

INTRODUCTION TO INDUSTRIAL PHARMACY



LAB 1

LAB INSTRUCTORS:

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DEFINITION OF INDUSTRIAL PHARMACY

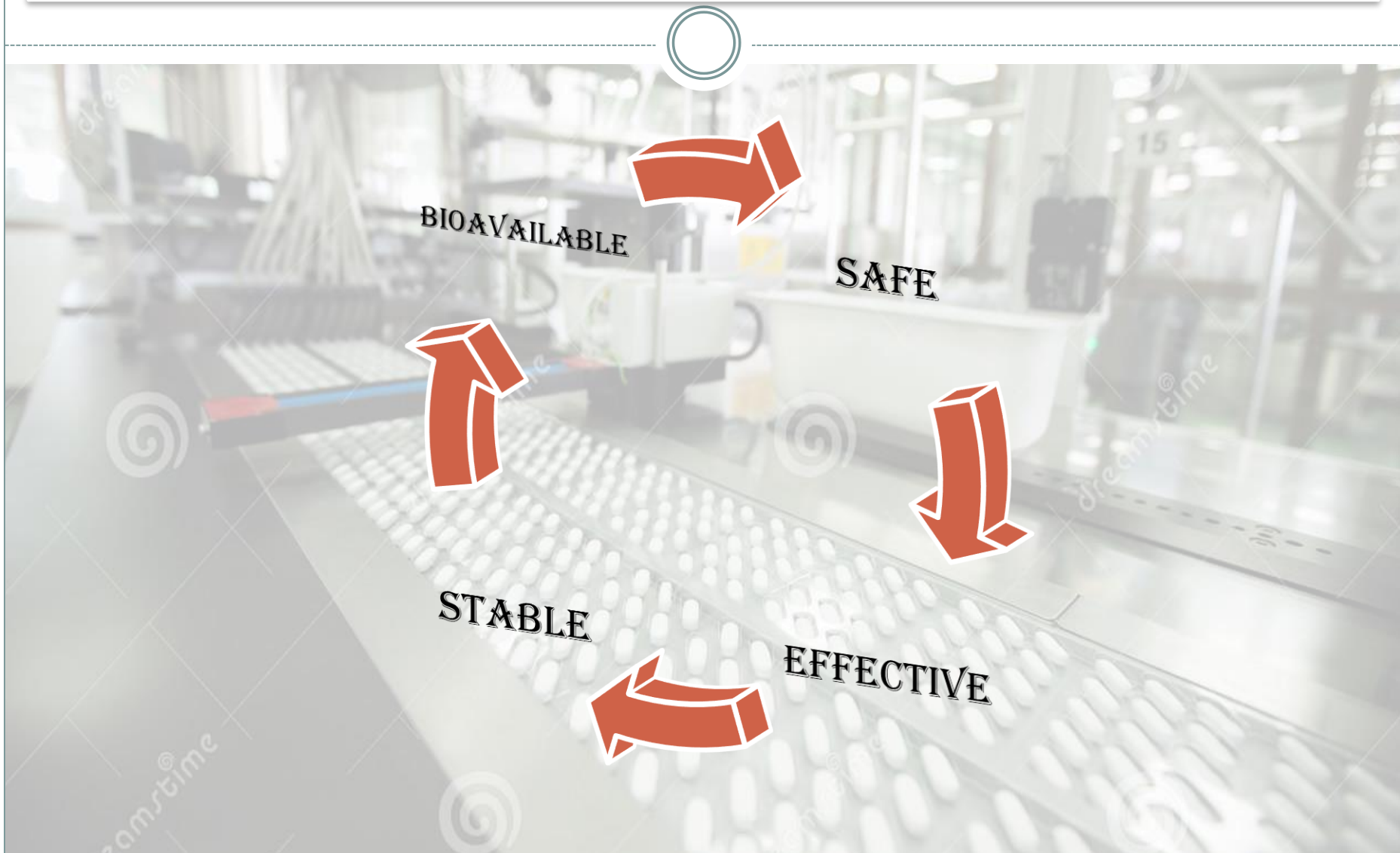


The conversion of raw materials into certain dosage forms.

Or it is manufacturing, development, marketing and distribution of drug products including quality assurance of these activities .

E.g.: Tablets, capsules, suspensions and ampoules.

Properties of Dosage Form



Requirements to Formulate Dosage Form

Physicochemical properties of active ingredient and additives

Physical properties
Appearance, Texture, Color, Odor, Taste, Melting point, Boiling point, Density, Solubility.

