

SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES

Coimbatore -641035



COURSE NAME : QCSH(BP 806 ET)

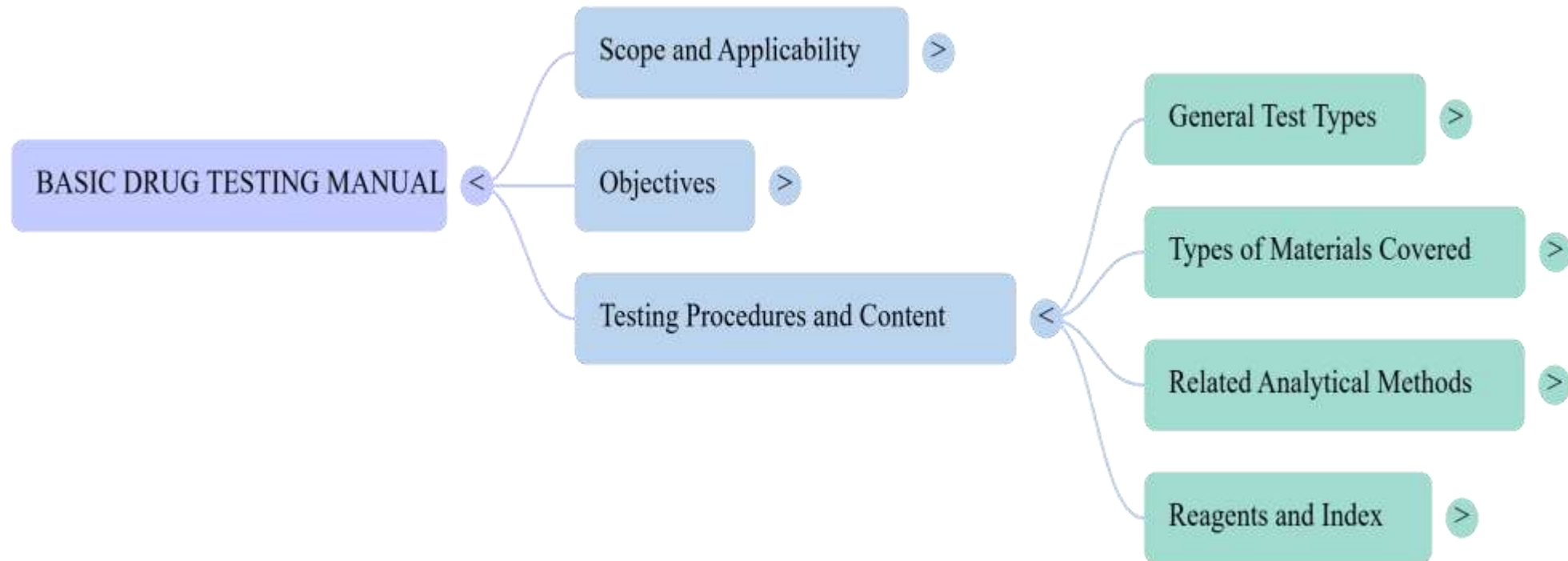
YEAR/SEM : VIII SEM

**TOPIC 1 : BASIC TEST FOR PHARMACEUTICAL
SUBSTANCE**

DESIGN THINKING IN QUALITY CONTROL OF PHARMACEUTICAL SUBSTANCE

- Empathize Understand challenges of herbal users. Engage farmers, manufacturers, and patients to identify pain points like adulteration and lack of standardization.
- Define ::Define Reframe problems: Need reliable tests to ensure identity, purity, and potency of herbal drugs. Core issue: Variability in plant materials affects safety and efficacy.
- Ideate : Ideate Brainstorm tests: Organoleptic, microscopic, physico-chemical. Explore innovative tools like HPTLC for markers and WHO guidelines integration.
- Prototype & Test Prototype: Develop test protocols (e.g., microscopic slides for authentication). Test Validate against adulterated samples to enhance compliance and quality.

