SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES

Affiliated To The Tamil Nadu Dr. MGR Medical University, Chennai

Approved by Pharmacy Council of India, New Delhi.

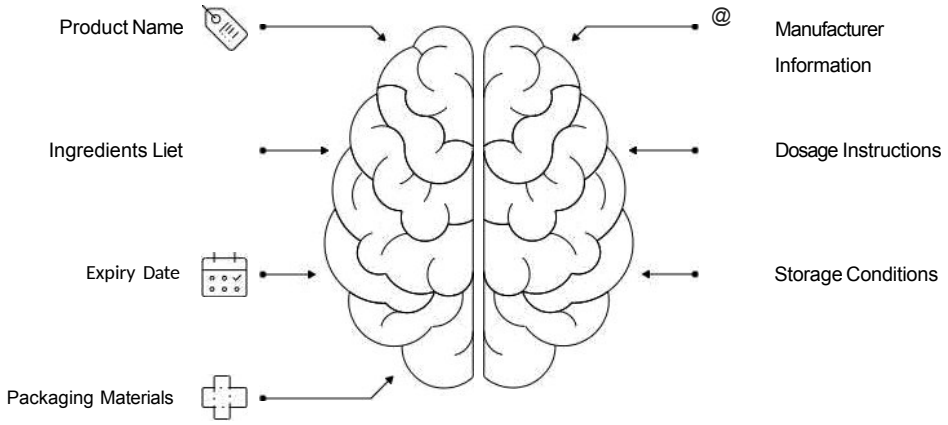
Coimbatore -641035

COURSE NAME : PHARMACEUTICAL JURISPRUDENCE (BP 505 T)

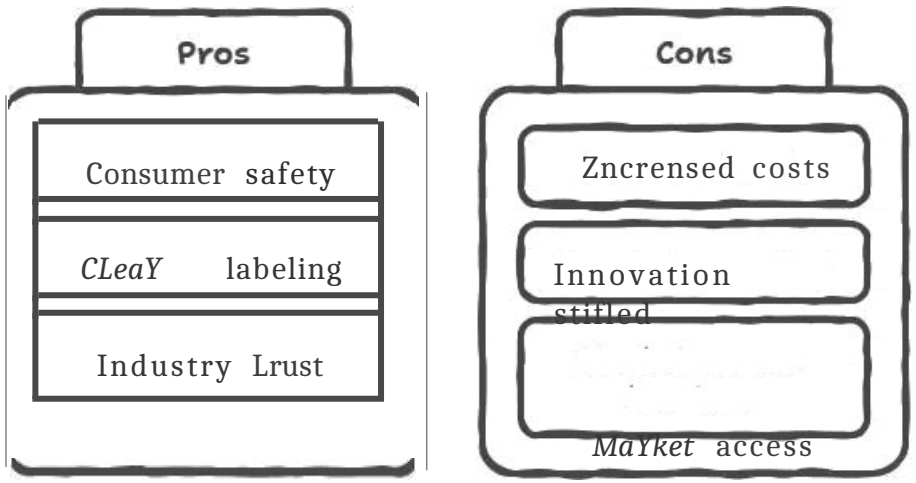
V SEM / III YEAR

UNIT 1 : DRUGS AND COSMETIC ACT, 1940 AND its rules 1945:

Comprehensive Drug and Cosmetic Labeling



Cosmetic regulations



Comprehensive Guidelines for Clinical Trials

Ethical Review

Ensures triajs.adhere tó ethical standards

Informed Content

Prótects.participants' rights through clear agreemerrt

Data Management

Maintaihsdata Integrity ai›d

Adverse Event Reporting

Mü.nitors and.reports.s.efety issues

Comparison of Oxug and

Cosrnatic Buses

Characteristi c	Conditions	Requirements
.Storage end .Sole.	Maintain quality, prevent deterioration	Prescription, :record m‹xi+ite«az\ce
Import and Export	Réyistration, documentation, inspection	Specified procedures

Comprehensive Product Labeling and Packaging

Oxug send Cosmetic Licansing

ound f¥tanufacLU¥'in@ RUINS

What do the Rules specir¿ regzxrding licensing?

