

SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES

Coimbatore -641035

COURSE NAME : QCSH(BP 806 ET)

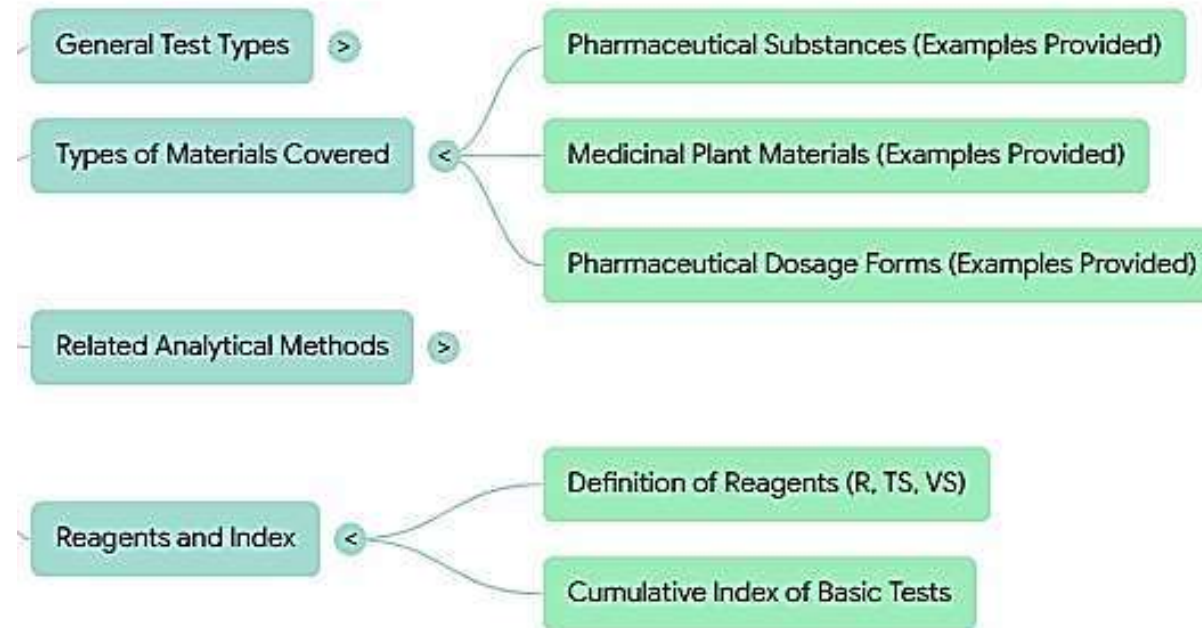
YEAR/SEM : VIII SEM

TOPIC 3 : PHARMACEUTICAL DOSAGE FORM

DESIGN THINKING IN QUALITY CONTROL OF PHARMACEUTICAL DOSAGE FORM

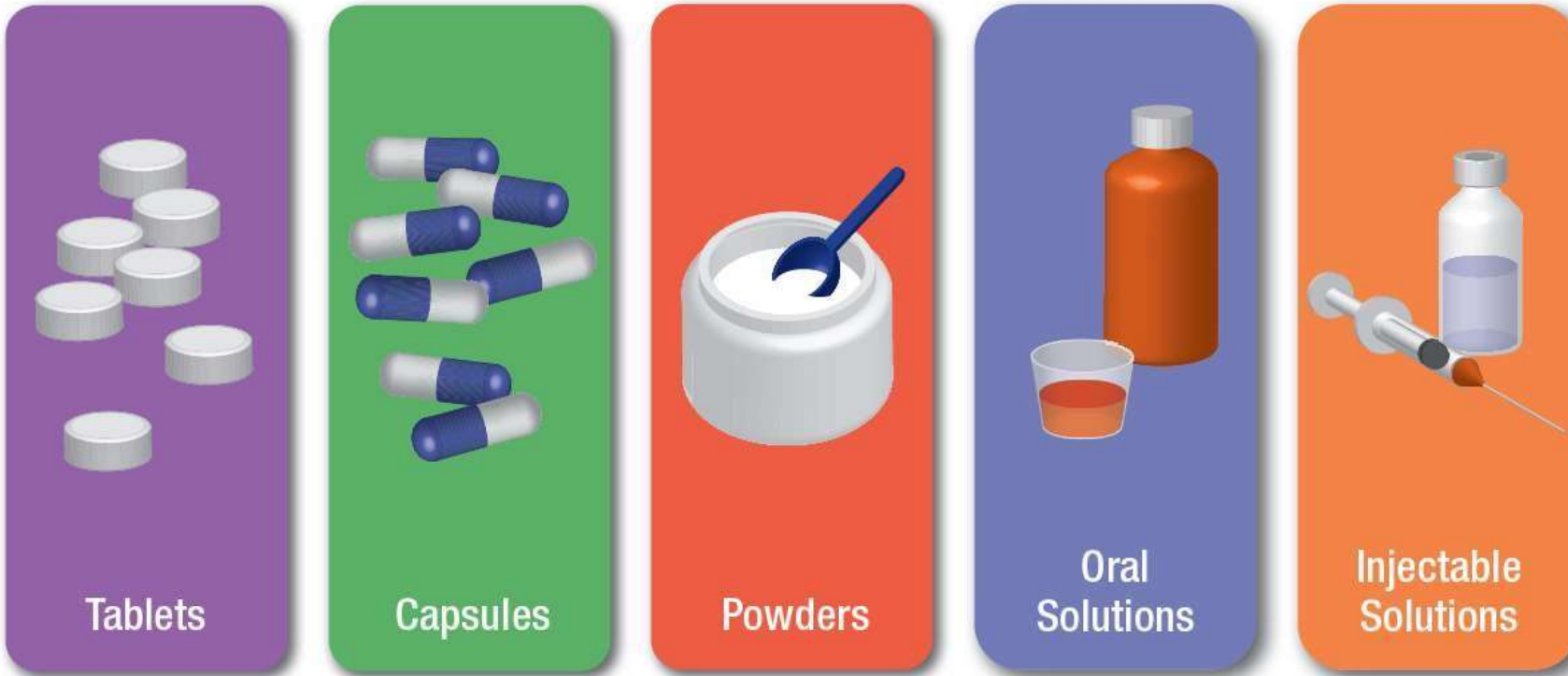
- **Empathize** Interview pharmacists and patients to identify dosage form issues
- **Define** Reframe problem: “Need standardized sample preparation and identity tests for diverse dosage forms.”
- **Prototype** Prepare test solutions
- **Test** Validate identity via physical description

