranded or spurious cosmetics is an offense under the DCA and can lead to:

Imprisonment: Up to 7 years for non-fatal cases and life imprisonment for causing death.

Fine: Up to three times the value of the adulterated cosmetic or ₹3 lakhs, whichever is greater.

Confiscation: Seizing and destroying the adulterated cosmetics.

Enforcement:

The CDSCO (Central Drugs Standard Control Organisation) is responsible for enforcing the regulations related to misbranded and spurious cosmetics. They conduct inspections, analyze samples, and take legal action against violators.

### **Regulatory Provisions for Obtaining a Cosmetics Manufacturing License in India:**

The production of cosmetics in India is governed by the Drugs and Cosmetics Act, 1940 (DCA) and the Cosmetics Rules, 2020. To obtain a license for manufacturing cosmetics, applicants must adhere to specific conditions:

#### **Eligibility:**

- Legal Entity: The applicant must be a legally established entity, such as a sole proprietorship, partnership, or company.
- Premises: The manufacturing facility must meet specific requirements related to:
  - Location: Not excessively close to sources of pollution or toxic materials.
  - Space: Adequate space for manufacturing, quality control, storage of raw materials, finished products, and packaging materials.
  - Hygiene: Clean and hygienic environment to prevent contamination.
  - Utilities: Proper water supply, sanitation, and drainage facilities.
- Technical Personnel: The applicant must have qualified technical personnel with relevant experience and expertise in cosmetics manufacturing.
- Manufacturing Equipment: Appropriate machinery and equipment for the intended cosmetic production.
- Testing Facilities: Adequate testing facilities are needed to ensure the quality and safety of raw materials and finished products.

#### **Licensing Process:**

- ✓ Application: The applicant must submit an application (Form 31) to the Licensing Authority, typically the State Drugs Controller of the concerned state.
- ✓ Documents Required: The application should be accompanied by various documents, including:
  - ✓ Layout plan of the factory premises
  - ✓ List of equipment and machinery installed
  - ✓ Details of the constitution of the firm
  - ✓ Proof of possession of the premises
  - ✓ Documents establishing the qualifications of technical personnel

- ✓ Fees as prescribed by the regulations
- ✓ Inspection: Once the application and documents are verified, the Licensing Authority will inspect the manufacturing facility to ensure compliance with the regulations.
- ✓ License Grant: Upon successful inspection and fulfilling all conditions, the Licensing Authority will grant the manufacturing license (Form 32).

**Additional Requirements:**

- Compliance with Good Manufacturing Practices (GMP): Manufacturers must follow the established GMP guidelines for cosmetics production.
- Product Registration: Each cosmetic product manufactured requires registration with the CDSCO before being placed on the market.
- Record-Keeping: Maintaining accurate records of manufacturing processes, raw materials, finished products, and quality control procedures is essential.

**Regulatory provisions relating to manufacture of cosmetics– prohibition of manufacture and sale of certain cosmetics,****Prohibition on manufacturing and selling certain cosmetics:**

The prohibition on manufacturing and selling certain cosmetics in India is outlined in Section 18 of the Drugs and Cosmetics Act, 1940 (DCA).

**Prohibited Ingredients:**

Schedule S of the DCA lists specific ingredients that are explicitly banned for use in cosmetics in India. This list includes substances known to be harmful or pose potential health risks, such as:

- Heavy metals like mercury, arsenic, lead, and cadmium.,
- Certain dyes and pigments like coal tar derivatives and p-Phenylenediamine (except for hair coloring products at permitted concentrations).
- Certain preservatives like formaldehyde and formaldehyde-releasing agents.
- Certain sunscreens like oxybenzone and octinoxate (proposed ban, not yet officially implemented).

**Other Prohibited Practices:**

- Using harmful or poisonous substances not explicitly listed in Schedule S but nonetheless considered hazardous to human health. Manufacturing cosmetics containing contaminants like microorganisms, heavy metals, or other harmful substances exceeding the permissible limits.
- Selling or distributing misbranded or spurious cosmetics as defined earlier.

**Enforcement:1**

The Central Drugs Standard Control Organisation (CDSCO) and State Drugs Controllers are responsible for enforcing these prohibitions.

They have the authority to:

- ✓ Conduct inspections of manufacturing facilities.
- ✓ Analyze samples of cosmetics.
- ✓ Take legal action against violators.

**Penalties:**

Manufacturing, selling, or distributing prohibited cosmetics is an offense under the DCA and can lead to,

- Imprisonment: Up to 3 years or a fine, or both.
- Enhanced penalties: In case of a subsequent offense, imprisonment can extend up to 7 years, and the fine can be significantly increased.
- Confiscation: Seizing and destroying the prohibited cosmetics.

**loan license:**

The concept of a "loan license" in the strict sense doesn't exist in the Indian regulatory framework for cosmetics manufacturing. There's a provision that allows contract manufacturing through Form 31A.

