

SHAMBHUNATH INSTITUTE OF PHARMACY

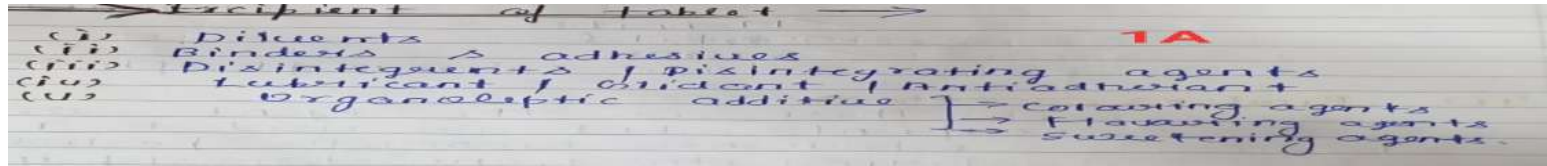
First Sessional Examination 2019-20

B. Pharm. 3rd Year 5th Semester

Industrial Pharmacy I (BP502T)

Q.1. Attempt all parts. Each part carries equal marks. (10X1=10)

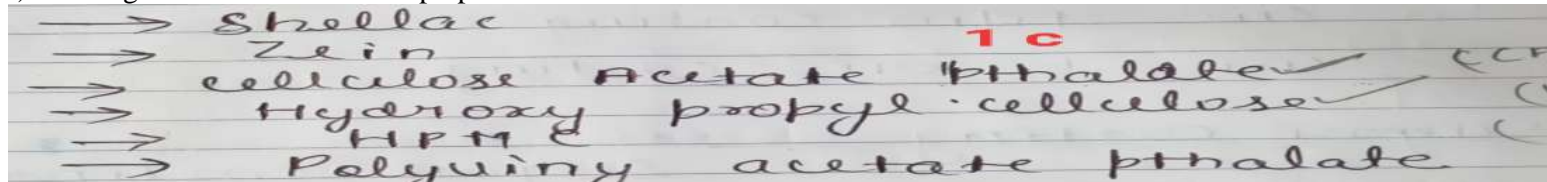
a). Excipients used in tablet preparation with one example of each.



b). Difference between capping and lamination.



c). Coating material used in tablet preparation.



d). Sizes of hard and soft gelatin capsules.

Size and Shapes of SGC → **1D (i)**

SGC is available in various shape and sizes

(i) spherical	(0.5 - 5ml)
(ii) elliptical	(1 - 10ml)
(iii) oblong	(1 - 7.5ml)
(iv) pear	(1 - 5ml)
(v) cylindrical	(1 - 2.5ml)
(vi) special type of tubes	(1 - 10ml)

Size of capsule → **1D (ii)**

Diagram showing capsule sizes on a scale:

- 000 (Bigger size, 1000mg / 10ml)
- 00
- 0
- 1
- 2
- 5 (small size, 0.15ml / 65mg)

e). Define suspension and classify it.

Suspension → **1E (i)**

Suspension may be defined as a heterogeneous biphasic liquid dosage form in which dispersed phase (internal phase) or dispersion medium (external phase).

By the help of or addition of suspending agent.

Classification of suspension:

- (B) Depending upon the concentration of dispersing agent:
 - Dilute suspension (2 - 10% w/v)
 - Concentrated suspension (> 50% w/v)
- (C) Depending upon the particle size:
 - Particle size with $\leq 1 \mu$ (colloid suspension)
 - Particle size with $> 1 \mu$ (coarse suspension)
- (D) Depending upon electrokinetic:
 - Flocculated suspension
 - Deflocculated suspension

Types → **1E (ii)**

(A) Route of administration →

- (i) Oral suspension (paracetamol suspension)
- (ii) External / topical suspension (calamine lotion)
- (iii) Parenteral suspension (Prednisolone, Cortison, Penicillin)

f). Define Pellet.

Pellets → →

1F

Pellets are defined as single free flowing small size discrete spherical shaped product which are made up of fine particulate matter along with active drugs.

- dimension and size of (500 - 1500 μm).
- this can be prepared by Pelletization techniques
- All pellets are discrete and small size

g). Classify parenterals.

Types

(A) Depending on volume

(B) Depending on route of administration

(C) Depending on type of product

1G

h). Key features of bacteriostatic water for injection.

(iii) Bacteriostatic water for injection

- These are sterile prepⁿ and some amount of antimicrobial agents are added to it.
- They are generally prepared up to 30ml preparation maximum.
- Along with the bacteriostatic agent water is also added to it.
- If the water content is more than 5ml antimicrobial w/fi are prepared. (B.W.F.I)
- Because of above 5ml prepⁿ more amount of antimicrobial agent to be added and more zone of it leads to toxic and severe sepsis in patients.

1H

i). Bufferants used in parenterals.

ex — Phosphate
Citrate
Acetate
Glutamate

j). Difference between single and multidose parenterals.

(i) Single dose parenterals are those which are used for a single dose of drug. These are not suitable for repeated administration. (ii) Multidose parenterals are those which are used for repeated administration of drug. These are suitable for repeated administration. Various types of multidose parenterals are given in the following table.

Q. 2. Attempt any two parts. (2X5=10)

a). Various methods of tablet coating. Describe any method with diagram.

Ex — Various methods of tablet coating are given in the following table.

