

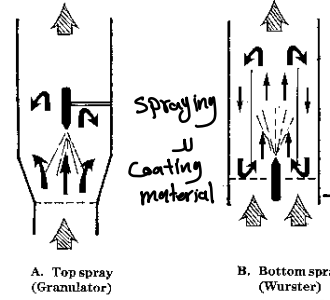
ال Formula لا Coating ① polymer ② plasticizer ③ solvent ④ color

w. soluble  
immediate release

w. insoluble  
functional polymer

all in one  
drying  
mixing  
granulation  
coating

# Film coating process



atomization لا  
اله اكثر من شكل  
اذا من الاعلى Top spray  
اذا من طرف بزوايا Tangential spray

## Fluidized-bed (Air suspension) coating

In this technique tablets are kept in motion inside a chamber by blowing hot air. At the same time coating solution is applied by an atomizing nozzle.

عالي بس ال labor (العالة) قليلة

ميزته

- ① Heat-mass transfer ممتاز
- ② mixing متالي

③ تقيد التحكم بحجم ال coating layer



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يستعمل ال small tablets ( pills ) او ال Spansules لبحن الاستاء المعيزة ودائرية زي Contraceptive

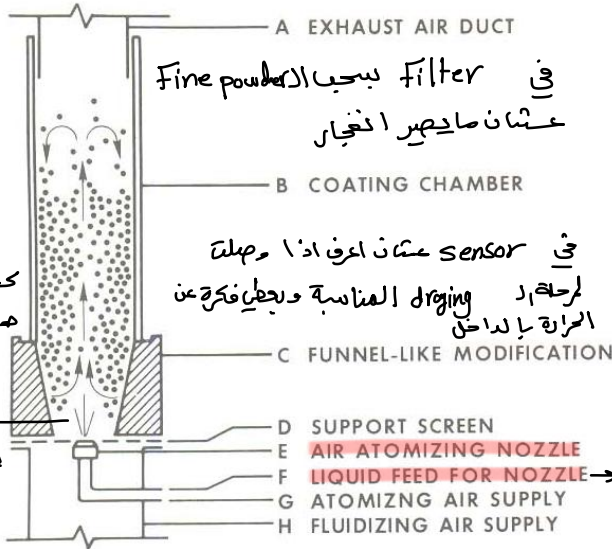


FIG. 12-12. Diagram of a fluidized bed coater.



لا Coating

يعرف ال Tablets ويستعمل المعيار 6 بفض هوا  
لعمل Fluidization الكبات بحمروا كل وحدة 44  
يعدن بفض ال coating material عن طريق Spraying

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## Ideal characteristics of film-coated tablets

1. Film coated tablets should display an even coverage of film and color. كل ال tablet مخمليه و اللون متساوي
2. There should be no abrasions of tablet edges or crowns. مافي اى نزع قسط او علامة
3. Logos and break lines should be distinct and not filled. حكيما ال sugar سهل القسط ال ماازف لا لونه mechanical strength
4. The tablet must be compliant with finished product specifications and any relevant compendial requirements. لونه polymer عبارة عن chains ستايجين

في quality control tests لل Coated ( official و nonofficial )

- disintegration
- dissolution
- weight uniformity
- Friability
- hardness
- Content uniformity

لازم نراجع لل Compendial ( pharmacopial ) او official requirements

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## Coating faults and film defects

ال tablets بي تطلع من ال tableting machine بتمر على زي الخزام المتحرك ويكون في عاملين بشيوا ال tablets ال صغيا Defects

- Variations in formulation and processing conditions may result in unacceptable quality defects in the film coating. These defects include:

Logos → Debossed : Engraving حفر lower than the tablet surface  
 → Embossed : Elevation نتوء



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punch بار picking uncoated يمكن لما يصير ejection لـ tablet جزء منها يلتصق بار punch

بار coated ما في punch في coating pan ، يلتصق بار coating pan وبار tablet وبار احاد ا طلعا جزء منها يلتصق وبار بصير لانه بار not dry-tablet فضات sticky او overwetting او inadequate drying عاد coating pan = picking

## Coating faults and film defects

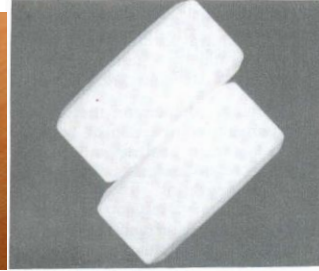


### Picking and twinning

- **Overwetting** and **inadequate** drying conditions will cause tablets to stick to each other or to the **coating pan**.

- Common problem with flat or capsule-shaped tablets = tablet

كل 2 او 3 tablets 8 twinning - ملتصقين بيهم بسبب overwetting او inadequate drying



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للاصصاق اصل لما بار tablet تكون flat لانه لسطوح يفتح اكثر من الجانبين

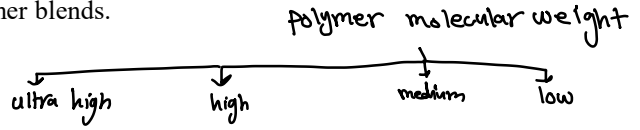
## Coating faults and film defects

لما تكس عدد كبير من الـ tablets يكونوا كلم صابون مع بعض ففني stress واي احمي في حركة في Heat / بالاصدم بعد الـ tableting نترك الـ tablet يصير لها relaxation يعني يصير Energy dissipation او Heat يعني الطاقة تصير zero بدين نقل coating .