They ouLtine. procedures for obtzxining ticanses for manufacturing, ¡zvtporting, selling, and distnbvGn druqsDnd cosrneLiñs, cs we((ozs. conditions for

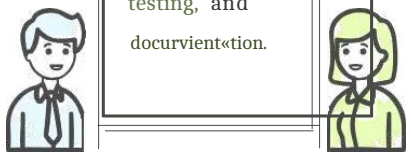
YertewiA , suspending, and gancelir\g ticensés.

Wh‹xt do the Rules prescribe for manufacturing?

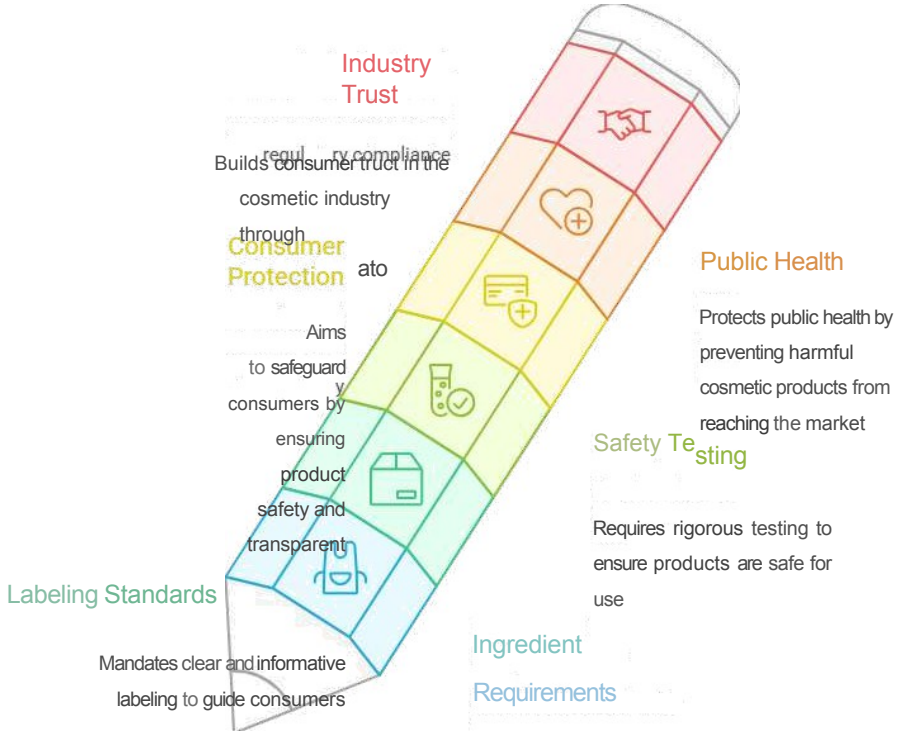
They prescribe requirefiients

‹nonufocLuring prerr ises, époiprnent, personnel and processes along with sLortdords for qo‹xlity control, testing, and

docurvient«tion.



Ensuring Cosmetic Safety and Trust



Industry Trust

regul ry compliance

Builds consumer truct in the cosmetic industry through

Consumer Protection

ato

Aims to safeguard y consumers by ensuring product safety and transparent

Labeling Standards

Mandates clear and informative labeling to guide consumers

Public Health

Protects public health by preventing harmful cosmetic products from reaching the market

