FPGEE®

REVIEW

THEORY

2026-2027 Edition



FPGEE Review

PREPARATION

THEORY

By Manan H. Shroff, R.Ph 2026-2027 Edition

RxExam's FPGEE®

Review Theory

2026 - 2027 EDITION

MANAN SHROFF

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PREFACE:

I am very pleased to introduce the latest edition of "RxExam FPGEE® Review – Theory" I have made every attempt to cover as much of the course as possible, which is outlined in the current FPGEE syllabus. I would recommend that students read our other publications, including "RxExam's FPGEE Review Questions and Answers," "RxExam FPGEE® Review Pharmacy Management - Theory" and "RxExam FPGEE® Review Pharmacy Management - Questions and Answers" to achieve competitive scores on the FPGEE exam.

I wish you much success.

Best of luck,

Manan H. Shroff

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PHARMACEUTICAL SERVICE MANAGEMENT
&
SOCIAL AND BEHAVIORAL SCIENCES

1. Pharmacy Law

PURE FOOD AND DRUG ACT OF 1906

Congress passed this law in 1906 to protect people from unsanitary and poorly labeled food.

FOOD, DRUG AND COSMETIC ACT OF 1938

This law suggests that no new drug can be marketed until proven safe by the FDA for public use.

DURHAM HUMPHREY AMENDMENT OF 1951

This law is also known as "Prescription Drug Amendment".

It differentiates between prescription and OTC drugs.

It also authorizes oral prescriptions and prescription refills.

It suggests that each drug should be labeled "Caution: Federal law prohibits dispensing without a prescription."

KEFAUVER HARRIS AMENDMENT OF 1962

It is also known as the "Drug Efficacy Amendment".

This law indicates that new approved drugs must be safe as well as effective.

It also establishes Good Manufacturing Practice requirements.

MEDICAL DEVICE AMENDMENT OF 1976

This law passed in 1976, and includes:

The classification of medical devices

Safety and efficacy of medical devices

ORPHAN DRUG ACT OF 1983

This law was passed for orphan drugs (drugs for diseases that affect very few people). Congress passed this act to provide tax relief and other incentives for the pharmaceutical manufacturers to develop and market orphan drugs.

DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984

This law is also known as Waxman Hatch Amendment.

This law was passed to make generic drugs more readily and easily available to the general public.

The law also provides more incentive to innovative pharmaceutical companies and encourages them to develop new drugs.

NATIONAL DRUG CODE NUMBER (NDC)

The NDC generally consists of ten to eleven letters.

1. The first four characters indicate the name of the manufacturer or distributor.
2. The middle four characters identify the drug name and strength.
3. The last two characters identify the package.

National Provider Identifier Standard (NPI)

The National Provider Identifier (NPI) is a Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification Standard.

The NPI is a unique identification number for covered health care providers. Covered health care providers and all health plans and health care clearing houses must use the NPIs in the administrative and financial transactions adopted under HIPAA.

The NPI is a 10-position, intelligence-free numeric identifier (10-digit number). This means that the numbers do not carry other information about healthcare providers, such as the state in which they live or their medical specialty.

The NPI must be used in lieu of legacy provider identifiers in the HIPAA standards transactions.

OVER THE COUNTER DRUG

The FDA classifies OTC drugs into three different categories.

Category I: It includes ingredients generally considered to be safe, effective and not misbranded.

Category II: It includes ingredients that are not considered to be safe or effective, or are misbranded.

Category III: It includes ingredients for which data are insufficient to permit their classification.

PATIENT PACKAGE INSERT

The FDA passed this law in 1970. The law states that a patient must be provided with the supplement drug information, commonly known as Patient Package Insert or PPI, by a pharmacist while dispensing certain drugs.

The list of such drugs are:

1. Isotretinoin
2. Oral contraceptives
3. Isoproterenol
4. Ticlopidine
5. Progesterone

6. Estrogen
7. Intrauterine device

OBRA ACT OF 1990

It is known as the Omnibus Budget Reconciliation Act of 1990. It requires that pharmacists must offer counseling to a patient.