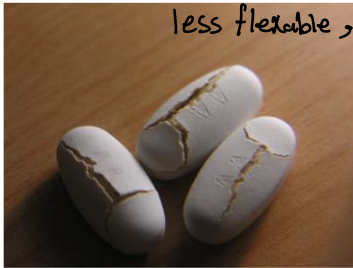
### Cracking and peeling

- Film cracking occurs if the internal stresses exceed the tensile strength of the film.
- Film peeling may also occur.
- This problem is usually overcome by improving mechanical properties of the film by:

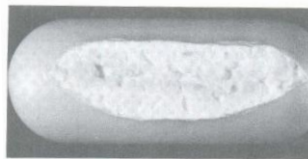
- Using <sup>low</sup> higher molecular weight polymers or polymer blends.
  - adjusting plasticizer type or concentration.
- اختار plasticizer مناسب او عدل التركيز ناعه لازم كميته وكفاءة لـ polymer لكي لا ندم بشتلوا مع بعض.



لازم تصير الطاقة هين وتوخذ شكلها النهائي بدين coating عنان ما يصير cracking



Film cracking



Film peeling

تقشر اذا الـ formula ما لالا adhering Good

الـ Coat في تشققان لانه في stress 48 داخل الـ tablet

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# Coating faults and film defects

**Blistering**: Bubbling

ارتقاع

- This results from too rapid evaporation of the solvent from the core
- Milder drying conditions are indicated in this case



Blistering

ال - Blistering لان في Heat / وهو جوا لسرعة تبخر جسي ما قدر يطالع من ال  
 حلا milderdrying خفق الحرارة واعطي زمن اطول عن يطالع الغاز Bridging

- During drying, the film may shrink and pull away from the sharp corners of an intagliation or bisect.

Detachment

- Increasing the plasticizer content or changing the plasticizer can decrease the incidence of bridging

ال - الاستاء ربي  
 تساعد ال Film  
 يوجد شكل tablet  
 ال plasticizer

فصل و صهار هبة وحدة / Debossed / حافظين حصر لعين ال Polymer غطي

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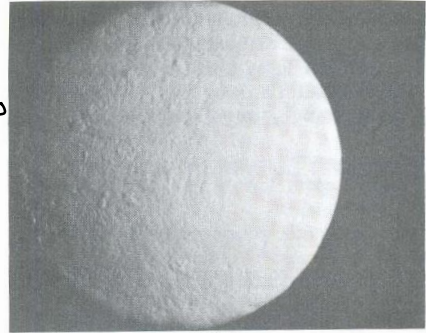
ال Deboss ال Deboss بصيرا خلال ال tableting / بال Film لا لزوم نغطي

كل ال Counter / bridging يح ال احرف يكون رايح منها لان ال polymer فصل عن ال Deboss  
 لعين انكسي فصار هبة وحدة كانه مافي احرف

# Coating faults and film defects

**Orange peel effects** يطالع حقل قشرة لبرتعال  
 حشونه بالسطح

- Inadequate spreading of the coating solution before drying causes a bumpy or "orange peel" effect on the coating



- Causes:
  - Two rapid drying
  - High solution viscosity



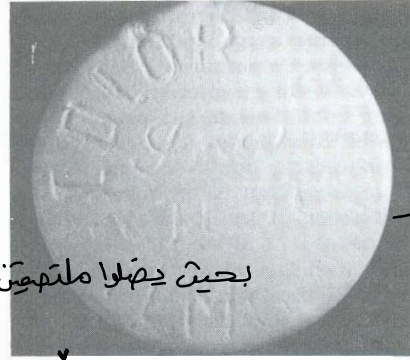
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ال Inadequate ؟ ال pan يتلف وانت بتعمل spraying / وحدة منهم غلطي مشكلة كانه بال pan  
 كلهم فوق بعين المعروضه كل وحدة عندها عزيمة تتعرض ل Coating ، اذا صار احسن منج احسن يتعرض ل Coating او تحمية ال Coating material  
 من حماية مراح يعطيني Smooth Coat و Coat متالفة

# Coating faults and film defects

## Bridging of logos

- Partial or complete detachment of the coating in the region of the logo.
- This can be solved through formulation of the coating formula by:
  - Improving film adhesion
  - Reducing stress within the film



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# Coating faults and film defects

## Color variation

في عدد حبات كثير بال pan فالألوان متسوية ممكن تكون

- This problem may result from:

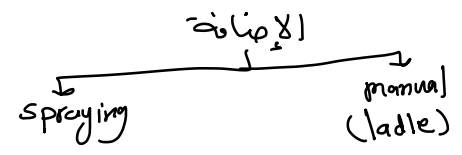
Uneven spray pattern → *صراة بنفعل spraying suspension واذا لم يوزع يمكن يترسب*  
 Improper mixing *لا يوزع انا كد انهم suspension*  
 Inadequate coating *تسوي وال coating*  
 Inadequate mixing *تساوي نكلار tablet وكلم*  
 Inadequate coating *تسوي بنفس المدة ولتس الكمية*  
 Inadequate mixing *اذا ما كلهم تعرضوا لا coating*  
 Inadequate coating *استي يكون لونه مائع والتمتع*  
 Inadequate mixing *المفردون اكلوا مثلا ال 2 layers*  
 Inadequate coating *استي ما تعرضوا لا coat يكون طبقات داخلية*  
 Inadequate mixing *usin baffles الى الى حواجز يتغل randomization*  
 Inadequate coating *بخطوا بال baffel وبيجدوا عن يحدن*

