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Coloring pharmaceuticals

- They are used in pharmaceutical preparations for **esthetics**
- Mostly synthetic.
- Few are obtained from natural mineral and plant sources.

Example: red ferric oxide is mixed in small proportions with zinc oxide powder to give calamine its characteristic pink color

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- About 90% of the dyes used in the products FDA regulates are synthesized from a single colorless derivative of benzene called aniline.

Classification of colorants according to their approved use:

- **FD&C color additives**,
  - Which may be used in foods, drugs, and cosmetics
- **D&C color additives**,
  - some of which are approved for use in drugs, some in cosmetics, and some in medical devices
- **External D&C color additives**,
  - the use of which is restricted to external parts of the body,
  - not including the lips or any other body surface covered by mucous membrane.

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Safety of colorants

- In USA, a study is carried out to evaluate toxicity and carcinogenicity of food additives.
- The study involves evaluating safety of colorants on animals

Colorant safety

According to the availability of evidence, colorants are categorized to:

a. "clear evidence" of carcinogenic activity
b. "some evidence"
c. "equivocal evidence" indicating uncertainty
d. "no evidence," indicating no observable effect.
e. "inadequate study" for studies that cannot be evaluated because of major flaws.

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Colorant safety

- This categorization is reviewed continually and some changes may be introduced including:

  - **Withdrawal of certification**
  - **Transfer of a colorant from one certification category to another**
  - **Addition of new colors to the list.**

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Amount of colorant

- A colorant should be added in exactly the same quantity each time the formulation is prepared,
- Otherwise the preparation would have a different appearance from batch to batch.
- This requires a high degree of skill.
- Amount of colorant generally added to liquid preparations ranges from 0.0005% to 0.001%.
- This depends upon:
  - the colorant
  - the depth of color desired.

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Dyes

- Dyes are potent colorants.
- Added in diluted solutions rather than dry powder.
- This permits greater accuracy in measurement and more consistent color production.

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Lake pigments

- An insoluble material that colors by dispersion.
- **An FD&C lake** is a pigment consisting of a substratum of aluminum hydroxide on which the dye is adsorbed or precipitated.
  - Having aluminum hydroxide as the substrate, the lakes are insoluble in nearly all solvents.

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Colorants for dosage forms

- Colored capsule shells are prepared with a capsule body of one color and a cap of a different color, resulting in a two-colored capsule.
- This is useful for identification.

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Colorants for dosage forms

- A larger percentage of dye (about 0.1%) is used for powders than that used for liquids.
- Sugar-coated tablets have been colored with syrup solutions containing varying amounts of the water-soluble dyes.

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Colorants for dosage forms

- Attractive film coating of tablets can be produced by spraying:
  - Aqueous solutions of dyes, or
  - Lakes dispersed in organic solvents

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Colorants for dosage forms

- For aqueous suspensions:
  - FD&C water-soluble colors or lakes may be satisfactory.
  - In other suspensions, FD&C lakes are necessary.
- Mostly, ointments, suppositories, ophthalmic and parenteral products assume the color of their ingredients and do not contain color additives.

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Considerations for colorants

- **Solubility**
  - Water soluble colorants
  - Oil soluble colorants
- **pH.**
  - Dyes can change color with a change in pH.
- To maintain their original colors, FD&C dyes must be protected from **oxidizing agents**, **reducing agents** **strong acids** and **alkalis**, and excessive **heating**.

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