THE FDA EMPLOYS A TWO LETTER CODING SYSTEM FOR THERAPEUTIC EQUIVALENCE OF DIFFERENT DRUGS

AA: Drugs that are available in conventional dosage forms and have no bioequivalence problems.

AT: Topical drugs that meet bioequivalence standards.

AB: Drugs meeting the necessary bioequivalence requirements.

BC: Drugs in extended release dosage form with bioequivalence issues.

BT: Topical drugs with bioequivalence issues.

BX: Drugs for which adequate information is not available to determine their bioequivalency.

POISON PREVENTION ACT

This law was implemented to prevent the death of children from accidental poisoning. This act was passed in 1973. It indicates that all dispensed drugs must be dispensed in a child proof or a child resistant container.

Drugs exempt from this law are:

1. Sublingual dosage form of nitroglycerine
2. Sublingual and chewable form of Isosorbide dinitrate (less than 10mg)
3. Cholestyramine powder
4. Methylprednisolone tablets (less than 84 mg)
5. Mebendazole tablets (less than 600 mg of drug)
6. Potassium supplements (unit dose form)
7. Erythromycin ethyl succinate (liquid and granules not more than 8 gm of drug)
8. Colestipol in powder form
9. Erythromycin ethyl succinate (tablets no more than 16 gm of drug)
10. Pancrelipase preparations
11. Prednisone (tablets no more than 105 mg)
12. Oral contraceptives

CONTROLLED SUBSTANCE ACT

CSA = Controlled Substance Act
DEA = Drug Enforcement Administration

The attorney general of United States has authority to place a drug into one of the five categories of schedule controlled drugs.

The controlled drugs can be classified into five different classes according to their potential for abuse.

The potency of abuse of controlled drugs should be I > II > III > IV > V. Schedule I shall be considered the highest potential for abuse whereas schedule V drugs shall be considered the lowest potential for abuse.

SCHEDULE II CONTROLLED DRUGS

- Cannot be refilled under any circumstances.
- The partial filling of this class of drugs should be done within 72 hours of their initial filling if a pharmacist is out of the stock of medication, and within 30 days of their initial filling if requested by a patient.
- The DEA 222 order form is required to order this class of drugs.

List of Schedule II controlled drugs:

1. Alfentanil (Alfenta)
2. Amobarbital (Amytal, Tuinal)
3. Amphetamine (Dexedrine, Biphetamine)
4. Lisdexamfetamine (Vyvanse)
5. Coca Leaves
6. Cocaine
7. Codeine
8. Dextropropoxyphene, bulk (non-dosage forms)
9. Dihydrocodeine (Didrate, Parazone)
10. Diphenoxylate
11. Diprenorphine
12. Ecgonine (Cocaine precursor, in Coca leaves)
13. Ethylmorphine (Dionin)
14. Fentanyl (Innovar, Sublimaze, Duragesic)
15. Glutethimide (Doriden, Dorimide)
16. Hydrocodone (dihydrocodeinone)
17. Hydrocodone and isoquinoline alkaloid
18. Hydrocodone combination product (Tussionex, Tussend, Lortab, Vicodin, Hycodan, Anexsia)
19. Hydromorphone (Dilaudid, dihydromorphinone)
20. Levo-Alphacetylmethadol (LAAM, long acting methadone, levomethadyl acetate)
21. Meperidine (Demerol, Mepergan, Pethidine)
22. Methadone (Dolophine, Methadose, Amidone)
23. Methamphetamine (Desoxyn, D-desoxyephedrine, ICE, Crank, Speed)
24. Methylphenidate (Ritalin)
25. Morphine (MS Contin, Roxanol, Duramorph, RMS, MSIR)
26. Opium poppy
27. Opium tincture
28. Opium, granulated
29. Opium, powdered
30. Opium, raw
31. Oxycodone (OxyContin, Percocet, Tylox, Roxicodone, Roxicet)

32. Oxymorphone (Numorphan)
33. Pentobarbital (Nembutal)
34. Poppy Straw Concentrate
35. Remifentanil (Ultiva)
36. Secobarbital (Seconal, Tuinal)
37. Sufentanil (Sufenta)
38. Tapentadol (Nucynta)

SCHEDULE CIII CIV and CV Controlled Drugs

- Cannot be refilled more than five times.
- Cannot be filled/refilled for the prescription older than six months.
- Do not require DEA 222 form to order these classes of drugs.