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# Sugar coating

- Sugar coating is the traditional method of coating tablets (الطريقة الاقدم واقلها من صناعة السكر مع تحديلات بسيطة)
- It involves successive application of (sucrose based solutions) to tablet cores. - بمزيج 20-30 حبيقة Syrup لحد ما اعمل على ال Coat فالوزن يزيد 30-50% والزمن 8 ساعات ليوما (Coating - drying - drying - drying)
- It is less common nowadays than film coating
- It takes time from hours to few days.
- The increase in tablet weight is 30-50 %
- In general the equipments used in film coating can, with suitable modification, be used for sugar-coating techniques.
- Methods of applying the coating syrup include manually using a ladle or by spraying.



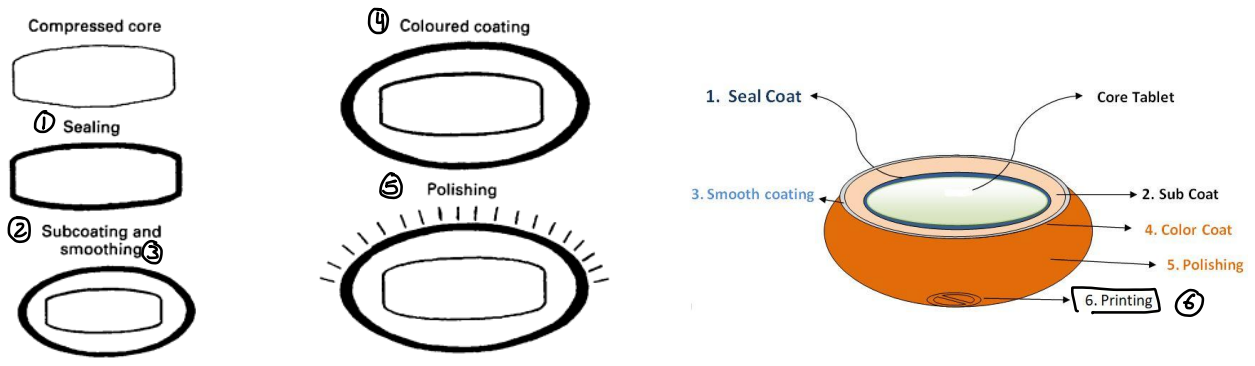
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استعمال زي المحزفة

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الكمية التي يستخدمها للزمن لتراعي الشركة وكمية ال tablets و يكون small batches 500-1000 - 300-400 حبة

## The stages in sugar coating



هل يمكن ان ينفى ال Syrup مباشرة ؟ (ال Syrup من Syrup USP الـ تركيزه عالي)

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ال Syrup عبارة عن مزيج خافذا ينفذه ال tablet ما راح تصير زي ما هي وراح تقسمنى 54 ، فلزوم اعلما نزل اول خطوة Sealing ، عازن hydrophobic / ليد ال Sealing بيجو sub coat هي طبقة Syrup سدوية بجدين اهنيف ال talc عن طريق ال dusting (رشت) [ Calcium carbonate او talc ]

بجيت يصير عندها نتوعان الحبة و يصير السطح خشن بحيث تأسس للصبقات الي لخصها كـ Adherence (في الـ film) ↓  
 بعد الـ subcoating بفعل Smoothing و لعله املس عن طريق 20-30 طبقة من الـ syrup [coating - drying - coating] -  
 معشان ما يصير الـ orange peel الي هو التكل الخشن بصيف الـ colorcoat (آخر استي يس يصير السطح املس تماماً)  
 بفعل الـ polishing مثل الـ beeswax (الشمع) Sugar coating  
 جدين printing → edible ink حبر قابل للأكل

### 1. Sealing of the tablet core

- A seal coat is applied to prevent moisture penetration into the tablet core (especially needed in pan-ladling processes).  
 خاصة اذا manual يتكون القرعة بطينة رخي جبال للي تدخل وتترن الـ tablet الى من الـ syrup الي راح احمسه
- In spray processes, it is possible to adjust the application of the subcoats and coat so that localized overwetting does not occur and therefore no need for sealing.