(i) Subcoating — This is the process of coating a tablet with a thin layer of material. It is done by dipping the tablet into a solution of the coating material. The coating material is usually a mixture of polyvinylpyrrolidone and hydroxypropyl methylcellulose. The coating is applied to the tablet and then dried.

(ii) Overcoating — This is the process of coating a tablet with a thick layer of material. It is done by dipping the tablet into a solution of the coating material. The coating material is usually a mixture of polyvinylpyrrolidone and hydroxypropyl methylcellulose. The coating is applied to the tablet and then dried.

(iii) Water-soluble coating — This is the process of coating a tablet with a water-soluble material. It is done by dipping the tablet into a solution of the coating material. The coating material is usually a mixture of polyvinylpyrrolidone and hydroxypropyl methylcellulose. The coating is applied to the tablet and then dried.

(iv) Enteric coating — This is the process of coating a tablet with a material that is resistant to stomach acid. It is done by dipping the tablet into a solution of the coating material. The coating material is usually a mixture of polyvinylpyrrolidone and hydroxypropyl methylcellulose. The coating is applied to the tablet and then dried.

(v) Controlled release coating — This is the process of coating a tablet with a material that controls the release of the drug. It is done by dipping the tablet into a solution of the coating material. The coating material is usually a mixture of polyvinylpyrrolidone and hydroxypropyl methylcellulose. The coating is applied to the tablet and then dried.

(vi) Flavored coating — This is the process of coating a tablet with a material that gives it a pleasant taste. It is done by dipping the tablet into a solution of the coating material. The coating material is usually a mixture of polyvinylpyrrolidone and hydroxypropyl methylcellulose. The coating is applied to the tablet and then dried.

(vii) Colored coating — This is the process of coating a tablet with a material that gives it a specific color. It is done by dipping the tablet into a solution of the coating material. The coating material is usually a mixture of polyvinylpyrrolidone and hydroxypropyl methylcellulose. The coating is applied to the tablet and then dried.

b). Method of preparation of soft gelatin capsule with diagram.

Method of preparation

(i) plate method,
 (ii) Drum rotating method..

2B

Soft gelatin capsule (S.G.C.)

Preparation of S.G.C. involves the following steps:

1. Preparation of gelatin solution
2. Addition of drug and other excipients
3. Formation of coarse liquid form
4. Sieving / screening through mesh
5. Formation of granules/pellets
6. Dried in oven (100°C for 1-2 hours)
7. Further passed through No. 12 sieve
8. Addition of lubricant and dye
9. Compressed to form tablet

(Finished S.G.C.)

2B

Method of preparation of soft gelatin capsule

The diagram shows the following components and steps:

- 1. Gelatin solution
- 2. Drug and other excipients
- 3. Formation of coarse liquid form
- 4. Sieving / screening through mesh
- 5. Formation of granules/pellets
- 6. Dried in oven (100°C for 1-2 hours)
- 7. Further passed through No. 12 sieve
- 8. Addition of lubricant and dye
- 9. Compressed to form tablet

2B

c). Wet granulation technique.

Wet granulation

Drug and other excipient like diluents

1. Addition of binder solution
2. Formation of coarse liquid form
3. Sieving / screening through mesh
4. Formation of granules/pellets
5. Dried in oven (100°C for 1-2 hours)
6. Further passed through No. 12 sieve
7. Addition of lubricant and dye
8. Compressed to form tablet

2B

Q.3. Attempt any two parts. Each part carries equal marks. (1X10=10)

a). QC evaluation studies of aspirin tablet.

QC TO ensure and control product quality

QC is a part of statistical quality and control system

The QC system is divided into two phases

(i) To process

To ensure that in each production are controlled by inspection of product

few corrections to be done during the process

(ii) To check individual entry of QA

QC to analyze the stated details found

(iii) To ensure that the product is free from defects

(iv) To ensure that the product is free from defects

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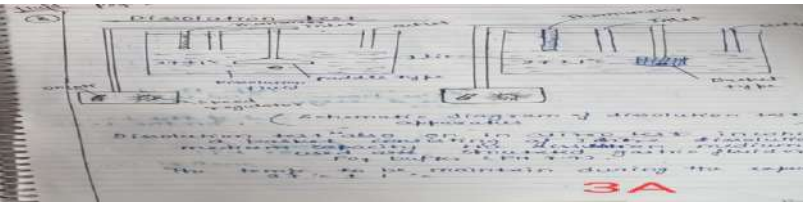
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Tablet type	Medium	Disintegration medium	Temp. and time
Uncoated tablet	Water	15 ml	37 ± 1°C
Subcoated tablet	Water	15 ml	37 ± 1°C
Effervescent tablet	Water	15 ml	37 ± 1°C
Enteric coated tablet	2 ml HCl, 15 ml water	15 ml	37 ± 1°C



Handwritten notes on a lined page, likely describing the procedure for the dissolution test. The text is dense and somewhat difficult to read due to the handwriting. A red '3A' is written at the bottom center.

b). Evaluation of elixir official in pharmacopoeia.

Handwritten notes on a lined page, likely describing the evaluation of an official elixir. The text is dense and somewhat difficult to read due to the handwriting. A red '3B' is written in the center.

pH value
 pH value of the finished product is evaluated by using pH meter.
 pH value of the syrup is b/w 6 to 7.

Solubility
 Solubility of the preparation can be checked by suitable dilution method with the use of suitable solvent.
 Syrup are generally soluble in water.