Schedule III Controlled Drugs:

1. Amobarbital and non-controlled active ingredients
2. Amobarbital suppository dosage form
3. Anabolic steroids
4. Barbituric acid derivative
5. Benzphetamine (Didrex, Inaptly)
6. Buprenorphine (Buprenex, Temgesic)
7. Butabarbital (Butisol, Butibel)
8. Butalbital (Fiorinal, Butalbital with aspirin)
9. Codeine and isoquinoline alkaloid (Codeine with papaverine or noscapine)
10. Codeine combination product (Empirin, Fiorinal, Tylenol, ASA or APAP w/codeine)
11. Dronabinol in sesame oil in soft gelatin capsule (Marinol)
12. Gamma-hydroxybutyric acid
13. Ketamine
14. Lysergic acid
15. Lysergic acid amide
16. Methyltestosterone (Android, Oreton, Testred, Virilon)
17. Nalorphine (Nalline)
18. Nandrolone (Deca-Durabolin, Durabolin, Durabolin-50)
19. Norethandrolone (Nilevar)
20. Opium combination product (Paregoric)
21. Pentobarbital and non-controlled active ingredients
22. Pentobarbital suppository dosage form
23. Phendimetrazine (Bontril)
24. Secobarbital and non-controlled active ingredients
25. Secobarbital suppository dosage form
26. Sodium oxybate (Xyrem)
27. Testosterone (Android-T, Depotest, Delatestryl)
28. Thiopental (Pentothal)

Schedule IV Controlled Drugs

1. Tramadol (Ultram)
2. Carisoprodol (Soma)
3. Alprazolam (Xanax)
4. Barbital (Barbitone)
5. Butorphanol (Stadol, Stadol NS, Torbugesic, Torbutrol)
6. Chloral hydrate (Noctec)
7. Chlordiazepoxide (Librium, Libritabs, Limbitrol, SK-Lygen)
8. Clonazepam (Klonopin, Clonopin)
9. Clorazepate(Tranxene)
10. Dexfenfluramine (Redux)
11. Diazepam (Valium, Valrelease)
12. Dichloralphenazone (Midrin)
13. Difenoxin 1 mg/ Atropine 25 mcg (Motofen)
14. Estazolam (ProSom, Domnamid, Eurodin, Nuctalon)
15. Ethchlorvynol (Placidyl)
16. Fenfluramine (Pondimin, Ponderal)
17. Flurazepam (Dalmane)
18. Fospropofol (Lusedra)
19. Lorazepam (Ativan)
20. Mazindol (Sanorex, Mazanor)
21. Meprobamate (Miltown, Equanil, Deprol, Equagesic, Meprospan)
22. Midazolam (Versed)
23. Modafinil (Provigil)
24. Oxazepam (Serax, Serenid-D)
25. Pemoline (Cylert)
26. Pentazocine (Talwin, Talwin NX, Talacen, Talwin Compound)
27. Phenobarbital (Luminal, Donnatal, Bellergal-S)
28. Phentermine (Ionamin, Fastin, Adipex-P, Obe-Nix, Zantryl)
29. Prazepam (Centrax)
30. Propofol (Diprivan)
31. Propoxyphene dosage forms with other ingredients
32. Quazepam (Doral, Dormalin)
33. Sibutramine (Meridia)
34. Temazepam (Restoril)
35. Triazolam (Halcion)
36. Zaleplon (Sonata)
37. Zolpidem (Ambien)
38. Zopiclone (Imovane)
39. Eszopiclone (Lunesta)

