Preparation of Hollow type Suppositories

Conventional Suppositories
Mold for Hollow Type Suppositories

Suppository Mold
Place the pipes at central of the hole

Hollow or Hole

H-type Suppo. With Thin wall
Add Warm water in the pipe

Make a hole via pull it out

Pull out
Hollow-Type Suppositories

Before

After
Slowly add drug powder into the hole

Add drug solution into the hole
Add drug solution into the hole

Top Closed with melted base
Wrapping with Aluminium Foil

Image of hands wrapping an object with aluminium foil.
Wrapping with Aluminium Foil

Finished Suppositories

Bad wrapping
Fatty Substitute as Suppo. Base

Bullet Shape Suppository

Suppository Production in Industrial Scale
Industrial Production

Rotary Suppository Molding Machine

1. Rotating Cooling Turntable
2. Feeding Device & Filling Hopper
3. Scraping Device
4. Refrigerant Inlet & Outlet
5. Suppository Ejection Station
Production Line

Plastic Mold for Suppositories
Quality Control of Suppository

Physical Feature
- Melting Time
- Drug Content
- Disintegration Time
- Release of Drug from Suppo.

Quality Control of Suppository

1. Physical Appearance: Absence of
   1. fissuring
   2. pitting
   3. exudation
   4. Precipitation
   5. contraction holes
   6. air bubbles
   7. Color Change
Quality Control (Cont.)

2. Hardness & Fragility Test
   Breaking Test Apparatus
   Erweka Hardness Tester

3. weight variation

Quality Control (Cont...)

4. Content Uniformity

5. Melting Point)
   • Capillary Tubes Method
6. Melting/Liquefaction Time
   • Krowczynski Apparatus
   • SOTAX Suppotest ST3 Not longer than 30 min.

7. Disintegration Time
   • Disintegration Apparatus
   • Not longer than 30 min.

8. Dissolution Testing
   • Direct partition :
   • Static diffusion : microbiological cup-plate assay technique
   • Dynamic diffusion : dialysis bag
Quality Control (Cont...)

8. Dissolution Testing

• Direct partition:
• Static diffusion: microbiological cup-plate assay technique
• Dynamic diffusion: dialysis bag

Weighing and Weight Variation
Breaking Test Apparatus

Disintegration Apparatus
Disintegration Apparatus

Muranishi’s Method

Cylindrical diffusion cell
Suppository
Millipore membranes

Thermostatic bath
Releasing fluid glass vessel
Releasing fluid
Stirring bar
Magnetic stirrer
Rotating Dialysis Cell Apparatus

Suppository

Phosphate buffer solution

Put Suppo. in and covered by memb.  
And add 5 ml of Buffer solution

Fixed with Stem  
and Immersed in Beaker
Set the parameter and run to start

Rotating Dialysis Cell
Drug released from Suppo.

Suppository
7-12 Samples Sampling @ 5, 10 mL

Flow Through Dissolution Apparatus

Analyze by HPLC / others
Various cells of Flow through Apparatus

1,2 Tablet, 3 powder, 4 for implant, 5 Suppository, Soft capsule

### Calculation of Drug Released

<table>
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<th>Sampling Time (h)</th>
<th>Absorbance (ug/ml)</th>
<th>Conc. in 700 ml (ug)</th>
<th>Q in 700 ml (ug)</th>
<th>Waste C</th>
<th>Waste Q (mg)</th>
<th>C Q</th>
<th>%</th>
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Release Profile of Morphine from Suppository

Washing and Cleaning after Laboratory Practice
In vivo test of Suppositories

Laboratory Animal

Balb C Mouse (~20-30 g)

Wistar Rat (~200-300 g)

Hairless Rat (~275-350 g)
Animal Experiment at Showa Pharm Univ.

Animal / Rabbit Blood Sampling
Blood Sampling Process from Rabbit

Blood Sampling Process from Rabbit
Plasma profiles of salbutamol sulfate suppository in human: (*) F 1; (■) F 2; (▲) F 3 and (×) Tablet.

Example

Dispensing of Suppository for Patients
Marketed Recatal Suppository

proctosedyl®
12 suppositories
Marketed Vaginal Suppo./Tablet
Foam, film, vaginal suppositories
How to Insert a Suppository

1. Remove foil wrapper.
2. Moisten the suppository with water or water-based lubricating jelly (such as K-Y).
3. Lie on your left side and bend your right knee up toward your chest. Gently push the suppository into your rectum so it is deep enough not to come out.
Thank for all Students (August 2001, 2002)

Evaluation and Examination

1. Lecture 10 Points
2. Lab. Paper 5 Points
3. Homework 5 points
เรื่อง ชวนคิด
สอนศิษย์ เป็นคนดี

DO IT WITH GOOD TARGETING

Snow in Toyama 1995
เมื่อมีความฝัน
ต้องลงมือทำ และ
ใส่ความพยายามให้มาก

IF YOU HAVE A DREAM
JUST DO IT
AND TRY IT HARD

นายกฯ ทักษิณ กล่าวให้สัมภาษณ์กรณีจะนำไทยเข้าเป็นสมาชิก กลุ่มประเทศ OECD
(กลุ่มประเทศที่มีความมั่นคงทางเศรษฐกิจ)

พระบรมราโชวาท... ...

ขอให้ฝันว่า...การทำหน้าที่ได้สมบูรณ์
เป็นทั้งแรงจูง และประโยชน์อย่างยิ่ง
จะทำให้ประเทศไทยเป็นสุขและมั่นคง
Where is your Car?
What is your Goal?
When will you want to reach the Goal?

Good Luck Everyone