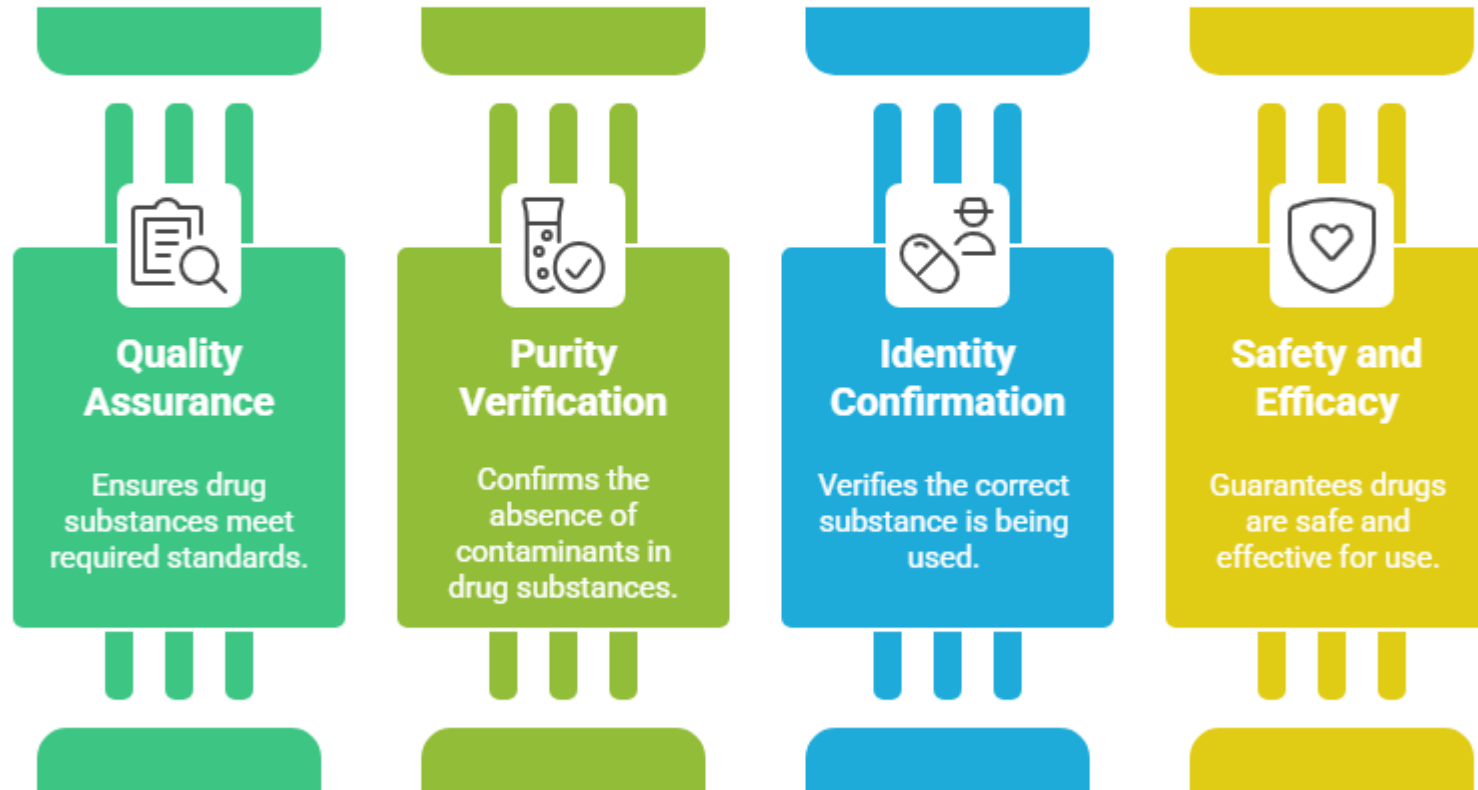
MIND MAP



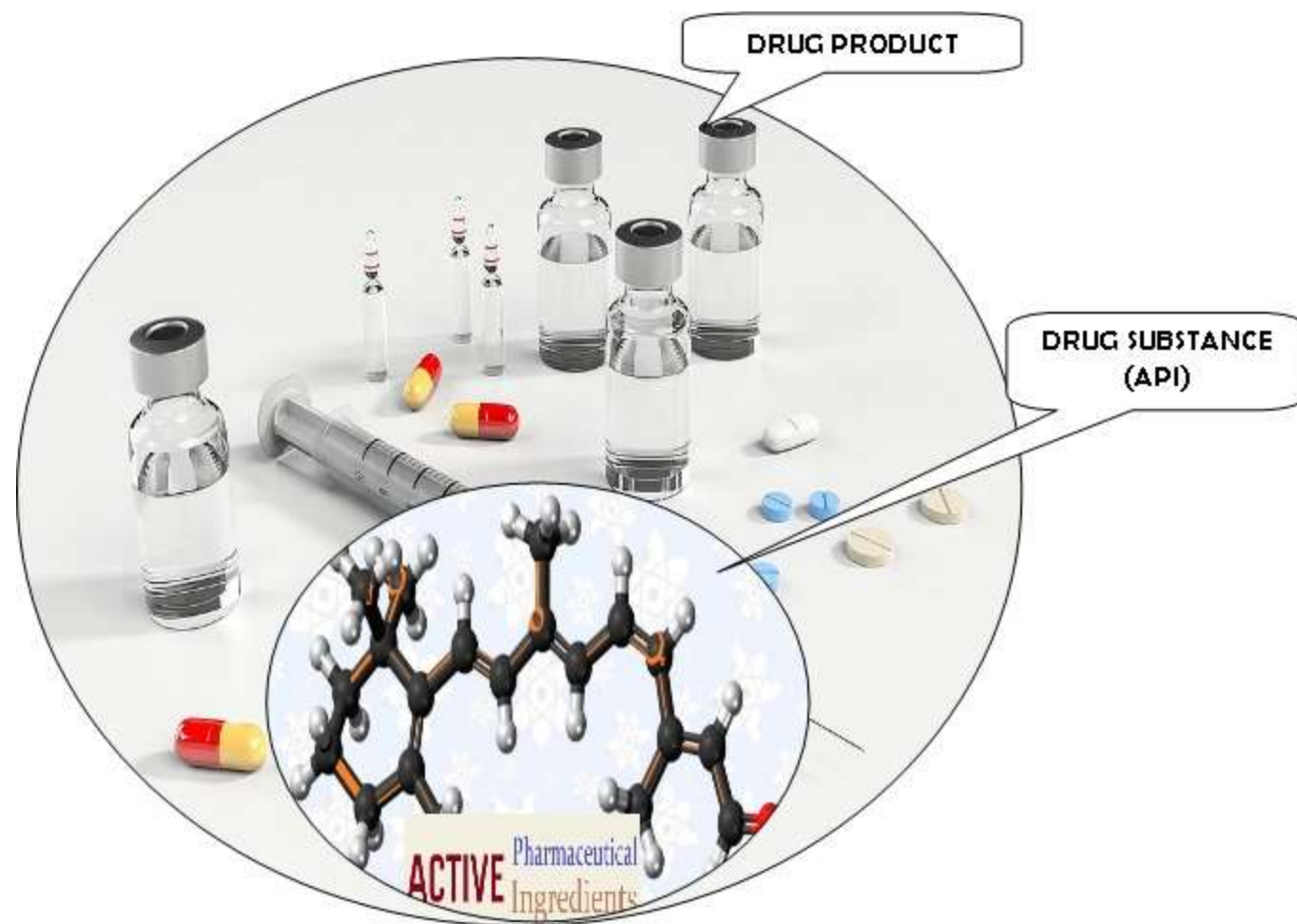
BASIC TEST IN QUALITY CONTROL OF PHARMACEUTICAL SUBSTANCE



Ensuring Pharmaceutical Quality



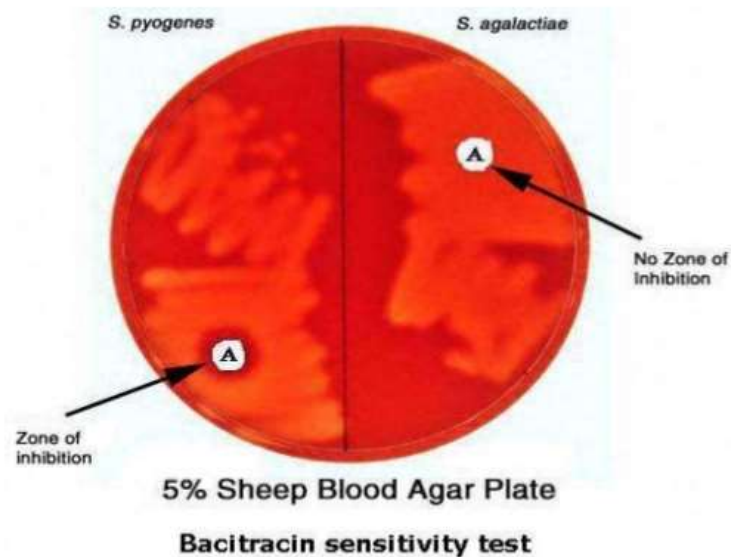
Made with  Napkin



TEST PROCEDURES FOR PHARMACEUTICAL SUBSTANCES

BACITRACIN ZINC

D. Bacitracin sensitivity test



AMIKACIN SULFATE



CHLORAMPHENICOL SODIUM SUCCINATE



CISPLATIN



COALTAR



FLUPHENAZINE DECANOATE

NDC 68083-476-01

Rx only

Fluphenazine Decanoate
Injection, USP

125 mg per 5 mL
(25 mg per mL)

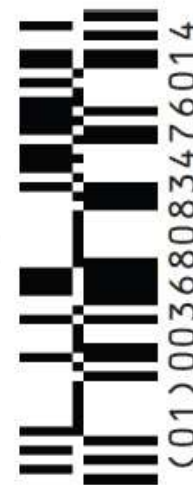
For Intramuscular or Subcutaneous Use.

5 mL Multiple Dose Vial

Sterile.

Each mL contains: Fluphenazine Decanoate USP 25 mg; benzyl alcohol 12 mg as a preservative; sesame oil, q.s

Usual dosage: See package insert.
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]. Protect from light (keep in outer carton).
The container closure is not made with natural rubber latex.



Lot:

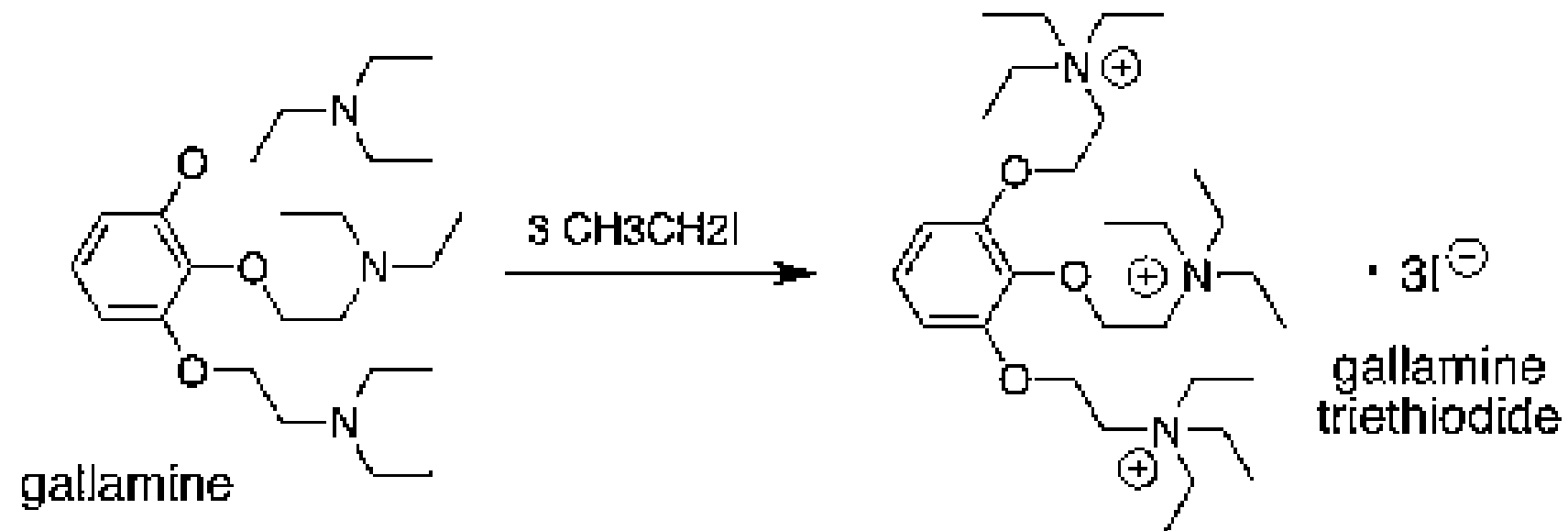
Exp.:

Manufactured by:
Gland Pharma Limited
Hyderabad -502307, INDIA.
ML No: 2/MD/TS/2015/F/G

PSLAB-XXXXXX-XX

Un Varnish Area
15 x 8 mm

GALLAMINE TRIETHIODIDE



HYDROCORTISONE SODIUM SUCCINATE



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

KETAMINE HYDROCHLORIDE

NDC 68083-504-01

Ketamine Hydrochloride Injection, USP

200 mg/20 mL
(10 mg/mL)

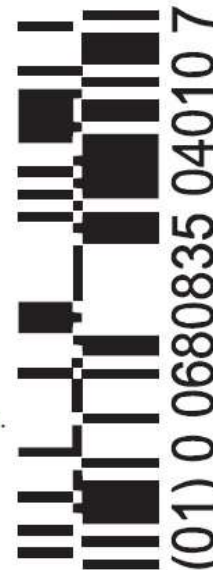
**For Slow Intravenous
or Intramuscular Use**

20 mL Multiple-Dose Vial

Rx only



Each mL contains 11.53 mg Ketamine Hydrochloride equivalent to 10 mg of ketamine base and 6.60 mg of Sodium Chloride with a pH range of 3.5 to 5.5. Contains not more than 0.10 mg/mL benzethonium chloride added as a preservative. Color of solution may vary from colorless to very slightly yellowish and may darken upon prolonged exposure to light. This darkening does not affect potency. Do not use if precipitate appears.
Usual Dosage: See full prescribing information. Store between 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F). (See USP Controlled Room Temperature.) Protect from light.



Manufactured by:



Gland Pharma Limited

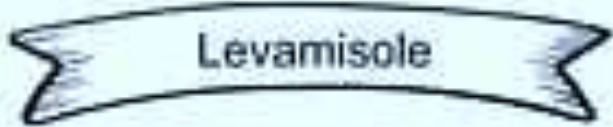
Pashamylaram, Patancheru,
Hyderabad-502 307, India
M.L.No.: 01/SRD/TS/2022/F/G
PSLAB-XXXXXX-XX

Lot:

Exp.:

Un Varnish Area
19 x 16 mm

LEVAMISOLE



Identity Tests :

Description : A white, hygroscopic, crystalline powder, characteristic odor.

Melting Point : About 59°C.