Chemical properties
Oxidation, Decomposition, Crystal structure, Toxicity, Thermodynamic properties

Department of Drug Industry

1. Research and development department

A- Small Scale department (pilot plant)

B- Responsible for formulation of a new dosage forms.

C- Need Wikipedia pharmacist

E.g.: Discover new drug like Evotaz (atazanavir and cobicistat) tablets for HIV and check its pharmacological properties then transfer to development department to develop the new drug



2- Production department



(A) Large scale department (full-scale plant).

(B) Responsible for production of dosage form in large scale department.

(C) Need skilled workers.

E.g. Area for production of tablets, capsules, ampoules and solutions.



3- Quality control department:

Evaluation department.

Responsible for evaluation of dosage form before going to the market and following up the product from the market to ensure the stability.

E.g.: Ensure no differences between batches for the same company within accepted evaluations.



4- Marketing department:



Responsible for marketing of drugs to pharmacies and hospitals.

5- Non-laboratory department:

Responsible for finding markets for dispense, management, accounting and personnel.

Drug Factories Requirements

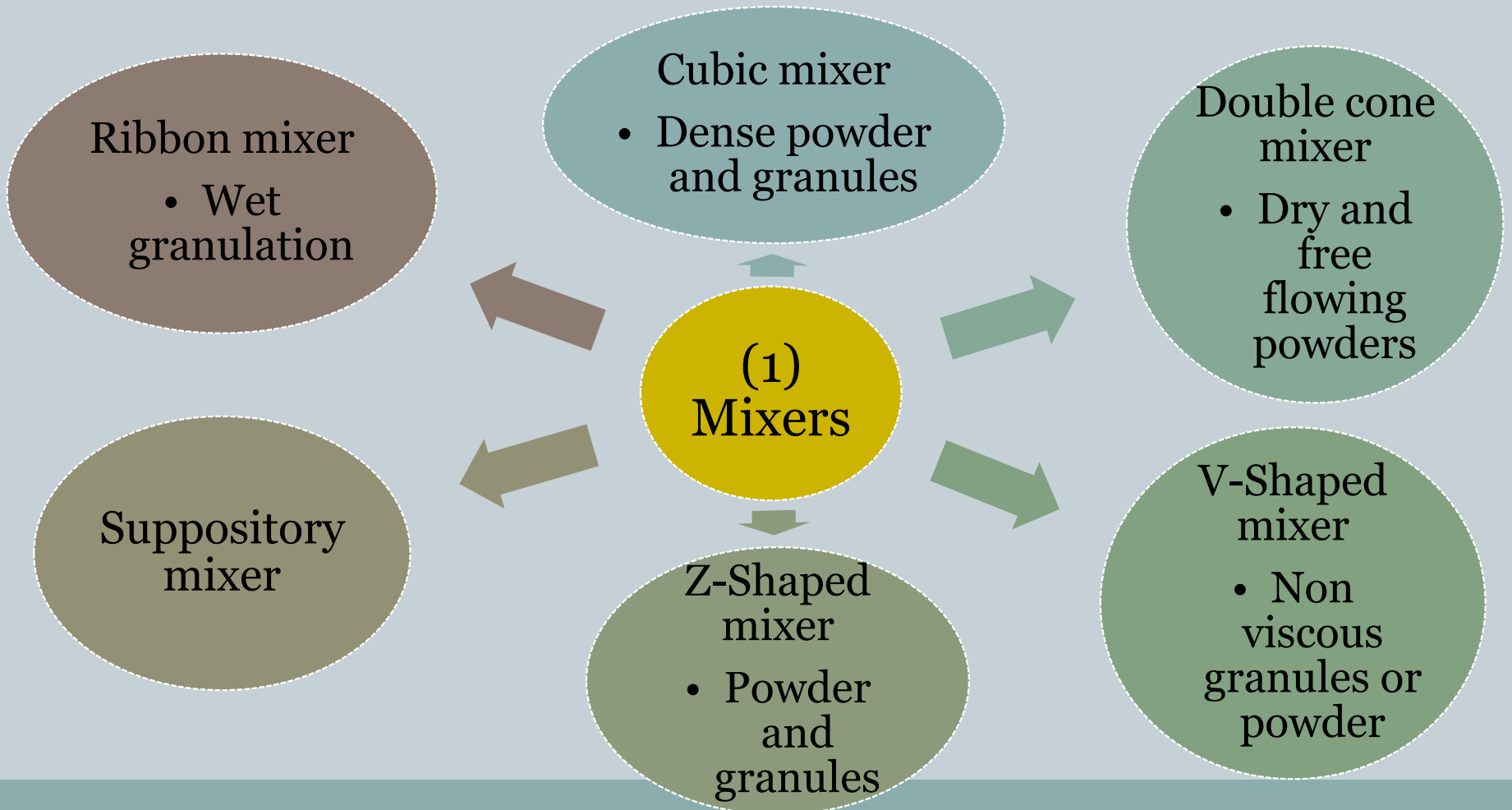
1- Compatible with the **GMP specifications** like clean, sterilization, and all personnel should wear certain protective work outfits.