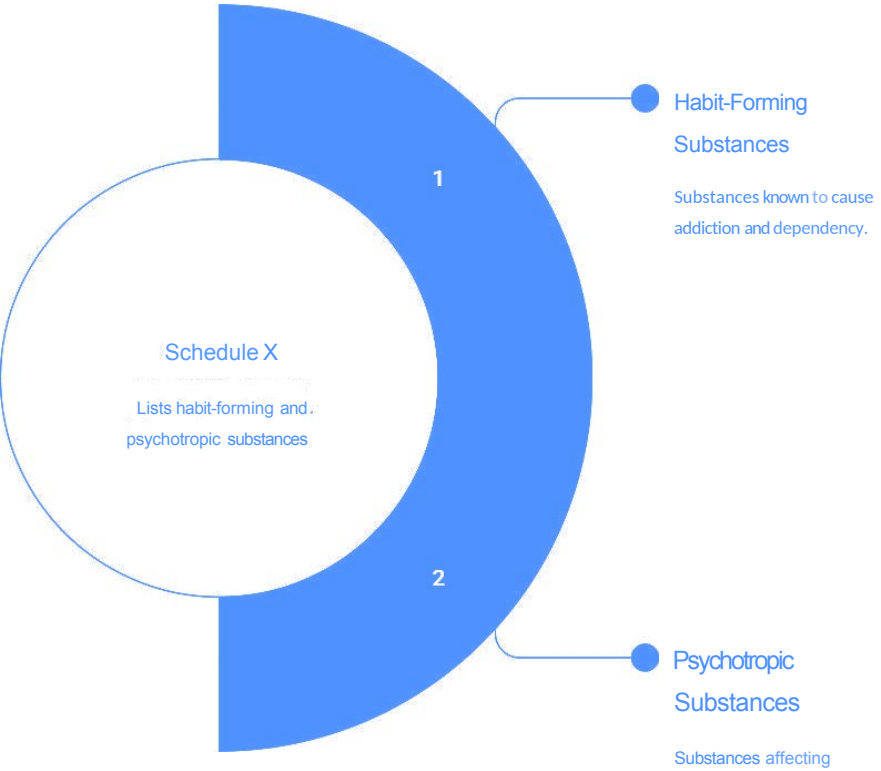
Safety Testing

Requires rigorous testing to ensure products are safe for use

Ingredient Requirements

Specifies the permissible and prohibited ingredients in cosmetics

Unveiling Schedule X: Habit-Forming and Psychotropic Substances



Habit-Forming Substances

Substances known to cause addiction and dependency.

Psychotropic Substances

Substances affecting mental state and behavior.

Schedule Y Clinical Trial Cycle

Define Trial Criteria

ESI tblish clear guidelines for trial design.

Conduct Clinical Trials

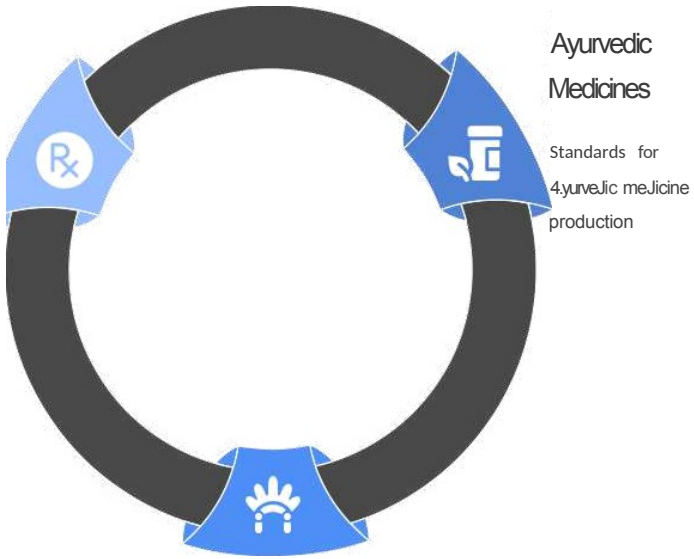
Execute trials according to defined protocols.

Evaluate Trial Results

Analyze data to assess drug efficacy and safety.

Grant approval for drugs meeting safety and efficacy standards.

GMP Standards for Traditional Medicines



Un
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Medicines

Regulations for
Unani medicine
preparation

Ayurvedic
Medicines

Standards for
4.yurveJic meJicine
production

Siddha
Medicines

Guiclelines for
Siddha i edicine
mai1›ufacturing

Classes of Drugs and Cosmetics Prohibited from Import

Understanding the regulatory landscape for safe trade and consumer protection.

Why Import Restrictions Matter

Public Health Protection

Prevent the entry of unsafe, adulterated, or misbranded products that could cause consumer harm.

Regulatory Compliance

Ensure all imported goods adhere to stringent domestic and international regulatory standards, such as those set by the FDA.

Prevent Misclassification

Stop unapproved drugs from entering the market disguised as less-regulated cosmetic products, bypassing safety checks.

Regulatory Authorities & Frameworks

A coordinated effort among global agencies establishes the framework for safe imports.

U.S. FDA

Enforces the Federal Food, Drug, and Cosmetic Act (FD&C Act), setting the primary standards for product safety and labeling.