Schedule V Controlled Drugs

1. Codeine preparations - Not more than 200 mg per 100 ml or 100 gm (Robitussin AC, Phenergan with Codeine).
2. Difenoxin preparations - Not more than 0.5 mg Difenoxin + 25mcg Atropine sulfate (Motofen).
3. Dihydrocodeine preparations - Not more than 100 mg per 100 ml or 100 gm.
4. Diphenoxylate preparations- Not more than 2.5 mg Diphenoxylate + 25mcg Atropine sulfate (Lomotil, Logen).
5. Ethylmorphine preparations - Not more than 100 mg per 100 ml or 100 gm.
6. Opium preparations - Not more than 100 mg per 100 ml or 100 gm (Parepectolin, Kapectolin PG, Kaolin Pectin P.G.).
7. Lyrica - Pregabalin
8. Vimpat - Lacosamide
9. Potiga – Ezogabine

Emergency Dispensing of Schedule CII Controlled Drugs

1. In case of an emergency situation, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving an orally or electronically transmitted authorization of a prescribing practitioner, provided that:

2. The quantity prescribed and dispensed shall be limited to the amount adequate to treat the patient during the emergency period.

3. The prescription contains all information required by the federal and state law except for the actual signature of the prescribing practitioner, and in the case of an oral prescription, or prescription transmitted electronically by computer modem or other similar electronic device, the prescription is immediately reduced to writing by the dispensing pharmacist; and

4. The dispensing pharmacist makes a reasonable good faith effort to determine that the orally or electronically transmitted authorization was issued by an authorized practitioner, which effort may include a callback to the prescribing practitioner or other good faith efforts to ensure the prescribing practitioner's identity.

5. Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the pharmacy which must have written on its face "Authorization for Emergency Dispensing" and should comply with federal and state law.

6. Upon receipt of the written prescription, the dispensing pharmacist shall attach the prescription to the orally or electronically transmitted emergency prescription which had earlier been reduced to writing.

7. The pharmacist must notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him/her; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

Faxing Schedule CII Controlled Drugs

A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the agent of the practitioner, but not by the patient or patient's agent, to a pharmacy via facsimile equipment, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance.

Faxing a prescription for Schedule II controlled drugs may serve as the original prescription only if:

1. A prescription is written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile.

2. A prescription is written for Schedule II substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.

3. A prescription is written for a Schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient.

Methadone Dispensing

1. A practitioner who wants to use Schedule II narcotic drugs for maintenance and/or detoxification must obtain separate registration from DEA as a narcotic treatment program pursuant to the Narcotic Addict Treatment Act of 1974.

2. This registration allows a practitioner to administer or dispense, but NOT PRESCRIBE, scheduled narcotic drugs that are approved by the United States Food and Drug Administration (FDA) for the treatment of narcotic addiction. Methadone and levo-alpha-acetyl-methadol (LAAM) are the only scheduled narcotics approved by FDA for use in maintenance and detoxification treatment.

3. An exception to the registration requirement, known as the "three day rule" (21CFR1306.07(b)), allows a practitioner who is not separately registered as a narcotic treatment program, to administer (but not prescribe) narcotic drugs to a patient for the purpose of relieving acute withdrawal symptoms while arranging for the patient's referral for treatment, under the following conditions:

a. Not more than one day's medication may be administered or given to a patient at one time;
b. This treatment may not be carried out for more than 72 hours and;
c. This 72-hour period cannot be renewed or extended.

4. The 72-hour exception offers an opioid dependent individual relief from experiencing acute withdrawal symptoms, while the physician arranges placement in a maintenance/detoxification treatment program. This provision was established to augment, not to circumvent, the separate registration requirement.

5. It should be noted that although Buprenex, a Schedule III controlled substance, is currently approved for the treatment of pain, it may not be prescribed or dispensed for use in narcotic addiction treatment, including

PHARMACEUTICAL SCIENCES

22. Suspension and Emulsion

Dosage forms are classified into three major categories:

1. Liquid dosage form
2. Solid dosage form
3. Semi-solid dosage form

From all these major categories, the following dosage forms are very important study-wise for FPGEE.