2- Departments separation

E.g.: Antibiotics department should be separated from other departments.

Equipments used in laboratory

1st: Tablet equipment







(2) Sieves

Get uniform particle size

Coulter counter

Measure number of particles and size ($< 1\mu\text{m}$).

Sub-sieve sizer

Separate particles according to their size (0.2 to $50\mu\text{m}$ range).

Dry granulator

granulate
slugs and
pellets.

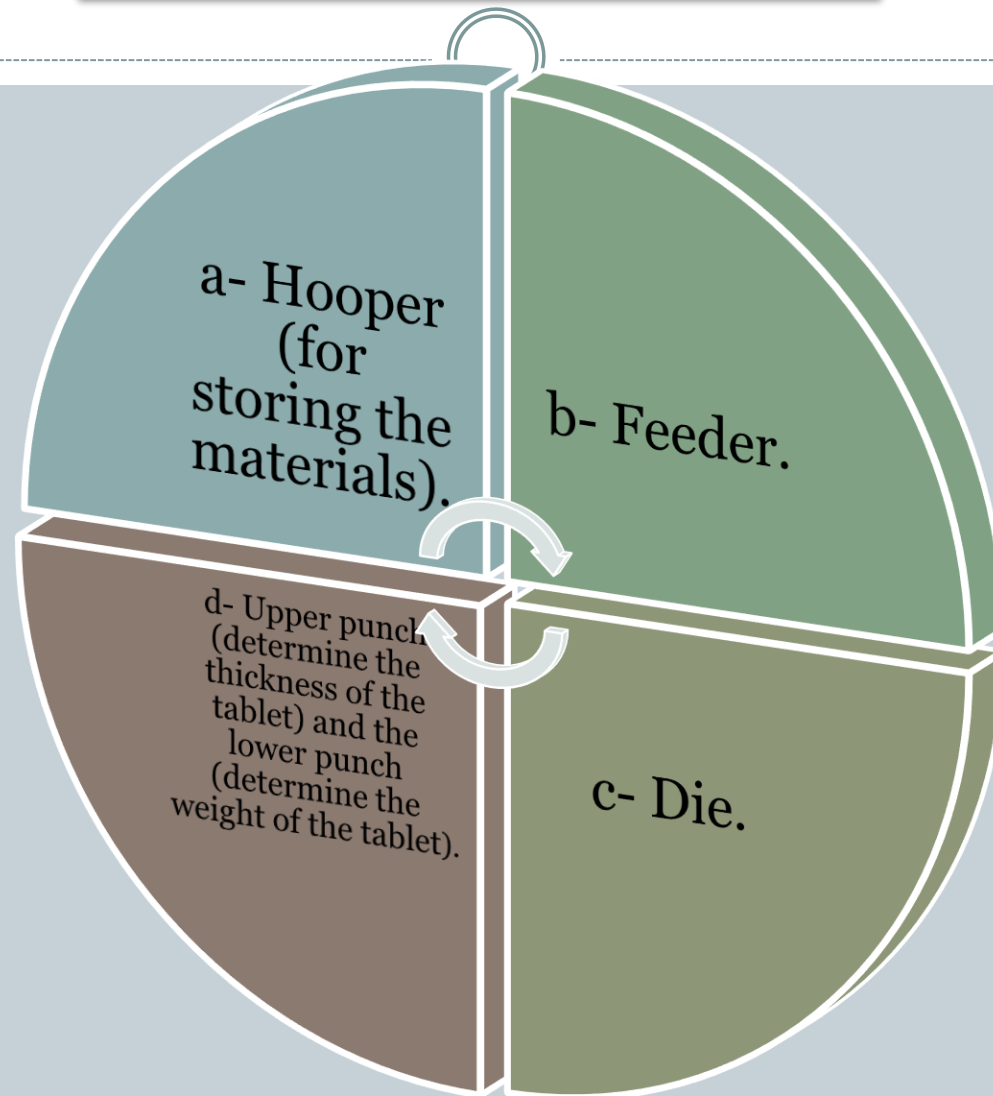
(3)
Homogenizer
[Granulator]