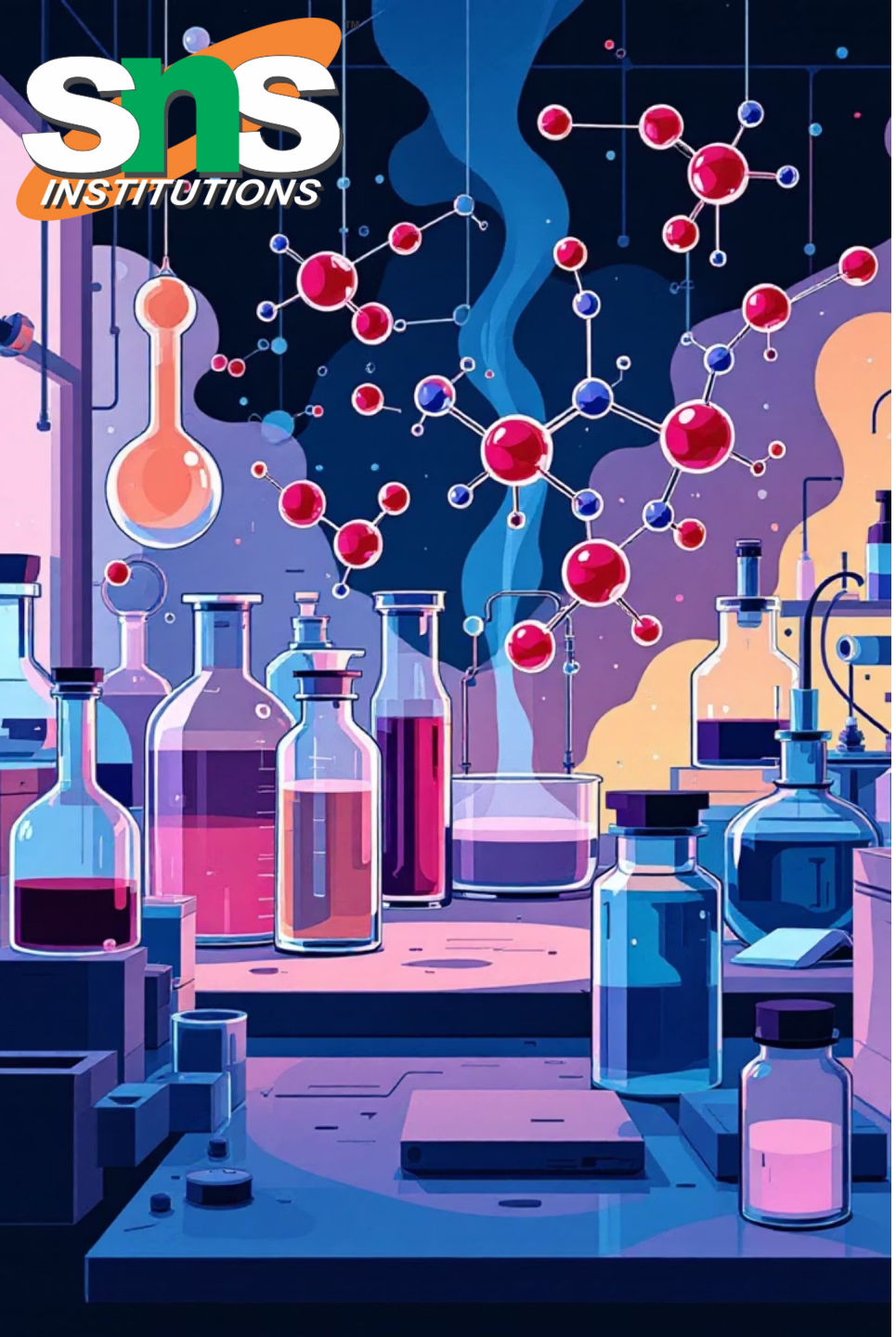
Customs and Border Protection (CBP)

Collaborates with the FDA to conduct physical inspections and implement import detentions at ports of entry.

Global Oversight

Frameworks like India’s Cosmetics (Amendment) Rules, 2025, strengthen international scrutiny, pushing for global coordination to combat counterfeit goods.

International regulatory bodies are increasingly aligning standards to enhance global supply chain security.



Prohibited Drug Classes for Import

Importation of certain drug substances is strictly banned due to their high potential for abuse and severe health risks.

Synthetic Opioids & Analogs

Includes dangerous substances like benzoylbenzylfentanyl and benzylfuranylfentanyl, known for extreme potency and overdose risk.

Designer Stimulants

Novel psychoactive substances like 3-chloromethcathinone and fluorodeschloroketamine, often marketed misleadingly.

