UNIT II

CAPSULES...

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HARD GELATIN CAPSULE

• DEFINITION:-
These are solid dosage form of medicaments, in which drug is enclosed within the shells made up of gelatin.

CAPSULE SHELL
These capsules are made up of gelatin blends, small amount of certified dyes, opaquants, plasticizers and preservatives.
Certified Dyes
Colour approved by D & C act.
Opacifiers
Tio2
Plasticizers
Sorbitol, Glycerin.
Preservatives
Propyl and Methyl Parabens
GELATIN

- Gelatin is heterogeneous product derived by hydrolytic extraction of animal's collagen.
- The sources of gelatins including animal bones, hide portions and frozen pork skin.

TYPES OF GELATIN

Type A
Type B
There are two basic types of gelatin

**TYPE A**
Derived from acid treated precursor that exhibits an iso electric point at pH-9. It is manufactured mainly from pork skin.

**TYPE B**
Derived from alkali treated precursor that exhibits an iso electric point at pH-4.7. It is manufactured mainly from animal bones.
PARTS OF CAPSULE

- CAP
- BODY
MANUFACTURE OF EMPTY GELATIN CAPSULES

Steps involved in making empty gelatin capsules...

- Dipping
- Spinning
- Drying
- Stripping
- Trimming and Joining
- Polishing
Dipping:
Pairs of the stainless steel pins are dipped into the dipping solution to simultaneously form the caps and bodies. The dipping solution is maintained at a temperature of about 50°C in a heated, jacketed dipping pan.

Spinning:
The pins are rotated to distribute the gelatin over the pins uniformly and to avoid the formation of a bead at the capsule ends.
Drying:
The gelatin is dried by a blast of cool air to form a hard shells.
The pins are moved through a series of air drying kilns to remove water.

Stripping:
A series of bronze jaws strip the cap and body portions of the capsules from the pins.
Trimming and joining

The stripped cap and body portions are trimmed to the required length by stationary knives.

After trimming to the right length, the cap and body portion are joined and ejected from the machine.
## SIZE OF CAPSULES

<table>
<thead>
<tr>
<th>Size</th>
<th>Volume in ml</th>
<th>Size in mm</th>
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<tbody>
<tr>
<td>000</td>
<td>1.37</td>
<td>26.3</td>
</tr>
<tr>
<td>00</td>
<td>0.95</td>
<td>23.7</td>
</tr>
<tr>
<td>0</td>
<td>0.68</td>
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</tr>
<tr>
<td>5</td>
<td>0.15</td>
<td>11.9</td>
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</tbody>
</table>
*The largest size of the capsule is No: 000.
*The smallest size is No: 5.
*The standard shape of capsules is traditional, symmetrical bullet shape.
Various Filling Machine Available…

- Eli-lily and Co
- Farmatic
- Hofliger and Karg
- Zanasi
- Parke-Davis.

- These machine differ in there design and output
ZANASI AUTOMATIC CAPSULE FILLING MACHINE

HOFLIGER KARG AUTOMATIC CAPSULE FILLING MACHINE
Polishing

Pan Polishing: Acela-cota pan is used to dust and polish.
Cloth Dusting: Capsule are rubbed with cloth.
Brushing: Capsule are fed under soft rotating brush.

Storage

Finished capsules normally contain an equilibrium moisture content of 13-16%.
To maintain a relative humidity of 40-60% when handling and storing capsules.
SOFT GELATIN CAPSULE
Definition:-
Soft Gelatin capsules are one piece, hermetically sealed, soft gelatin shells containing a liquid, a suspension, or a semisolid.

Soft gelatin is mainly composed of gelatin, plasticizers, preservative, colouring and opacifying agents, flavoring agents and sugars.
APPLICATION OF SOFT GELATIN CAPSULE:

The pharmaceutical applications of soft gelatin capsules are:

- as an oral dosage form
- as a suppository dosage form
- as a specialty package in tube form, for human and veterinary use, single dose application for topical, ophthalmic, and rectal ointments.
Plasticizer and Gelatin ratio

In soft gelatin capsule the amount of plasticizers used is more.
In soft gelatin capsule the plasticizer and gelatin ratio is 0.8 : 1.
In hard gelatin capsule the plasticizer and gelatin ratio is 0.4 : 1.
SHAPE OF CAPSULE

The shape of soft gelatin capsule are round, oval, oblong, tube.
MANUFACTURE OF SOFT GELATIN CAPSULES

Is manufactured by four methods

• Plate process
• Rotary die process
• Reciprocating die
• Accogel machine
Plate process:

• Place the gelatin sheet over a die plate containing numerous die pockets,
• Application of vacuum to draw the sheet in to the die pockets,
• Fill the pockets with liquid or paste,
• Place another gelatin sheet over the filled pockets, and
• Sandwich under a die press where the capsules are formed and cut out.
Rotary die process:

The material to be encapsulated flows by gravity. The gelatin sheets are fed on rolls contain small orifice lined up with the die pocket of the die roll.

Two plasticized gelatin ribbons are continuously and simultaneously fed with the liquid or paste fill between the rollers of the rotary die mechanism where the capsule are simultaneously filled, shaped, hermetically sealed and cut from the gelatin ribbon.

The sealing of the capsule is achieved by mechanical pressure on the die rolls and the heating (37-40°C) of the ribbons by the wedge.
The rotary die process
**IMPORTANT SPECIFICATIONS OF GELATIN**

**Bloom or gel strength:** It is a measure of cohesive strength of cross-linkage that occurs between molecules and is proportion to the molecular weight of gelatin.

Bloom is determined by measuring the weight in grams required to move a plastic plunger of 0.5 inches in diameter, 4mm into a 62/3% gelatin that has held at 10°C for 17 hrs.

The unit of bloom is grams and it is between 150-250g
**Viscosity:** Is determined on a 62/3% gelatin of water at 60°C and it is a measure of the molecular chain length.
Standard used: 25-45 mill poise.

**Iron content:** Iron is always present in raw gelatin, and its concentration usually depends on the iron content of the large quantities of water used in its manufacture. Amount should not exceed 15ppm.
EVALUATION OF CAPSULES:

- Weight variation
- Content uniformity
- Dissolution test
- Disintegration test
Thank You