1. Suspension
2. Emulsion
3. Tablet and capsule

SUSPENSION

It can be used for oral, external or parenteral use.

The ideal suspension consists of small, uniform sized particles of dispersed phase suspended uniformly without any tendency to settle.

The particle size of suspended particles normally ranges from 0.5 to 5.0 microns.

The sedimentation property of suspension is best described by Stoke's law:

$$V = 2r^2 \frac{(\delta 1 - \delta 2)g}{9\ \eta}$$

V = sedimentation rate in cm/sec
r = radius of suspended particles
$\delta 1$ = density of dispersed phase
$\delta 2$ = density of dispersion medium
η = viscosity of continuous phase in poise
g = gravitational constant = 980 cm/sec^2

The formulation of suspension requires the following agents:

a. Suspending agent
b. Flocculating agent
c. Wetting agent
d. Dispersant
e. Preservative

We will discuss all above agents in detail in chapter "Pharmaceutical Additives".

A suspended system can be classified into two major categories:

a. Flocculated suspension
b. Deflocculated suspension

Flocculated Suspension	Deflocculated Suspension
The rate of sedimentation is high.	The rate of sedimentation is very low.
The particles of the dispersed phase are in contact with one another and form a network like structure.	The particles of the dispersed phase exist as a separate entity.
The sediment is loosely packed.	The sediment forms a hard cake.
The suspension can be easily redispersed by shaking.	The suspension cannot be easily redispersed.
The supernatant liquid of suspension is clear.	The supernatant liquid of suspension is cloudy.

The stability of suspension can be evaluated by measuring sediment ratio and rate.

A sedimentation ratio of suspension can be expressed by the following equation:

Sedimentation ratio: Hu / Ho, where;

Hu = The volume of sediment in period of time (t_1)
Ho = The initial volume of sediment at time (t_0)

EMULSION

Emulsion: It is defined as a heterogenous system of two immiscible phases, one of which is water and the other is oil.

The particle size of an emulsion droplet ranges between 0.1 and 100 microns.

Emulsion is divided into the following categories:

a. O/W emulsion
b. W/O emulsion
c. O/W/O emulsion and W/O/W emulsion
d. Microemulsion
e. Nanoparticle

a. O/W emulsion: In this type of emulsion, water is continuous phase and oil is dispersed phase. Emulsion for oral administration is generally O/W type to hide taste and increase palatability of medicinal oil.

b. W/O emulsion: Oil is present as continuous phase, while water is present as dispersed phase.

c. O/W/O or W/O/W emulsion: It is also known as multiple-emulsion.

d. Microemulsion: They are W/O or O/W emulsions with a particle size ranging from 100° A to 600° A. Unlike emulsion, they are clear and thermodynamically stable. Sodium lauryl sulfate or Potassium oleate is normally used as an emulsifying agent. They are generally used to solubilize drugs in the pharmaceutical industry.

e. Nanoparticle emulsion: It is similar in size and shape to the globule of microemulsion. It is prepared by the process of polymerization, and is used to solubilize drugs, globulins and toxoids.

The total surface free energy in emulsion can be calculated by the following:

$$F = 6\lambda\, V/d$$

V = volume of dispersed phase in ml,
d = mean diameter of the particle,
λ = interfacial tension between dispersed phase and dispersion medium and
F = surface free energy.

The formulation of emulsion requires the following agents:

a. Emulsifying agent
b. Preservative
c. Antioxidant
d. Viscosity enhancer

Creaming and cracking are the major problems with the stability of emulsion.