اذا spray ممكن ما تعمل هاي الخطوة / اذا ما في overwetting مافى رطوبة والقرعة سرولية  
 ما يجبل sealing

## Sugar coating

### Examples of materials used in sealing:

- Shellac من هاي القرعة  
 - This is a purified resinous secretion of the insect *Laccifer lacca*.  
 - It suffers from occasional supply problems and quality variation. → لانها من مصدر طبيعي  
 - there are also stability problems associated with increased disintegration and dissolution times on storage. لكن في Variation مترو حسب من اي بلد او بالهين والاشياء
- Zein (extracted from corn gluten meal) من الازرة  
 - It is a natural protein من بروتيني - بيتي اصن
- cellulose acetate phthalate
- polyvinyl acetate phthalate } Synthetic  
 حكتنا عنه بال Enteric

# Sugar coating

بدي احضرا حامان لدر coating

## 2. Subcoating

- The subcoating is applied to round the edges and build up the tablet size
- The process is usually performed by applying sticky solution of **sugar**, **gelatin** or **acacia** to the tablet and then adding (dusting) the subcoating powder (bulking agent) such as **calcium carbonate** or **talc** to the tablets and then drying
- Subsequent subcoats are applied in the same manner until the tablet edges have been covered and the desired thickness is achieved
- For spray processes, a subcoating suspension containing both binder and the subcoating powder is sprayed intermittently on the tablet bed

اذا spraying ← ال talc بخلطه مع syrup او gelatin او acacia او syrup  
 ممكن

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يا بنه فان يدري او على مرحلتين او بال spraying مرحلة وحدة

# Sugar coating

## 3. Smoothing

- Tablets will have a rough surface after subcoating.
- The purpose of this step is to remove the imperfections in the tablet surface (rough surface) caused by subcoating process. coating مرة 20-30
- In this step, few sugar syrup coats are applied (the first usually contains some suspended particles and called grossing syrup).



المرحلة الاولى من ال smoothing ال tablet بعد  
 ال subcoating علما dusting ال grossing syrup فيه تحية solid  
 كافية تغطي قدر الامكان بين ال talc الموجود

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عشان نردح المنتوعات و اسرع عملية اني اوصل لسطح كل 20

## Sugar coating

### 4. Coloring

آخر احسن ليس يصير السطح smooth

- In general colors should be added when the tablets become quite smooth.

ال dye موجود حوا Syrup

- Syrup solutions containing the dye are applied until the final size and color are achieved.

- In the final syrupeing or finishing step, a few clear coats of syrup may be applied.

صهارت smooth لجدين تمتعت اللون الاظهنر  
 لجدين بدع اهنق Syrup بدون dye (clear Syrup)  
 عثمان احفظ على اللون وما يتغير

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## Sugar coating

### 5. Polishing

- Tablets are moved to the polishing pan and solutions of beeswax or carnauba wax in suitable volatile solvent are applied until the tablets become shiny.

بحرق ال wax د volatile solution موش د water

زي الكحول

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# Sugar coating

±

## 6. Printing

- It is a common practice to identify all oral solid dosage forms with a manufacturers logo, product name, dosage strength or other appropriate code.
- For sugar coating such identification can be done only by printing using special edible inks. قابل الاكل  
Food grade

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## Sugar coating problems

زی ای با Film

### Cracking, chipping and splitting of coat

- Sugar coatings are inherently brittle. → سلبه، لقمه
- Tablet cores that expand cause cracking. Expansion بهر اعلی tableting machine لاخیس قلع من
- Expansion may result from:
  - Moisture sorption
  - Stress relaxation of the core
 energy / Heat / mechanical stress  
 يكون منیا  
 فبترکها فترة تبرد رتوضه سکلما، لسانی بچین ال Coating  
 اذ اعلی هیک بهر اذ Expansion طار Cracking
- Addition of small quantity of polymer often helps to improve structure integrity.

کیف اعطی ال mechanical strength  
 ا هنیف polymer علی ال Sugar solution

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## Sugar coating problems

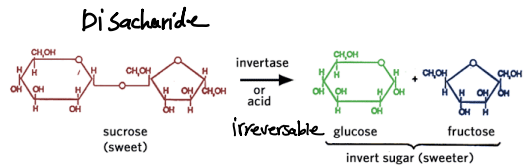
تجدال drying بين جدي الطبخ والtablets ان ال **Twinning** pan  
 يداقي اكثر من دصة ملتصقين ببعض بسبب ال drying صناعي او تحة ال liquid  
 اعلى من حرارة ال drying



- Results from drying after sticking of tablets.
- كل ما كانت Flat بتزيد فرصة ال twinning / اذا spherical العزبة اقل

### Non drying coating

- This a result of sugar inversion.



كرايميل لونه افتح وطعمه احلى  
 من السكر الحادي  
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\* انبت اعد drying وما ينشف الاصل اذا استخدمت المراته صح (syrup concentration) صح يصير drying  
 Sugar inversion : الاصل ال sucrose هو لي بتخدمه اذا ال sucrose عن ال coating ال drying  
 لدره من حرارة عالية اول acidity (invertase enzyme) بتفكك ويطلع glucose + fructose / دره اذا  
 صا حاض ال pan ما ينشف وما يرج irreversible

## Sugar coating problems

**Uneven color** ال pan وال tablets مع بعض بتحركوا الاصل  
 كلهم العرقتي العزبة ل ال coating اذ ال color

### Causes:

- Poor distribution of coating liquids. → ما توزع يكله الصبغات
- Color migration of water soluble dyes while the coating is dried. اذا كان ال color دال ب ال solvent ال بي ابحته راح يطالع ال solvent دراج يصير في اختلافات الي بتبخر (اخر) والي ما صا ال migration رهي
- Unevenness of the surface of the subcoat. (orange peel) صنف
- Excessive drying between color application can cause erosion of the color layer ال اصل ال Coat يضل فيها
- **Marbling** excessive drying Flexibility عنان فصل متماسكة حول ال tablet اذا دخلت حنيفة صا ال Coat يطلع ويغطي شكل قطن (erosion)
- It may result from rough surface after smoothing so that the thickness of polish layer varies



