SEMINAR ON LOZENGES

BY

USHASRI .K
M.PHARM ,1ST SEMESTER

DEPARTMENT OF INDUSTRIAL PHARMACY
UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES
KAKATIYA UNIVERSITY, WARANGAL
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INTRODUCTION

Lozenges are solid and flavored medicated dosage forms intended to be sucked and held in the mouth or pharynx.

They can be prepared by:

A) Molding

   Ex: Pastilles

   These are soft variety of lozenges contains medicament in gelatin or glycero gelatin base or acacia, sucrose, water.

B) Compression of sugar based tablets.

   Ex: Troches
Lozenges are OTC and prescription products.

- Provide drug delivery locally to the mouth and tongue, throat, etc.
- Maximizes the local activity of the drug.
- Contains variety of active ingredients like Local Anesthetics, Antimicrobials, Antibiotics, vitamins, Decongestants, Analgesics, Cough suppressants, Nicotine like substances for smoking cessation.
Advantages over conventional tablets:

1. No disintegration
2. Slower dissolution rate
3. Pleasant taste
4. Organoleptic properties like color, smoothness
5. Slow release of medicament.
SHAPES OF LOZENGES:

Flat
Circular
Octagonal
Biconvex
Cylindrical
TYPES OF LOZENGES:

1. Medicated lozenges
   Based on manufacturing
   A) Hard candy lozenges
      i) Center filled hard candy lozenges
         Liquid filled
         Fruit centers
         Paste centers
         Fat centers
      ii) Chewy or caramel base medicated tablets
          Caramels
          Toffees
• B) Compressed lozenges
• Tablets compressed in weight range of 1.5-4 g.
• Large in diameter.
• Having desired area of activity on mucous membrane and mouth.

2. Non medicated lozenges
   * sugar candies,
   * Lollypops.
Cough Drop (Throat lozenges)

A Cough drop is medicated candy intended to deliver active ingredients which suppress or relieve the cough reflex. They are made just like hard candies. These are sweet in taste and good mouth feel characteristics.

BRANDS:
Capacol
Halls
Chloraseptic
Fishermans friend
Lokerol
Lockets
Ricola
Strepsils
Vicks
1. Hard candy lozenges
   a) Sugars:
      Dextrose, sucrose, corn syrup,
   b) Acidulants:
      Citric acid, Fumaric acid, Tartaric acid,
   c) Colourants:
      Dyes, Organic colourants.
   d) Medicaments
      Local anesthetics
      Ex; Benzocain, Hexyl resorcinol,
      Diperidon Hcl, Benzyl alcohol, Diclomine.
E) Antihistamines;  
   Chlorpheniramine maleate , Phenyltolaxamine Dihydrogen citrate, Diphen hydramine HCl.
F) Antitussives;  
   Dextro methorphan hydrobromide.

g) Analgesics;  
   Asprin, Acetaminophen.

H) Decongestantants;  
   Phenyl propanolamine HCl, d-pseudo ephedrine HCl.
A) For chewy or caramel base:

- Candy base
- Humectants
- Lubricants
- Medicaments
- Seeding crystals
- Flavours

B) Center filled hard candy lozenges
2) COMPRESSED TABLETS

1. Tablet base or vehicle :
   a) Sugars: Dextrose, Nu-tab, Royal T, Di-pac, Sugar tab, Honey tab, Mola tab
   b) Sugar free vehicles: Sorbitol, Mannitol, Polyethylene glycol-8000,6000
   c) Other fillers: Dicalcium phosphate, calcium sulphate, calcium carbonate, Lactose, Micro crystalline cellulose

2. Binders:
   Acacia, corn syrup, Sugar syrup, Gelatin, Polyvinylpyrrolidione, Tragacanth, Methyl cellulose.

3. Colours:
   Water soluble dyes and Lakolene dyes
FORMULATION

1. Hard candy lozenges
   A) Medicament-Flavour-Ground Salvage Method of Addition
   B) Direct Medicament Addition
Ex: Analgesic lozenges(162.5mg or 4 gm)

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid sugar(67.5%)w/w cornsyrup</td>
<td>88.9lb</td>
</tr>
<tr>
<td>Ground candy solvage</td>
<td>49.7lb</td>
</tr>
<tr>
<td>Aspirin 100 mesh</td>
<td>2.0lb</td>
</tr>
<tr>
<td>Imitation orange flavour</td>
<td>1.85kg</td>
</tr>
<tr>
<td>Menthol crystals</td>
<td>35.0g</td>
</tr>
<tr>
<td>Orange colour paste</td>
<td>50.0g</td>
</tr>
<tr>
<td>Orange colour paste</td>
<td>12.0g</td>
</tr>
</tbody>
</table>
C) Medicament Addition via Granulation
D) Dual-Granulation Addition to Reduce chemical incompatibilities
E) Addition of Liquid salvage with colour
F) Addition of liquid salvage with colour and Medicament