Creaming: The concentrated layer of dispersed phase particles in the form of loosely attached floccules is defined as creaming. The emulsion can be redispersed by vigorously shaking the bottle. The rate of creaming can be calculated by Stoke's equation:

$$V = 2r^2 \frac{(\delta 1 - \delta 2)g}{9\,\eta}$$

V = sedimentation rate in cm/sec
r = radius of suspended particles
$\delta 1$ = density of dispersed phase
$\delta 2$ = density of dispersion medium
η = viscosity of continuous phase in poise
g = gravitational constant = 980 cm/sec^2

Cracking: It is more severe of a problem compare to creaming. In cracking, emulsion is destroyed and separated into two phases. High temperatures and the addition of electrolytes, microorganisms or an opposite type of emulsifying agent may cause cracking.

Stability of emulsion:

The stability of emulsion can be evaluated by phase separation, globule size, flow properties and the effect of thermal stress on emulsion.

The rate and degree of phase separation in an emulsion can be calculated by measuring the volume of separated phases after definite time intervals.

Tablets and Capsules:

Tablet and capsules fall under the category of oral solid dosage forms.

Tablets are further classified into the following categories:

a. Oral tablet
b. Chewable tablet
c. Buccal tablet
d. Sublingual tablet
e. Lozenges
f. Solution tablet (Solu-tab)
g. Effervescent tablet

a. Oral tablet: It is meant to be swallowed. The tablet disintegrates in the stomach and dissolves in G.I. fluid. The medication is then slowly absorbed from the G. I. fluid into systematic circulation.

b. Enteric coated tablets: They are designed to release medication in the small intestine. The coating of the tablets is meant to dissolve with an alkaline pH, and therefore it by passes the stomach.

c. Chewable tablets: They are meant to be chewed between teeth. These types of tablets are designed for children, older patients, or patients having difficulties in swallowing.

d. Buccal/sublingual tablets: Buccal tablets are designed to stay in the buccal cavity while sublingual tablets are designed to stay under the tongue. The principal advantage of sublingual tablets is their rapid onset of action and ability to bypass liver metabolism.

e. Lozenges: They are meant to provide local rather than systematic action. They provide local action to throat issues. They dissolve slowly in the mouth and provide prolonged action. They do not contain any disintegrant.

f. Solution tablets: They are dissolved completely in water to produce a solution. The principal advantage of such tablets is their rapid onset of action, accuracy of dosage and immediate onset of action.

g. Effervescent tablets: They provide effervescent when dissolved in water. They dissolve completely in water. Most antacids, analgesics and antipyretic products are available as effervescent tablets or in powder form.

The formulation of tablets requires the following pharmaceutical additives:

a. Diluent
b. Adsorbent
c. Binder
d. Disintegrant
e. Glidant
f. Lubricant
g. Anti-adhesive

*(Please refer to Chapter Pharmaceuticals Additives.)

The manufacturing of tablets requires the following steps:

1. Mixing
2. Granulation
3. Compression
4. Coating

The list of the manufacturing defects normally reported with the formulation of tablet:

a. Capping, lamination and chipping
b. Picking and sticking
c. Mottling

a. Capping, lamination and chipping

1. Capping is normally defined as when a tablet is separated partially or completely from the main body.
2. Lamination is defined as when a tablet breaks into two or more layers.
3. Chipping is defined as when a small portion of tablet may come off.

Causes:

1. Entrapment of air within compressed granules.
2. Defective punch or die

Remedies

1. Prevent entrapment of air during granules' compression.
2. Change defective punch or die.

b. Picking and sticking:

Picking is defined as when ingredients come off from the tablet surfaces and adhere to the face of the punch. It is normally reported when one tries to print CFR codes on tablets, especially with letters like A, B, M or W. Sticking is defined as when granules adhere to the die wall.

Remedies:

This can be prevented by the proper design of letters and by regulating tablet size.

c. Mottling:

It is defined as when the surface of tablets appears with dark or light zones due to uneven distribution of color.

It is normally reported due to:

1. Migration of dye during granule's drying process.
2. Decomposition or degradation of one or more ingredients of tablet.
3. Color difference between drug additives.