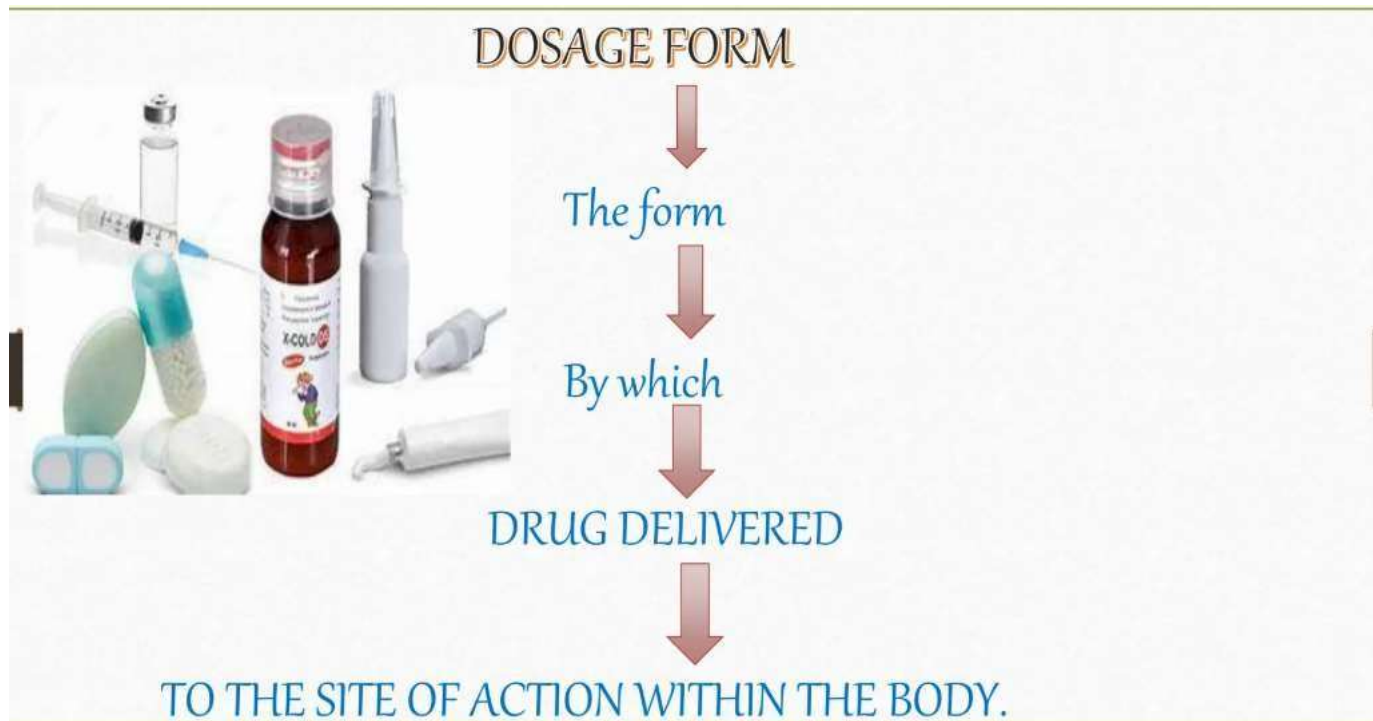
MIND MAP



BASIC TEST-DOSAGE FORMS

Dosage Form





CLASSIFICATION OF DOSAGE FORM

▪ Based on Route of Administration

- * Oral
- * Parenteral
- * Topical
- * Transdermal
- * Ophthalmic
- * Otic
- * Respiratory/inhaled
- * Rectal/Vaginal

▪ Based on Physical Form

- * Solids
- * Liquids
- * Semi-solids
- * Gases



TEST PROCEDURES FOR PHARMACEUTICAL DOSAGE FORMS

AZATHIOPRINE SODIUM POWDER FOR INJECTION



BARIUM SULFATE POWDER FOR SUSPENSION

Single dose bottle – For oral use only

Directions for use: Accurately measure 65 mL of water. Add the water to the E-Z-HD™ bottle and replace lid securely. Invert bottle and tap with fingers to mix contrast into the water. Shake vigorously for 30 seconds. Wait 5 minutes and then reshake thoroughly.

To use with a straw, remove adhesive label on top of cap. Remove cap and use straw to push out cap liner. Replace cap.

After reconstitution with 65 mL of water, each mL contains 2.38 g barium sulfate (approx. 140 mL)

Use immediately upon reconstitution. Discard any unused suspension.

DO NOT USE IF INNER SEAL IS BROKEN OR MISSING

rev. 12/21

DOUBLE CONTRAST UPPER GI STUDIES

 **Bracco Diagnostics**

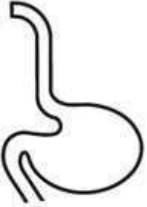
340 g NDC 32909-764-01

E-Z-HD™

(BARIUM SULFATE)

FOR ORAL SUSPENSION,

98% w/w



For Oral Use Only

Rx only

Manufactured by
E-Z-EM Canada Inc,
Anjou, Quebec H1J2Z4, Canada
for Bracco Diagnostics Inc.
Monroe Twp., NJ 08831

See prescribing information for complete dosage and administration information.

Store at USP controlled room temperature, 20 to 25°C (68 to 77°F).

Each bottle contains 334 g barium sulfate and the following inactive ingredients: Acacia, artificial cherry flavor, artificial strawberry flavor, carrageenan, citric acid, ethyl maltol, polysorbate 80, saccharin sodium, simethicone, sodium citrate, sorbitol.