- الحلول
1. uniform distribution
  2. نقل الذاتية
  3. unevenness نتجنبه ال
  4. avoid excessive drying

marbling  
 اللون في تلوّج ريجردي نتودان وال smoothing  
 متساوي في بهير marbling وما في shininess (polish) سيرة  
 rough بجي بعد ال crossing

## Sugar coating problems

### Blooming and sweating خلال التخزين في عبوات الجبزي الذي

- This result from residual moisture.
- This moisture can diffuse out and affect the product quality.
- Moderate levels of moisture egress causes the polish to take on a fogged (fade) appearance (**Blooming**). بحالي اللون فاتح
- Higher levels of moisture egress the moisture may appear like beads of perspiration (**Sweating**) which may cause tablets stored in closed containers to stick.



BLOOMING: FADING OR DULLING OF A TABLET COLOR AFTER A PROLONGED PERIOD OF STORAGE AT A HIGH TEMPERATURE



degradation تتحلل (Sweating) ← ممكن ان Coat

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اذا تمتع المر الى طلمت خفيفة (Blooming) اذا الكبيرة (Sweating) droplets

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## Press coating

- The technology of press coating differs from the film and sugar coating techniques.
- Press coating involves the compaction of granular material around already (performed core) using compressing equipment (specialized tableting machine) similar to that used for the core itself.

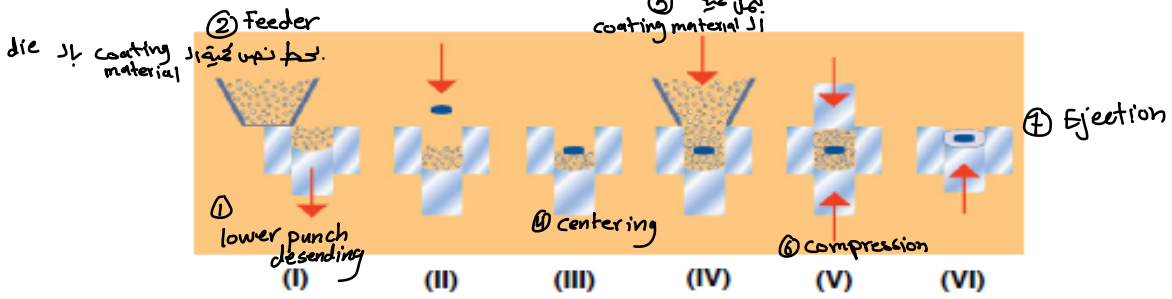
او tablet الى تصنع  
بماكنة خاصة

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نفس ماكينة الكبس - die - lower punch - upper punch

③ arm  
تخطيط الـ tablet  
بالـ die



- I: Prefilling the half amounts of outer coating materials into the die.
- II: Putting the inner core tablet on the powder bed of outer coating materials.
- III. Centering. *وزن تكون بالنص لانها لو كانت مالتفة ممكن تتكسر*
- IV: Filling the residual half amounts of outer coating materials.
- V. Compression
- VI. Ejection of press-coated tablet from the die.

الماكينة العادية ما فيها Feeder و ما فيها arm بتعمل centering

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Coat يكون دوا ثاني] ويمكن نفس الدوا الـ Core يكون Sustained Coat يكون immediate

## Press coating

- Press coating is used mainly to separate chemically incompatible drugs.
- Two steps of press coating can be used for perfect separation between two ingredients by an [inert middle layer] → *tableting يكون عليها inert layer لما غلتها tableting*
- There has been increased use of compression coatings for the purpose of modified release products (e.g. Adalat® CC). *بجدين تخطيط عليها النوع الثاني (Coating)*
- The disadvantages of the process arise from the complexities of the mechanism used in the compressing machine.

① quantitative Feeder  
بدي

اول مرة دحط زحم الكمية بجدين لثاني لثاني  
① ربي arm

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QC test

- Disintegration
- Dissolution
- weight uniformity
- Content uniformity
- Hardness
- thickness
- Friability

official

non official

Official 14 ال اجباري سيجعل و يوجد 2 من 1 non official

# Standards for coated tablets

- In general pharmacopeias have similar requirements for coated and uncoated tablets, the difference being that:
  - Film coated tablets must comply with the (uniformity of mass) test unless otherwise justified and authorized. *weight uniformity*
  - Disintegration test

## Immediate release tablets

Film coated: 30 min (except for enteric) *suger سكر*

Other types of coating: 60 min

The test may be repeated using 0.1 N HCl in the event that any tablets fail to

disintegrate in the presence of water.