Remedies:

1. Use color-dye which can mask the color of tablet's ingredients.
2. Try to dry granules at low temperature.

Evaluation of tablet:

The evaluation of a tablet can be done by the following tests:

A. Weight uniformity of tablet
B. Hardness of tablet
C. Thickness of tablet
D. Friability of tablet

A. Weight uniformity: In this type of evaluation study, normally 20 or more tablets are picked randomly from a single batch. All tablets are weighed individually and collectively. From the collective weight one can calculate the average weight of the tablet, which is then compared with the individual weight of tablets. The permissible limit for tablets weighing 130 milligrams or more would be + 10% and for tablets weighing 325 mg or more would be + 5%. Nonuniformity in weight may lead to dosing variation.

B. Hardness of tablets: It is normally evaluated by hardness testers. Hardness of tablets normally indicates the tensile strength of tablets. It is normally measured in the load or pressure required to break a tablet. It greatly affects the dissolution and disintegration time of tablets.

C. Thickness of tablets: This can be easily calculated by a capillary scale. It is normally measured in terms of micrometers. It should not vary more than + 5% of standard value.

D. Friability: It is normally defined as loss in weight of a tablet due to chipping or fragmentation in the form of fine particles. It is normally measured by fibrillators. The pre weighed tablets are placed in different compartments which are rotated at the speed of 25 R.P.M. Normally, 100 revolutions are applied to tablets. Each tablet is weighed again and loss in weight of tablet can be determined by the difference. The loss in weight of a tablet should not be more than 1%.

Capsule formulation is a very important and convenient form of dispensing solids, semisolids and liquids. The solid ingredients are normally dispensed in hard gelatin capsules, while liquids or semi-solids are dispensed in soft gelatin capsules.

Capsule dosage form is not meant for dispensing the following:

1. Highly water-soluble ingredients such as ammonium chloride, potassium bromide and potassium chloride, since immediate release of these substances may cause extreme G.I. irritation.

2. Deliquescent substances, since this type of ingredient may absorb moisture from the capsule shell and make it more brittle.

3. Effervescent materials may cause a softening of the capsule by releasing moisture.

The formulation of a capsule requires the following pharmaceutical additives:

a. Diluents
b. Protective sorbents
c. Glidant
d. Anti-dusting compound

The finishing of capsule can be done by the following:

a. Salt polishing
b. Cloth dusting
c. Brushing
d. Inspection

The evaluation of capsules can be done by the following:

a. Weight variation
b. Disintegration time
c. Dissolution time
d. Drug content uniformity

23. Pharmaceutical Additives

Pharmaceutical additives are defined as non-drug adjuncts in a formulation to aid stability, strength and protectivity to final dosage forms.

Below is a list of the commonly used additives in pharmaceutical dosage forms:

Surfactants (surface active agent)	Diluents
Emulsifying agents	Binders
Suspending agents	Disintegrants
Flocculating agents	Sweetening agents
Wetting agents	Glidants
Dispersants	Lubricants
Antioxidants	Anti-adhesives
Preservatives	Adsorbents

1. Surface Active Agents (Surfactants):

The pharmaceutical additives that reduce the interfacial tension between the dispersed phase and dispersion medium are defined as surface-acting agents. They are normally classified into four different categories:

a. Anionic agents
b. Cationic agents
c. Nonionic agents
d. Amphoteric agents

a. Anionic agents: They are groups of surfactants which ionize in an aqueous media and whose surfactant activity is related to anionic parts. They can be subdivided into:

1a. Soap
1b. Sulfated compounds
1c. Sulfonated compounds

1a. Soap

They are normally prepared by the saponification of natural fatty acid triglycerides in an alkaline solution. The most common cations associated with soaps are sodium, potassium, ammonium and triethanolamine.

The degree of water solubility is greatly influenced by the length of the alkyl chain and the presence of double bonds.

Multivalent cations such as calcium and magnesium produce marked water insolubility, and therefore soaps are not useful in hard water which is high in content of these ions.

1b. Sulfated compounds

They are a derivative of sulfuric acid in which one of the hydrogen atoms is replaced by the 'R' group. They can be represented by $R.SO_4H$. Example: Sodium lauryl sulfate, Sodium cetyl sulfate.