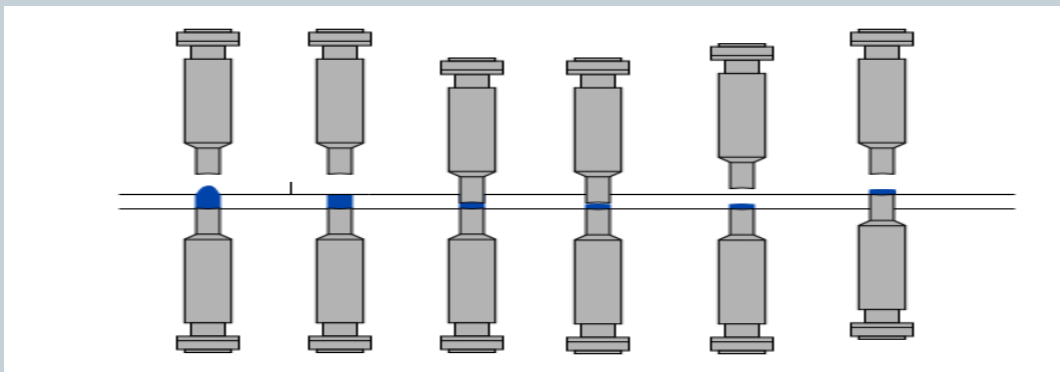
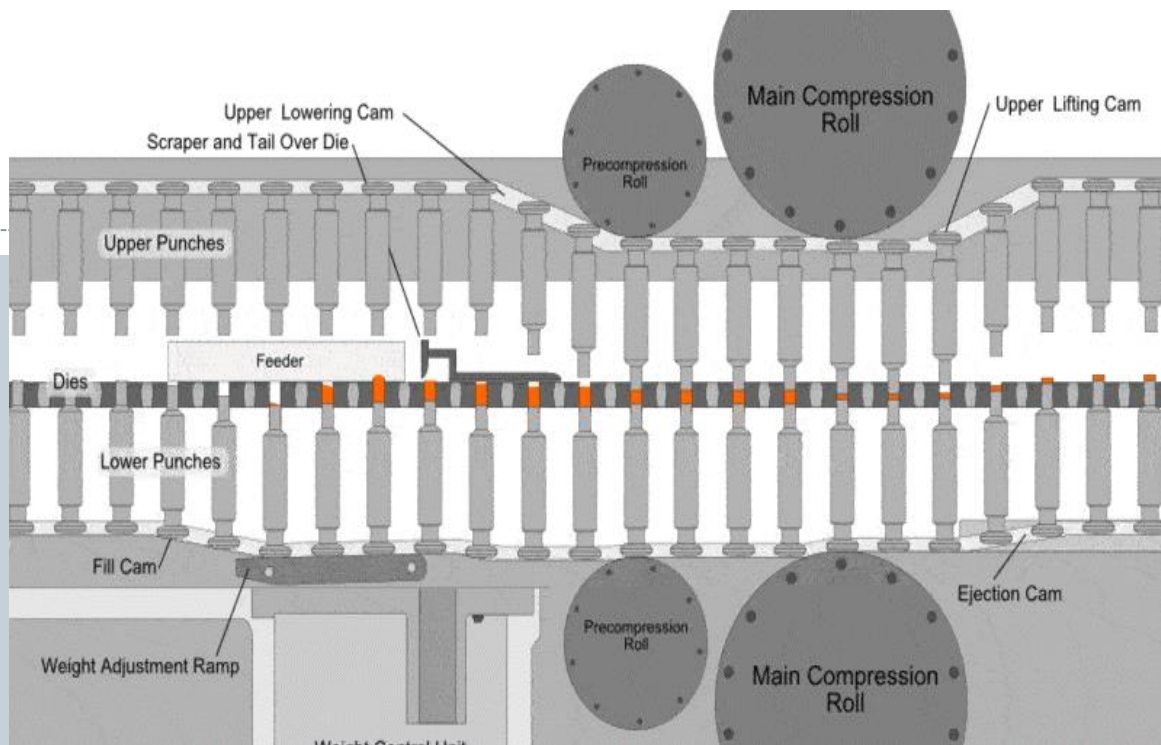
Wet granulator

granulate
suspensions,
emulsions
and
dispersions.