PH (1.2) Immediate release *تجربه على PH الحامض لانه*

## Enteric coated tablets

A challenge test in acidic medium (e.g. 0.1 N HCl for 1.5 - 2 hours) is done, where no disintegration should occur. Then the tablets are transferred to buffered medium where disintegration should occur within 45-60 min

break down  
swelling

في سلكه منبها 6 tubes كل واحد في واحد في tablet والحرارة 37°C عاد mesh

69 intact *تضمن* Disintegration لا يجب ان *لا يجب ان* [pH = 1.2] *لحمه 1.5 - 2* *Stomach Emptying*

45-60 min *Disintegration* *في سلكه منبها* pH=7.8 *buffer*

# Coating of multiparticulates

**Multiparticulates**, often referred to as **“pellets”** or **“beads”** possess many benefits compared to conventional non-disintegrating tablets. *very hard*



- They may be used in extended release or delayed release dosage forms.

70 *pellets* *spansules* *زيد* *tablets* *Coating* *لا سيما* *تأثيره* *عزل* *ممكن* *اعلى* *70*  
*interaction* *release* *او* *اخر* *بين* *وصول* *بينهم* *عشان* *التحكم* *بال*

# Coating of multiparticulates

## Advantages of multiparticulates:

Their small size (typically 0.5-2 mm) allows them to pass through the pyloric valve. Therefore, the GIT transit is more consistent than that of tablets.

سهولة انتقالها من المعدة لـ intestine

disintegration

They allow the release to be optimized for individual drugs in a system delivering two or more active drugs. → 2 ingredients

They are less likely to suffer from problems associated with film failure or poor coating uniformity. peeling - twinning - bridging

Whole non-disintegrating tablets can potentially lodge in restriction within the GIT and this can lead to ulcerative mucosal damage.

اصيائاً الـ size غير مناسب فـ يمكن تدخلها بـ أماكن داخل الـ stomach والـ intestine و تعلقها في الـ lode وتعمل الـ inflammation

## Types of multiparticulate

**Drug crystals** → size shape Crystals



They should have appropriate size and shape

**Irregular granules**

These can be coated but it is difficult to achieve uniform coating thickness.

الافضل احسن الـ regular عشان الـ coat يكون الـ uniform

**Spheronized granules**

These can be prepared by extrusion/spheronization or rotor granulation.

**Drug loaded nonpareils**

من جهاز الـ Extruder يطبع الـ Strings بعين الـ spheronization بعلم الـ milling بعين

These are preformed spherical particles about 1 mm in diameter consisting primarily of (sucrose and starch) → core without drug (inert)

The drug (dissolved or suspended in a suitable solvent containing also a polymer binder) is usually sprayed onto the surface of nonpareils and then they are film coated.

**Minitablets (1-2 mm)**

↓  
tablet machine → محطرة  
عادية بس حجمها صغير

Drug loaded

هي نفسها ما فيها الـ drug انما حبيباتها دوا خلال الـ coating  
يمكن احترمن طبقة و احترمن دوا بعين الـ Core ما في دوا نصائياً

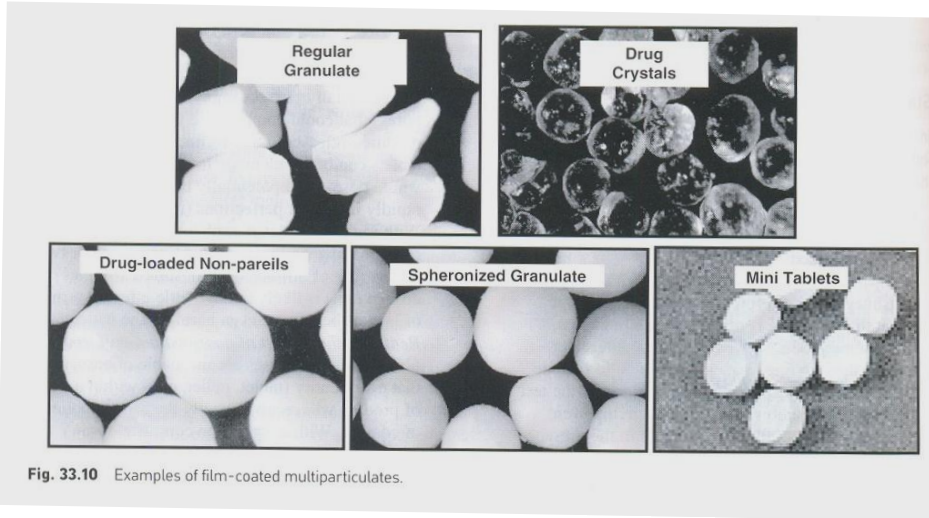


Fig. 33.10 Examples of film-coated multiparticulates.

## Process for coating multiparticulates

- Traditionally multiparticulates were coated using pan coating processes.
- Today fluidized bed coating is preferred because of their ability to:

- Enable discrete coating while minimizing the risk of agglomeration
- Ensure that coatings are uniformly deposited on the surface of each multiparticulate in the batch.