1c. Sulfonated compounds:

They are a derivative of sulfurous acid in which one of the hydrogen atoms is replaced by an organic group. They are normally represented by $R.SO_3H$ Example: Dioctyl sodium sulfosuccinate.

b. Cationic agents:

They are a derivative of quarternary ammonium compounds in which all of the four hydrogen atoms are replaced by alkyl groups.

A number of long-chain cations, such as amine salts and quaternary ammonium salts are often used as surface active agents when dissolved in water; however their use in pharmaceutical preparation is limited to that of antimicrobial preservatives rather than surfactants. Example: Benzalkonium chloride, Cetyl trimethyl ammonium bromide.

c. Nonionic surfactants

They are the most widely used surfactants in pharmaceutical industry since they are highly stable and compatible at a wide range of pH.

They can be generated by reacting with any hydrophobic compounds having COOH, OH, $CONH_2$ or NH_2 groups with ethylene oxide. Example: Spans (esters of sorbitan), tween, polyoxyethylene glyceryl.

d. Amphoteric agents

They can be generated by reacting carboxylate or phosphate groups with amino or quarternary ammonium groups. The former group is represented by various polypeptides and proteins while the latter group consists of natural phospholipids such as lecithins and cephalins. Example: Dodecyl alanine.

2. Emulsifying agents: The additives that maintain the stability of the dispersed phase and dispersion medium in emulsion are defined as emulsifying agents.

They are normally classified as anionic, cationic, ampholytic and nonionic surfactants and have a high molecular weight.

3. Suspending agents: The additives that increase the viscosity of the continuous phase are known as suspending agent. Examples of suspending agents:

a. Methylcellulose
b. Carboxymethylcellulose
c. Gelatin
d. Hydroxypropyl methyl cellulose
e. Sodium carboxymethyl cellulose (for injectable suspension)

4. Flocculating agents: The flocculating agents that are employed in pharmaceutical formulation can be electrolytes, polymers or surfactants.

The efficiency of electrolytes in flocculate particles normally depends on the presence of the valence of ion. Trivalent ions are 1000 times more effective than monovalent ions and 100 times more effective than divalent. Example : NH_4^+, K^+, Na^+, Li^{+++}, Cl^-, Mg^{++}

5. Wetting agents: The additives that normally reduce the interfacial tension and increase the interaction between solid particles of the dispersed phase and dispersion medium. Example: Surfactants.

6. Dispersants: The additives that carry good ionic charge and increase the zeta potential of the system are known as dispersants. They discourage suspended particles to break the energy barrier and form aggregates. Example: darvan, daxads, maraspearses.

7. Antioxidants: The additives that protect the formulation from oxidative degradation are defined as antioxidants. The additives that enhance the effects of antioxidants by only their presence are defined as synergist.

Below is the list of Antioxidants:

Water soluble antioxidants:	Oil soluble antioxidants:	Synergist:
sodium bisulfite	tocopherol	citric acid
propylene glycol	ascorbyl palmitate	lecithin
sodium metabisulfite	butylated hydroxyanisole (BHA)	glycerine
sodium thiosulfate	butylated hydroxytoluene (BHT)	phosphoric acid
thiourea		PEG
		propylene glycol

8. Preservatives: The additives that prevent microbial growth and prohibit large scale chemical changes in formulation are defined as preservatives.

Below is the list of preservatives:

phenol	boric acid
benzoic acid	phenylmercuric nitrate
salicylic acid	formic acid
benzalkonium chloride	

9. Diluents: The inactive solid ingredient that can be mixed up with medication to bring up the weight of a tablet so that the tablet can be easily compressed. Lactose is available in different grades such as lactose, anhydrous lactose and spray dried lactose. The principal disadvantage of lactose is its tendency to go brown. The crystalline lactose however, has the least tendency to go brown among other grades.

Sucrose is a useful diluent for chewable tablets however it also has a tendency to go brown over a period of time.

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