



Drug & Cosmetic Act 1940 & Rules 1945

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Objective



- The D&C Act was passed in 1940 (10th April 1940), with the main object to
 - Import,
 - Manufacture,
 - Distribution &
 - Sale of drug & cosmetics.
- The act regulates the import of drugs in India, so that no substandard or spurious drug will enter into our country.
- The act prohibits the manufacture of substandard or spurious drug in the country.
- The act provide for the control over the sale & distribution of drugs by only trained & qualified persons.
- The act also provide for the control over the manufacture, sale & distribution of Ayurvedic, Siddha, Unani & Homeopathic drugs.

Objective (cont.)

- Certain provisions of the act regulates the import, manufacture, sale & distribution of cosmetics.
- To have regular inspection of licensed premises by drug inspectors.
- To have control over the standards of drugs & cosmetics by taking samples & analyzing them at approved laboratories.
- To provide special provisions to regulate the preparation, standardization & storage of biological & special products.
- To prescribe the manner of labeling & packing of the various classes of drugs & cosmetics.



Chapters of the act



- **Chapter I:** Introduction & Definitions
- **Chapter II:** DTAB, DCC, CDL
- **Chapter III:** Import of drugs & Cosmetics
- **Chapter IV:** Manufacture, Sale & distribution of drugs & cosmetics
- **Chapter IVA:** Provisions relating to Ayurvedic, Siddha & Unani drugs.
- **Chapter V:** Miscellaneous



Definitions



Drug



“drug” includes—

- All medicines for **internal or external** use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any **disease or disorder** in **human beings or animals**, including preparations applied on human body for the purpose of repelling insects like mosquitoes;
- Such substances (other than food) intended to affect the structure or any function of human body or intended to be used for the destruction of (vermin) or insects which cause disease in human beings or animals,
- All substances intended for use as components of a drug including empty gelatin capsules; and
- Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals,

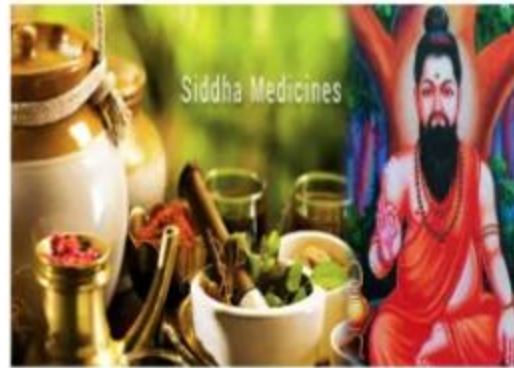
Cosmetic

- “cosmetic” means 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



Ayurvedic, Siddha, or Unani drug

➤ Includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha and Unani systems of medicine, specified in the First Schedule.



Standards of quality:

➤ Standards of quality in relation to a drug means that the drug complies with the standard set out in the Second Schedule and in relation to a cosmetic that the cosmetic complies with such standards as may be prescribed.



Misbranded drugs:

A drug shall be deemed to be misbranded—

- (a) if it is **so coloured, coated, powdered or polished** that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or
- (b) if it is **not labelled in the prescribed manner**; or
- (c) if its **label or container or anything** accompanying the drug bears **any statement, design or device** which makes any false claim for the drug or which is false or misleading in any particular.

FAKE



REAL



This counterfeit Botox used the wrong name for the active ingredient.

Look for a holographic image with the maker's name, in this case, Allergan.

FAKE



REAL



Authentic



Fake



CAN YOU TELL WHICH MEDICINE IS FAKE?



Authentic



Fake



CAN YOU TELL WHICH MEDICINE IS FAKE?



Misbranded cosmetic:

A cosmetic shall be deemed to be misbranded—

- If it contains a **colour which is not prescribed**; or
- If it is **not labelled in a prescribed manner**; or
- If the **label or container or anything** accompanying the cosmetic bears any statement which is false or misleading in any particular.