Spraying    Rolling    Drying/Solidifying    Layer formation    Pellet

اصنع اتي - Fluidized bed  
 spray  
 ادل اتي - core يكون حله  
 عبارة عن starch او sucrose

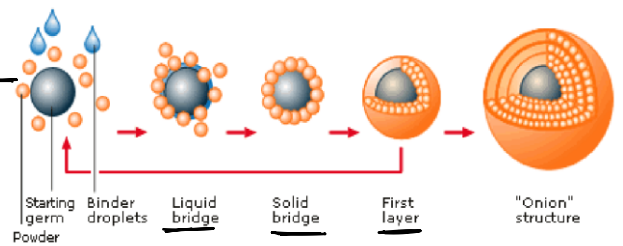


Fig. 2: Principle of Powder layering

بدونه تا لا يمكنه و بعد fluidization بال -  
 ① liquid bridge  
 ② solid bridge  
 تكون اول layer لطيف الحيزان و بغير اد spray لهما حيزه او Enteric coated  
 spray حله الي هو اد drug<sup>74</sup> Coating solution

## Other coating methods and technologies

- Dip coating** ما يتبرصوه حالياً  
 - Tablets are coated by dipping into coating solution. تخليل بال Coating Solution  
 - Not commonly used nowadays.
- Hot melt coating** Solution مائي  
 - Melt is sprayed and not solution  
 - Materials used (M.P. 55 -65 °C): beeswax, synthetic monoglyceride and diglycerides, synthetic spermaceti.  
 - Fluidized-bed coating is preferable. ال Coating material يمكن تدويرها بجلعها و drying / عاد و cooling بصير لها Solidification
- Electrostatic powder coating process** يعني مائي drying ولا Solution في Solidification و melting  
 - Uses principles similar to those used in photocopying.

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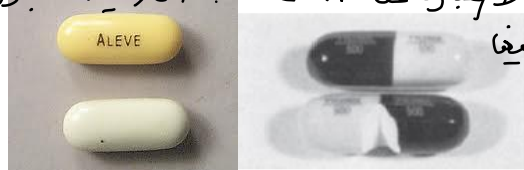
الطريقة القادرة بالمستقبل

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يسعملوا اد printing حال photo Copying بتجهيز الدعا  
 بتحمه عاد Electrostatic يعني اسبق ink Ionized و باد tablet powder Coating

## Gelatin-coated tablets

- A recent innovation is the gelatin-coated tablet. تغير بيهم يطعوا اسبق حيد
- Advantages:**
  - It allows the coated product to be about **one-third** smaller than a capsule filled with an equivalent amount of powder. الكبسولة دلتا يكون مش مجيبه كعلا حكا خذ ال 2/3 والكبسول وغلظم Gelatin tablet 1- سهل للبلاع
  - The gelatin coating facilitates swallowing,
  - Gelatin-coated tablets are more tamper evident than unsealed capsules. لاخد ال Gelatine مش قطعين و body + cap لا يبارة عن coat ما ينفصل زي الكبسولة

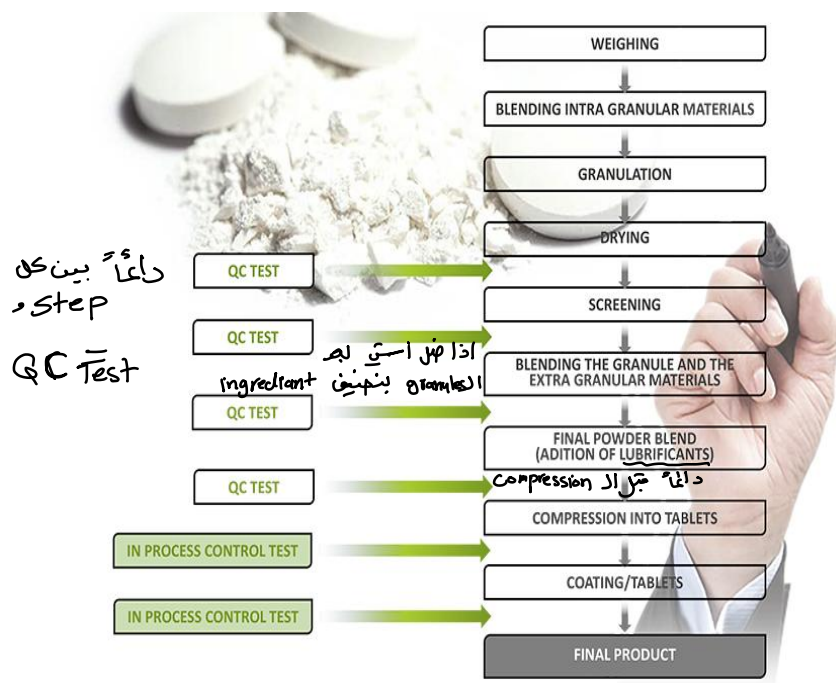


دليل التلاعب مغنا  
 واهنح

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tamper evident

دليل التلاعب - لفتحوها و يطلعوا اسبق زيادة  
 ال الاصل الكبسولة تكون ملغومة بحرارة  
 فلا يمكن فتحها بتخرب  
 كل ادادوية عموماً tamper evident  
 38



## Types of Quality control tests

### 1. Official tests - Compendial - pharmacopial

- Weight variation test
- Drug content
- Disintegration time test
- Dissolution test

للمواد الصيدلانية اجباري مع 2  
من اد un official عن سنة

### 2. Unofficial tests

- Thickness
- Hardness
- Friability
- Organoleptic characters

To use The special ? to Describe something

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متى توصف اللون - الرائحة - الطعم اذا سمح حدوثه  
تتمثل الحواس