 (01)10332909764019



LOT
EXP

 **C180704**

MAGNESIUM SULFATE POWDER



BENZATHINE BENZYL PENICILLIN POWDER FOR INJECTION



CALCIUM GLUCONATE INJECTION



CETRIMIDE CREAM



CHLORPROMAZINE HYDROCHLORIDE INJECTION



CIMETIDINE INJECTION



DEXTRAN 70 INJECTION



DIPHENHYDRAMINE HYDROCHLORIDE

TABLETS

Drug Facts

Active ingredient (in each caplet) Purpose
Diphenhydramine HCl 25 mgAntihistamine

Uses Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • itchy, watery eyes • itching of the nose and throat • sneezing

Warnings Do not use • with any other product containing Diphenhydramine, even one used on skin. • to make a child sleepy

Ask a doctor before use if you have • glaucoma • difficulty in urination due to enlargement of the prostate gland • a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product • marked drowsiness may occur • avoid alcoholic drinks • alcohol, sedatives and tranquilizers may increase the drowsiness effect • use caution when driving a motor vehicle or operating machinery • excitability may occur especially in children

LOT#
EXP. DATE:

NDC 53598-004-01

Bonita
Pharmaceuticals

Diphenhydramine
HCl 25 mg

Antihistamine
Allergy Relief for:
•Sneezing •Runny Nose
•Itchy, Watery Eyes
•Itchy Nose & Throat

*This product is not manufactured or distributed by McNeil Healthcare LLC, distributor of Benadryl®.

100 CAPLETS • 25 mg Each

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions • take every 4 to 6 hours as needed • do not take more than 12 caplets in 24 hours or as directed by a doctor
Adults and children 12 years and older • 1 or 2 caplets (25 mg to 50 mg)
Children under 12 years • consult a doctor

Other information • Store at room temperature • Keep lid tightly closed in a dry place • **Do not use if imprinted safety seal under cap is broken or missing**

Inactive ingredients Croscarmellose Sodium, D&C Red #27, Dicalcium Phosphate Dihydrate, Hydroxypropyl Methylcellulose, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Propylene Glycol, Silica, Stearic Acid and Titanium Dioxide.

Questions? If you have any questions or comments, or to report an adverse event, please contact (855) 729-7200.