Procedure

Dissolve 0.05 gm in 25 ml of water

↓

Add 1 ml of sodium hydroxide

↓

Boil for 10 minutes, and cool

↓

Add a few drops of sodium nitroprusside

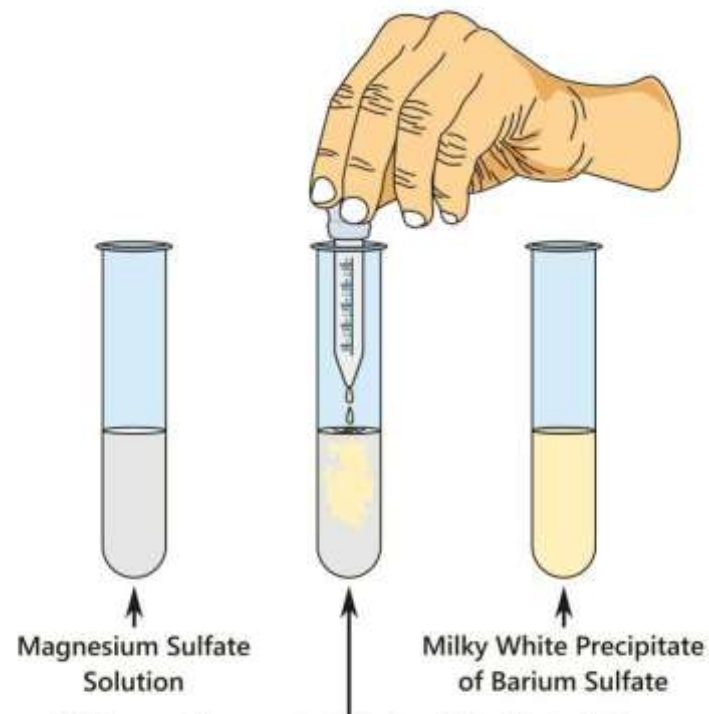
↓

Red color is produced which fades with time.

LEVAMISOLE HYDROCHLORIDE



MAGNESIUM SULFATE



Adding small amount of Barium Chloride Solution to Magnesium Sulfate Solution (which contains dissolved sulfate ions in dilute hydrochloric acid).



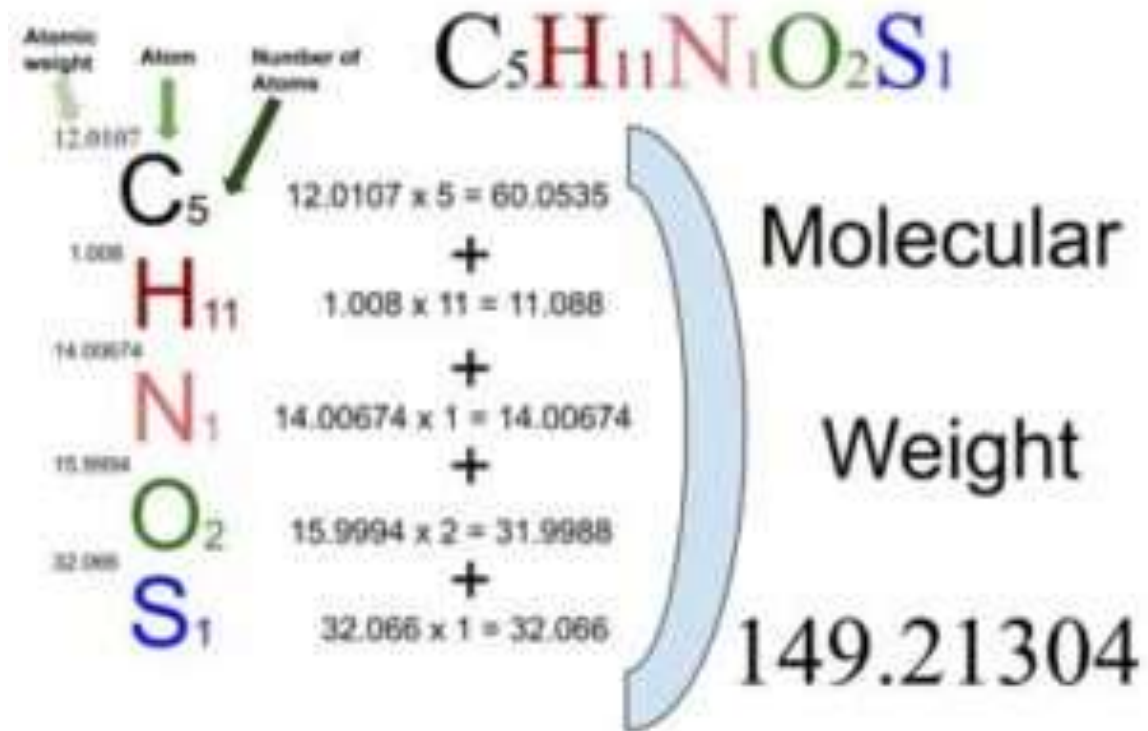
* A milky white precipitate of barium sulfate is formed which indicates presence of sulfate ions.