Parameters and frequency of In Process Checks for Tablets (Coating & Polishing Stage) TABLE C

Tablets for in process frequency and sample size during Coating & Polishing				
Sr. No	In Process Parameter	In process checks by Production	In process checks by QA	Sample Quantity in No.
1	Physical Appearance توصف وصف كامل	After each coating cycle/ every 30 min and at the end of lot/ batch and after polishing.	QA person shall be done in-process checks as per instruction given in BMR.	20
2	Average Weight اد Film 2-3% زيادة اما Sugar زيادة بحارة	After each coating cycle/ every 30 min and at the end of lot/ batch and after polishing.		20
3	Thickness	Coated tablets after polishing of lot/ batch.		10
4	(Tablets Breaking force) (If applicable) hardness	Coated tablets after polishing of lot/ batch.		10
5	Disintegration Time.	Coated tablets after polishing of lot/ batch.		6
6	Diameter	Coated tablets after polishing of lot/ batch.		10
7	LOP of Tablets لتوزن و ضبطها بال even لحد ما يثبت الوزن / تفرق لوزن	Coated tablets after coating of lot/ batch.		No. of tablets equivalents to 10 gm.
8	Inlet, outlet Temperature, Spray rate, Pan RPM and weight gain water solvent	After each coating cycle/ every 30 min and at the end of lot	20	

Note: In process checks shall be carried out after machine stoppage or breakdown.

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حسب الراسلة من لفظها  
ما يعرف قصبها اسألها

# Formula

①

	Formula Variation		
	I	II	III
Gelatin	60 g	5.4 kg	
Acacia	60 g	2.7 kg	450 g
Sugar, cane	1500 g	53.7 kg	
Syrup, corn			450 g
Syrup, USP			3.785 L
Water, distilled	1.0 L	44.3 kg	

②

	Formula Variation					
	I	II	III	IV	V	VI
Kaolin		225 kg				
Dextrin		112 kg	185 kg			
Cocoa powder		60 kg				
Calcium carbonate, pptd			480 kg		7.72 kg	
Sugar, cane, powdered	4.1 kg	112 kg	240 kg	40 kg	0.9 kg	180 g
Acacia, powdered	0.12 kg			6 kg		1 g
Starch, corn	1.35 kg				0.9 kg	60 g
Talc, USP	0.23 kg					1 g
Calcium sulfate, NF						

	Grossing Syrups			Heavy Syrups		Regular Syr
	I	II	III	I	II	I
Colorant	q.s. ad	q.s. ad	q.s. ad	q.s. ad	q.s. ad	q.s. ad
Subcoating powder	22.7 kg					
Calcium carbonate, light		7.75 kg	69 g			
Sugar, cane, powder	136 kg	22.7 kg	572 g	2.73 kg	181 kg	85 g
Starch, corn		1.36 kg	69 g			
Syrup, USP		22.7 L		3.785 L	256 kg	
Water, distilled	76 kg		290 ml			q.s. 100 ml

	Formula Variation	
	I	
Wax, carnauba, yellow		0.09 kg
Beeswax, white		0.09 kg
Wax, paraffin		0.02 kg
Naphtha		3.785 L

## Sugar coating example

Smoothing by Grossing solution

بكون في solid material كبيرة  
regular

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تقرأ

## Film coating example

INGREDIENT	TABLET CORE/ COATING %	QUANTITY (mg)
<b>Tablet core</b>		
API Cyclophosphamide monohydrate	22	53,45 (50 mg anhydrous)
DC vehicle (Diluent/Binder) Microcrystalline cellulose (Vivapur®)	43	102,00
DC vehicle (Diluent/Binder) Anhydrous dibasic calcium phosphate (Anhydrous Encompress®)	31	75,00
Disintegrant Sodium starch glycolate (Explotab®)	2,5	6,00
Glidant Colloidal anhydrous silica (Aerosil®)	0,5	1,15
Lubricant Magnesium stearate	1	2,40
<b>Coating</b>		
Plasticizer Sorbitol	17	5,60
Solvent/Plasticizer Glycerol	68	22,42
Film-forming agent Povidone (Kollidon®)	5,2	1,72
Coloring agent FD&C Blue No. 1 (E133) Aluminum lake	0,09	0,03
Opacifier Titanium dioxide	0,7	0,23
Solvent Water	9	3,00

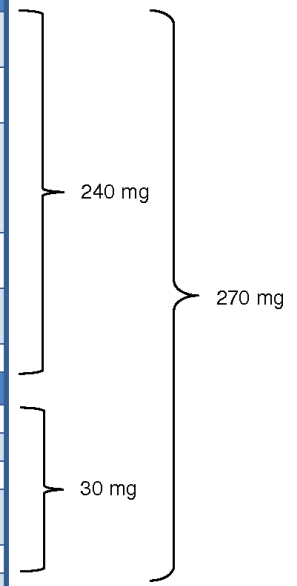


Figure 9. Formulation of cyclophosphamide sorbitol film-coated tablets.

في 2 plasticizer  
Sorbitol Glycerol  
water soluble  
تعمل

Intensity  
بجزي اللون بال liquid  
يشيل الشفافية

ببال Coating لل tablets  
لما تيجي تكون ابيضه  
اخرى من انك تكون ابيضه off white