(4) Tablet machine







(5) Coating pan:
produce uniform coating
on tablet by either sugar
or thin film.



(6) Polishing drum:
add polishing materials
during operating the
drum.

**(7)
Evaluation
equipment**

Quality control department
to determine the
manufactured tablet fall
within required standards.

- (A) **Flow meter:** measure the flowability of the tablets.
- (B) **Flame photometer:** measure the concentration or amount of ions such as K and Na.

(C) **Hardness tester:**
measure the hardness of the
tablet





**TABLET HARNESS TESTER
(MONSANO TYPE)**

**Manual
hardness
tester**

such as
Monsanto
hardness
tester.

**Electrical
hardness tester**

such as Erweka
hardness tester.

**HARDNESS
TESTER:**





**1- very friable
tablet**



crack rapidly



(D)

**Tablet
friabilator:**

measures the
tablet friability
that means



**2- very solid
tablet**



will not crack
easily.





(E) Disintegration apparatus:

measure the time required for disintegration and evacuation from the stomach.

The disintegration time is between 15-30 minutes.

consist of 2-4 baskets each has 6 cylinders, the dosage form placed in the cylinder, which will be immersed in buffer and placed in water bath operating at 37° C.

EXCEPTION: (Hard tablet) with higher quantity of binder will require > 30 min. to disintegrate.





(f) Dissolution rate apparatus

In vitro method to measure the dissolution of drugs inside the body.

Consist of 2-6 jars filled with buffer (0.1N HCl, phosphate) and the (Tablet, film or In-situ gel) is placed in the jar and a sample is taken every 10 min.

2nd: Semi solid dosage form equipment:

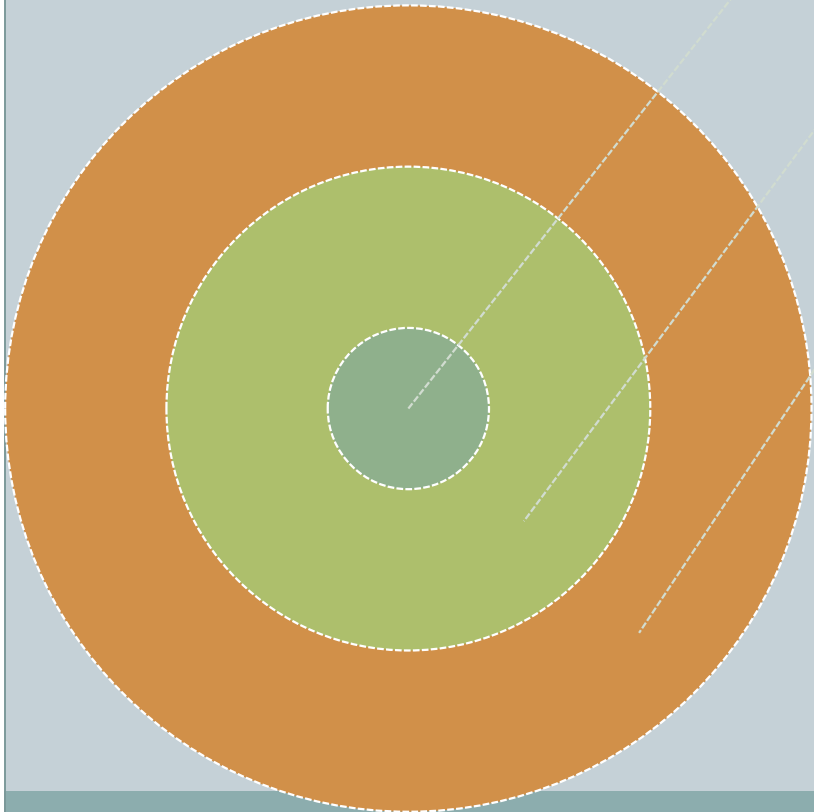
Ointment agitator (Filler).



Three roller mill.



Collapsible closer (to close the tubes).