MEDROXYPROGESTERONE ACETATE

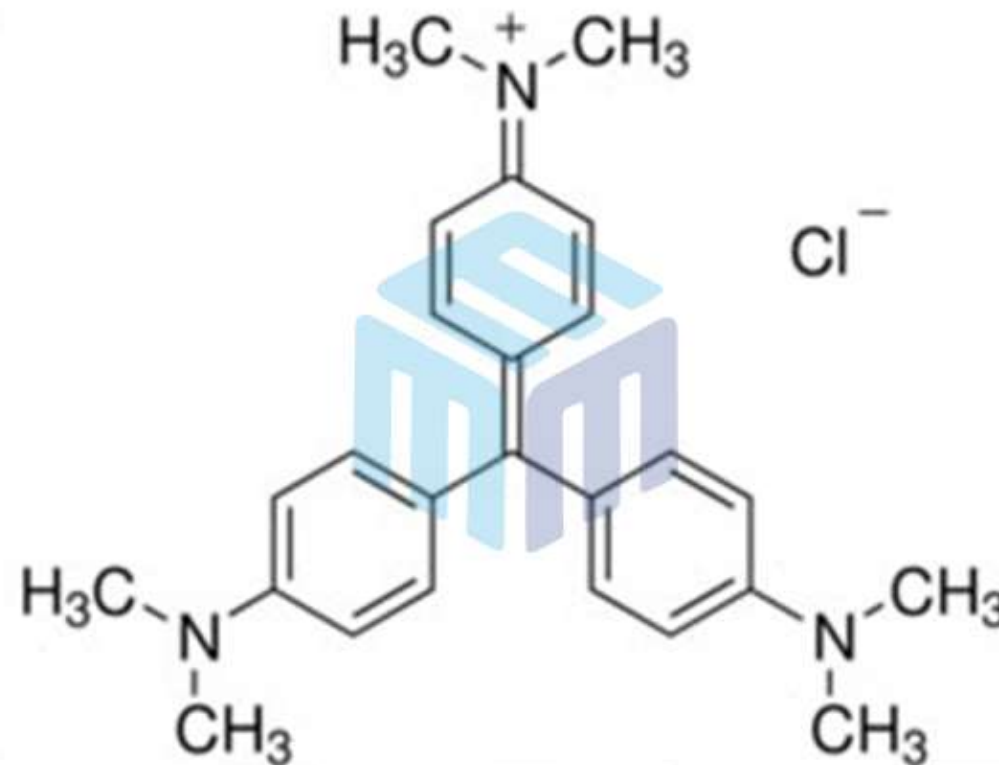


METHIONINE

Methionine



METHYLROSANILINIUM CHLORIDE



PENTAMIDINE ISETIONATE

PENJ-VL-01
Preservative Free
Sterile, Nonpyrogenic.
Each vial contains:
Pentamidine Isethionate 300 mg.