2) Compressed based:
   a) wet granulation techniques
   b) Direct compression techniques
Wet granulation techniques:

Antitussive-Anesthetic Lozenges(2.5g)

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dextromethorphan HBr</td>
<td>4.05%</td>
</tr>
<tr>
<td>Benzocaine</td>
<td>2%</td>
</tr>
<tr>
<td>Confectioner sugar</td>
<td>58%</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>15%</td>
</tr>
<tr>
<td>Corn starch</td>
<td>12%</td>
</tr>
<tr>
<td>Gelatin</td>
<td>3%</td>
</tr>
<tr>
<td>Spray dried powder</td>
<td>Q.S</td>
</tr>
<tr>
<td>Lakolene colour</td>
<td>Q.S</td>
</tr>
<tr>
<td>Magnesium stearate USP</td>
<td>0.5%</td>
</tr>
<tr>
<td>Polyethylene glycol 8000</td>
<td>1.0%</td>
</tr>
</tbody>
</table>
MANUFACTURING OF LOZENGES

1. Hard candy lozenges:
   A) Cooking
      3 types of candy base cookers
      a) Fire cookers
      b) High speed atmospheric cookers
      c) Vacuumed cookers

1. Precooked sugar glucose solution 1a. Feed pump
B) Batch cookers

* Batch cookers working based on the principle of stirring.

* Produces lighter and more reproducible products.
C) Pure sugar cookers:  
*The pure sugar cookers lend themselves to easy wash out sugar crystals which are formed on the sides of the kettle.

D) Standard vacuum cookers  
*continuous batch process cooker  
*Pre cooker
E) Cooking machines
F) Candy base preparation:
PRINCIPLE: The entire unit is heated to candy base cooking temperature by passing the steam into and around the copper coil.
G) Mixing
H) Batch processing
I) Rope sizing
J) Adjustment of weight
K) Lozenge formation
L) Cooling
M) Lozenge storage
2) Compressed Tablet lozenges
   a) Wet granulation
      Anaesthetics, Antitussives
   b) Dry granulation
      Analgesics, Antihistamine lozenges

Compression sequences:
   A) Die -filling
   B) weight adjustment
   C) Compression hardness
Compression process
Packaging:

a) Individual bunch wrap
   it is Cellophane, Aluminium foil tissue paper impregnated with a wax or FDA food approved releasing agent.

b) Container
   Plastic tubes, moisture resistant glass, polyvinyl chloride or metal container over wrapped with cellophane or aluminium foil.
c) Carton overwrap

Over wrapped with nitro cellulose cellophane or saran wrap and stored at 25°C with a relative humidity of 80%.

d) Bundle wrap

Waxed aluminium foil, saran wrap, polypropylene, waxed paper used.

e) Foil pouches: They employs aluminium foil as thin as 0.0008inch laminated with poly ethylene and tissue paper.
STORAGE:

The properly sized lozenges are transferred to a conditioning area i.e., maintained at a temperature of 15 to 20°C and controlled relative humidity of 25 to 35%.
Quality control tests

1) General checks
   * Forming checks
   * Cooling checks
   * Moisture analysis

2) Microbiological testing
   * Total plate count
   * Total coli form count
   * Staphylococcus, Salmonella tests.
3) Batch release test
   * Test for grittiness
   * Dosage uniformity
4) Stability testing:
   * Shelf life determination
   * Flavour stability test
Physical stability study:
   * Colour
   * odour
   * Taste
   * Hardness,
   * Bunch wrap
   * Appearance
Recent advances

- The USP currently recognizes Cetyl pyridinium chloride Lozenges and Nystatine lozenges.
- Sublingual Zolpidem tartarate lozenge for the treatment of Insomnia was developed.
- Bacitracin was developed in the form of lozenge for the treatment of infections caused after burns, scars etc.,.
Nicotine lozenges

- These are the newest form of Nicotine replacement therapy on the market. The FDA recently approved the first Nicotine-containing lozenge as an over-the-counter aid in smoking cessation.
- These are available in 2 strengths: 2 mg and 4 mg.
CONCLUSION

- Lozenges are medicated confections designed to locally deliver drug to mouth and throat.
- Provide slow dissolution and drug release.
- These are totally different from other dosage forms in terms of ingredients, method of manufacturing, therefore require specialized facilities.
- For these and other reasons, lozenges are produced by few pharmaceutical manufacturers and represent a very small percentage of pharmaceutical sales.
REFERENCES

5. www.pharmainfo.net
THANK
YOU