**Contract Manufacturing and Form 31A:**

Form 31A: This form allows manufacturers to apply for an additional license to use the premises of another licensed manufacturer for specific production activities related to their own cosmetics.

**Process:**

- A manufacturer (Company A) seeking to utilize another manufacturer's (Company B) facility can apply for Form 31A.
- Company B must hold a valid manufacturing license (Form 32) for its own products.
- Form 31A needs to clearly define the specific production activities that Company A intends to conduct at Company B's premises.

**Benefits:** This provision allows companies to:

- Utilize existing infrastructure: Contract manufacturing can be a cost-effective option for companies lacking their own production facilities.
- Focus on specific expertise: Companies can leverage the expertise of other manufacturers for specific product types or production stages.

**Important Points:**

- Compliance Responsibilities: Both companies involved (Company A and B) remain responsible for adhering to relevant regulations and GMP guidelines.
- Clear Agreements and Documentation: A clear agreement between the two companies outlining the terms, responsibilities, and quality control procedures is crucial.

- Licensing Authority Approval: Ultimately, the Licensing Authority has the discretion to grant or deny the Form 31A application based on specific circumstances and compliance considerations.

### Process Flow for Form 31A Approval

Step	Action Required	Responsible Party	Considerations
<b>Agreement</b>	Company A (brand owner) and Company B (contract manufacturer) sign a <b>contract manufacturing agreement</b> .	Company A & Company B	<ul style="list-style-type: none"> <li>• Define scope: Specific products, processes (e.g., filling, packaging).</li> </ul> Ensure Company B's Form 32 license covers the intended product category.
<b>Application Submission</b>	Company A submits <b>Form 31A</b> to the <b>State Licensing Authority (SLA)</b> where Company B's facility is located.	Company A	Attach: <ul style="list-style-type: none"> <li>- Copy of Company A's Form 32 license.</li> <li>- Company B's Form 32 license.</li> <li>- Site Master File of Company B.</li> <li>- Contract agreement (stamping fees may apply).</li> </ul>
<b>3. Inspection</b>	SLA inspects <b>Company B's facility</b> to verify: <ul style="list-style-type: none"> <li>- GMP compliance.</li> <li>- Infrastructure for the contracted work.</li> <li>- Quality control systems.</li> </ul>	SLA (State Drugs Control)	<ul style="list-style-type: none"> <li>- Non-compliance leads to rejection.</li> <li>- Company B must allow access to all relevant areas.</li> </ul>
<b>4. Approval</b>	SLA grants <b>Form 31A approval</b> if compliant.	SLA	<ul style="list-style-type: none"> <li>- Approval is <b>product-specific</b>.</li> <li>- Validity aligns with Company A's Form 32 license (renewal required periodically).</li> </ul>
<b>5. Production Start</b>	Company A can now manufacture its products at Company B's facility <b>under its own brand name</b> .	Company A & Company B	<ul style="list-style-type: none"> <li>- <b>Labeling:</b> Must show Company A's license number (not Company B's).</li> <li>- <b>Records:</b> Both parties maintain separate batch records.</li> </ul>
<b>6. Ongoing Compliance</b>	Regular audits by Company A and SLA inspections.	Company A (primary liability)	<ul style="list-style-type: none"> <li>- SLA can suspend Form 31A if:               <ul style="list-style-type: none"> <li>- Company B violates GMP.</li> <li>- Company A fails quality checks</li> </ul> </li> </ul>

### Cosmetics Licenses in India: Form 31 vs. Form 32 vs. Form 31A

Form 31 (Manufacturing License)	Form 32 (Loan License)	Form 31A (Contract Agreement)
To <b>manufacture</b> cosmetics in <b>your own factory</b>	To <b>sell</b> cosmetics <b>without manufacturing</b> (brand ownership)	To <b>legally outsource production</b> to another manufacturer
Factories producing cosmetics (e.g., "ABC Cosmetics Ltd.")	Brands <b>without manufacturing capability</b> (e.g., "GlamBoss Cosmetics")	<b>Both parties</b> when outsourcing production
Required to have GMP-compliant facility	Requires <b>either</b> : 1. Form 31 (if self-manufacturing) 2. Form 31A (if outsourcing)	Requires <b>both</b> : 1. Your Form 32 2. Contractor's Form 31
Can manufacture	Cannot manufacture alone (Must pair with Form 31 or 31A)	Enables production <b>via contractor</b>
"Manufactured by [Your Company]"	If outsourcing: "Manufactured <b>for</b> [Your Brand] <b>by</b> [Contractor]"	Must reference contractor's license
Full responsibility for production	Full responsibility <b>even if outsourcing</b>	Defines shared compliance duties
"L'Oréal's Pune factory"	"Fenty Beauty India" (if outsourcing)	Agreement between Fenty and L'Oréal