Distributed By: Bonita Pharmaceuticals
6380 Commerce Dr., Westland, MI 48185

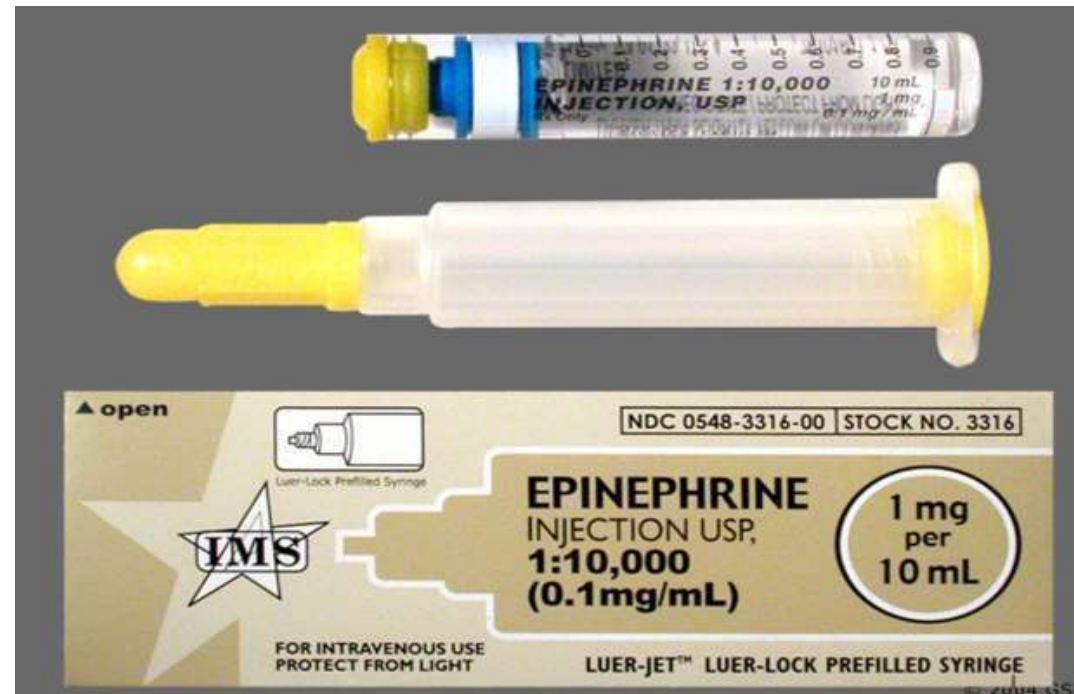
Rev. 03/13

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DOXORUBICIN HYDROCHLORIDE POWDER FOR INJECTION



EPINEPHRINE HYDROGEN TARTRATE INJECTION



LEVOTHYROXINE SODIUM TABLETS

Usual Dosage: 100 to 200 mcg daily. See package circular for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.

Manufactured by:
Neulpharma, Inc.
Caguas, Puerto Rico 00725
Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136
Product of Austria

L7094
L832824301
Issued 10/2019

NDC 0527-3282-43

**Levothyroxine
Sodium
Tablets, USP**

75 mcg (0.075 mg)

**Rx Only
1000 Tablets**

Lannett

0527-3282-43 7

GTIN: 00305273282437

P09427
LOT: /EXP:

FLUCYTOSINE TABLETS



GENTAMICIN SULFATE INJECTION



HYDRALAZINE HYDROCHLORIDE TABLETS

Each tablet contains 10 mg of hydralazine hydrochloride, USP.

Usual Dosage:
Read accompanying prescribing information.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

Keep this and all medications out of the reach of children.

Rev: 02/21

Manufactured by:
ScieGen Pharmaceuticals, Inc.
Hauppauge, NY 11788 USA

Distributed by:
Radha Pharmaceuticals, Inc.
Hauppauge, NY 11788 USA

NDC 77771-182-10

HydrALAZINE
Hydrochloride
Tablets, USP

10 mg

1,000 Tablets **Rx Only**

 **Radha**
Pharmaceuticals, Inc.



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77771-18210
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NO VARNISH

HYDROCORTISONE OINTMENT



HYDROCORTISONE ACETATE CREAM



HYDROCORTISONE SODIUM SUCCINATE POWDER FOR INJECTION



Hydrocort Inj 100mg
Hydrocortisone (100mg) 500 vials + WFI per case

IRON DEXTRAN INJECTION



CLASS ASSESSMENTS

Descriptive-Based Assessment

Question 1 : A sample of **Chlorpromazine Hydrochloride Injection** (25 mg/ml) is received for quality control testing. Describe in detail the **complete sample preparation procedure** as per the basic protocol



CLASS ASSESSMENTS

Descriptive-Based Assessment

Question 2: You are provided with **Hydrocortisone Acetate Cream** (10 mg/g). Outline the **step-by-step sample preparation method** for identity testing, and describe **three critical physical characteristics**



SUMMARY

- Basic procedure for pharmaceutical dosage forms begins with sample preparation like dilution, pooling, or direct use as per form (tablet, injection, cream).
- Identity tests rely on physical description (color, form, powder/liquid), odour, and specific content (e.g., 100 mg allopurinol/tablet).
- Injections require sterile solutions with defined concentrations (e.g., 250 mg amikacin sulfate/ml); powders are used directly or reconstituted.
- Creams and ointments specify active content per gram base (e.g., 10 mg hydrocortisone acetate/g); tablets list mg per unit.
- Design Thinking ensures standardized testing protocols to confirm identity, purity, and safety across diverse dosage forms

REFERENCE

1. Pharmacognosy by Trease and Evans
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4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
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7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.

THANK YOU