Controlled Precursors

Chemicals such as PMK glycidic acid and its esters, essential for the illicit manufacture of controlled substances.

Emerging Narcotics

Highly potent, newly synthesized nitazene derivatives, including methylenedioxynitazene and metodesnitazene.

Prohibited Cosmetic Ingredients

Safety regulations prohibit the use of ingredients proven to be toxic, carcinogenic, or harmful in cosmetic formulations.

- **Toxic Metals:** Mercury compounds and bithionol are banned due to heavy metal toxicity and neurotoxicity concerns.
- **Carcinogens:** Chemicals like vinyl chloride and halogenated salicylanilides are prohibited.

- **Aerosol Risks:** Zirconium complexes are banned in aerosol products due to their potential link to serious lung disease.
- **Solvents & Propellants:** Chloroform, methylene chloride, and chlorofluorocarbon propellants (CFCs) are restricted due to toxicity and environmental impact.

Nail Product Alert: Methyl methacrylate monomer is banned in artificial nail products due to instances of severe, permanent finger and nail injuries.

Misclassification Risks: Drugs Masquerading as Cosmetics

Products making therapeutic claims but marketed as cosmetics face strict import refusal by the FDA.

Deceptive Labeling

FDA actively rejects imports where manufacturers attempt to mislabel unapproved drugs to circumvent rigorous drug approval processes.

Toxin Examples

Unapproved botulinum toxin (Botox) products marketed online pose a serious public health threat, including the risk of botulism.

Enforcement Outcomes

Recent FDA actions, including 89 refused batches, demonstrate the high rate of import refusals and mandated product destruction for misclassification.

Labeling and Compliance Requirements

Clear, accurate labeling is non-negotiable for market entry and consumer safety.

Truthful English Labels

All imported cosmetics must feature labels in English that are accurate and devoid of any unproven medical or drug claims.

No Drug Claims

Any product with claims to treat, mitigate, or prevent disease will automatically be regulated as an unapproved drug, not a cosmetic.

Ingredient Disclosure

Accurate disclosure of all ingredients and certification for all color additives are mandatory requirements for compliance.

Recent Enforcement Highlights (2025)

U.S. FDA Actions

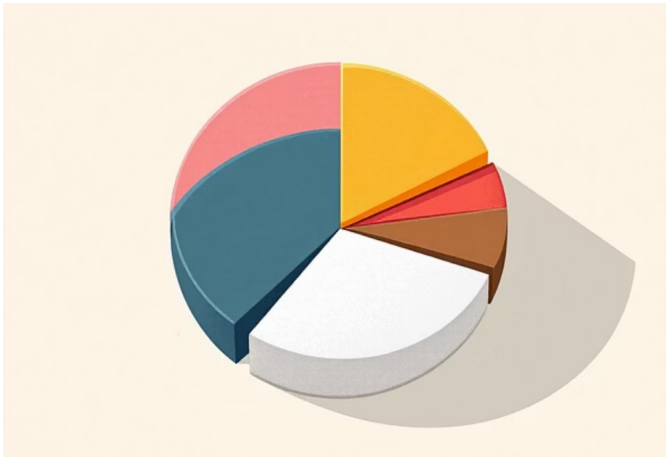
- Issued 18 warning letters targeting the illegal online marketing and sale of unapproved botulinum toxins.
- Over 89 imported cosmetic batches were detained and rejected in a single month (May 2025) for regulatory violations.

Global Shifts

- India’s 2025 Cosmetics Amendment Rules impose stricter demands for licensing, mandatory testing, and comprehensive record-keeping.
- The elimination of the de minimis import exemption has increased scrutiny on nearly all low-value international shipments.

Visualizing the Impact: Import Refusal Data

Analysis of recent FDA import alerts reveals key areas of non-compliance and product rejection trends.



21%

Rejections from India

India accounts for the largest share (21%) of rejected cosmetic batches, indicating challenges in meeting U.S. standards.

28%

Skin Care Leads

Skin care products are the most frequently rejected category, followed by hair preparations and other general cosmetics.

Conclusion: Ensuring Safe Imports for Consumer Protection

Proactive Compliance is Key to Market Access

Strict import prohibitions on dangerous drugs and harmful cosmetic ingredients are the foundation of consumer health safety. Importers must prioritize ongoing vigilance and stay proactive regarding evolving global regulations to avoid costly refusals and protect brand integrity worldwide.