Usual Dosage:
See package insert.
Reconstitute vial contents with
Sterile Water for Injection or 5%
Dextrose Injection only as directed
in Package Insert.
Store dry product at 20° to 25°C
(68° to 77°F) [See USP Controlled
Room Temperature]. Protect dry
product and reconstituted
solution from light.

Manufactured For:
X-GEN Pharmaceuticals, Inc.
Big Flats, NY 14814

NDC 39822-3050-1

Pentamidine Isethionate
for Injection

300 mg per Vial

Lyophilized

For Intramuscular or Intravenous Use

Single-Dose Vial
Discard unused portion

XGEN
Pharmaceuticals, Inc.

BARCODE

Lot: Exp:

PENTAMIDINE MESILATE

Pentamidine Injection



PREDNISOLONE SODIUM PHOSPHATE



N 0121-0759-08 6

NDC 0121-0759-08

**Prednisolone Sodium
Phosphate Oral Solution**

15 mg/5 mL*

ALCOHOL FREE / DYE FREE

Rx Only

8 fl oz (237 mL)



Pharmacist: Dispense in tight, light-resistant glass or PET plastic containers as defined in the USP.

USUAL DOSAGE: See accompanying package insert for complete prescribing information.

WARNINGS: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Store at 2° to 25°C (36° to 77°F). May be refrigerated.

*Each 5 mL (teaspoonful) contains 20.2 mg prednisolone sodium phosphate (equivalent to 15 mg prednisolone base) in a palatable solution.

Manufactured by:
PAI Pharma
Greenville, SC 29605

X0759080423
R04/23

TAMOXIFEN BITRATE



VINBLASTINE SULFATE



PYRIMETHAMINE

NDC 43598-672-01

**Pyrimethamine
Tablets, USP**

25mg

Rx Only

100 Tablets

Dr.Reddy's 

Each scored tablet contains
25 mg of Pyrimethamine, USP.

Warning: Potent Drug – do not
exceed recommended dosage.

Store at 15° to 25°C (59° to
77°F) in a dry place.

Dispense in tight, light-resistant
container as defined in the USP.

Usual Dosage: See
accompanying prescribing
information.



3 4 3 5 9 8 6 7 2 0 1 4

Rev. 02/2020

Manufactured by:
Cerrovene, Inc.
Valley Cottage, NY
10989 USA

Distributed by:
Dr Reddy's Laboratories Inc.
Princeton, NJ 08540 USA

CLASS ASSESSMENTS

1. Which of the following pharmaceutical substances is described as a brown-black or black, viscous liquid with a characteristic strong odour resembling naphthalene?



CLASS ASSESSMENTS

2. State the melting point and physical appearance of Levamisole Hydrochloride as per its identity test description.



SUMMARY

- Identity tests for 20+ substances rely on physical description (color, form, powder/liquid), odour (characteristic, faint, or odourless), and hygroscopicity.
- Key examples: Coal Tar (brown-black viscous liquid, strong naphthalene-like odour), Cisplatin (yellow powder, very toxic), Levamisole HCl (white powder, melts $\sim 228^{\circ}\text{C}$).
- Bacitracin Zinc is a zinc-polypeptide complex from *Bacillus subtilis*; Fluphenazine Decanoate appears as pale yellow viscous liquid or oily solid.
- Melting point specified for select drugs (e.g., Pentamidine Isetionate $\sim 190^{\circ}\text{C}$, Tamoxifen Citrate $\sim 142^{\circ}\text{C}$ with decomposition).
- Tests ensure identity, purity, and safety; toxic substances (Cisplatin, Vinblastine Sulfate) require careful handling

REFERENCE

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I, Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
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.

The background of the slide is split. The left half is a solid green rectangle with the text 'THANK YOU' in white, uppercase, sans-serif font. The right half is a photograph of a wooden surface with several small bowls containing green liquid, two wooden spoons filled with green powder, and some green leaves. There are also some small white and yellow dots scattered on the green background.

THANK YOU