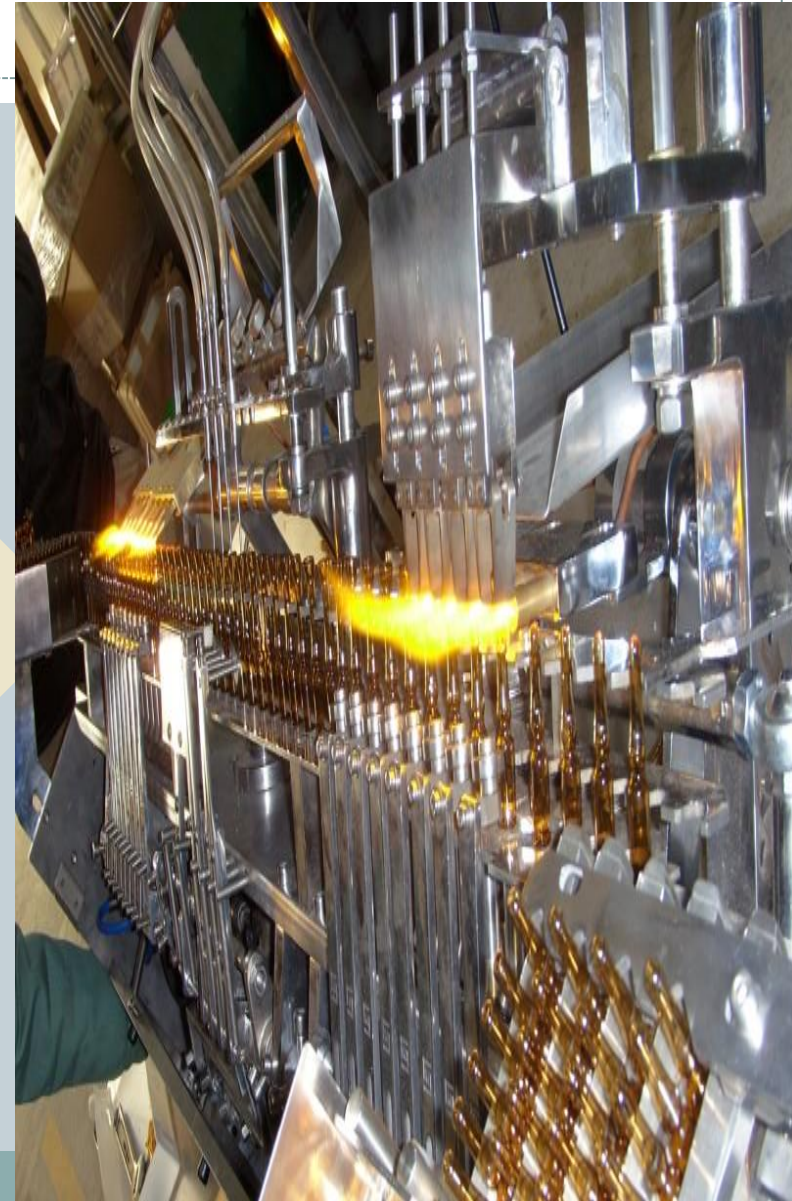
3rd: Ampoules equipment:

(A) Ampoule filling machine
(consist of manual tool fills the ampoule in every push is 1 ml).

(B) Ampoule filling and sealing machine
(connected with other device that control it's operation).

(C) Ampoule sealing machine
(utilize high temperature heat to seal the tip of the ampoule).

(D) Millipore filter
(sterilization of liquid because of small pores (0.3 – 0.5 μ)).

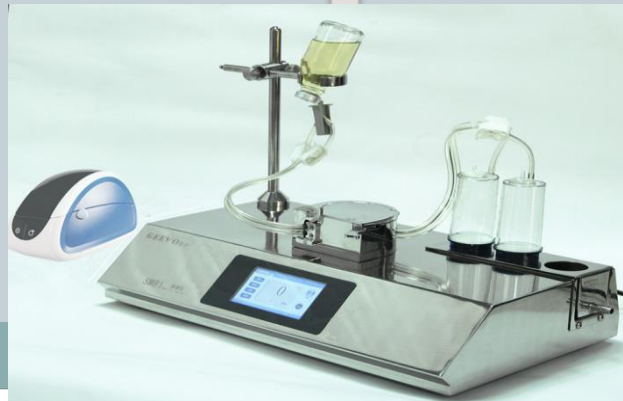


Devices for evaluation of ampoules:

(1) Clarity test device.



(3) Sterility test.



(2) Leaker test apparatus.



4th: Drying equipment:

Dry oven

For dry heat or heat sterilization that require long time.

Autoclave

For moist heat sterilization.

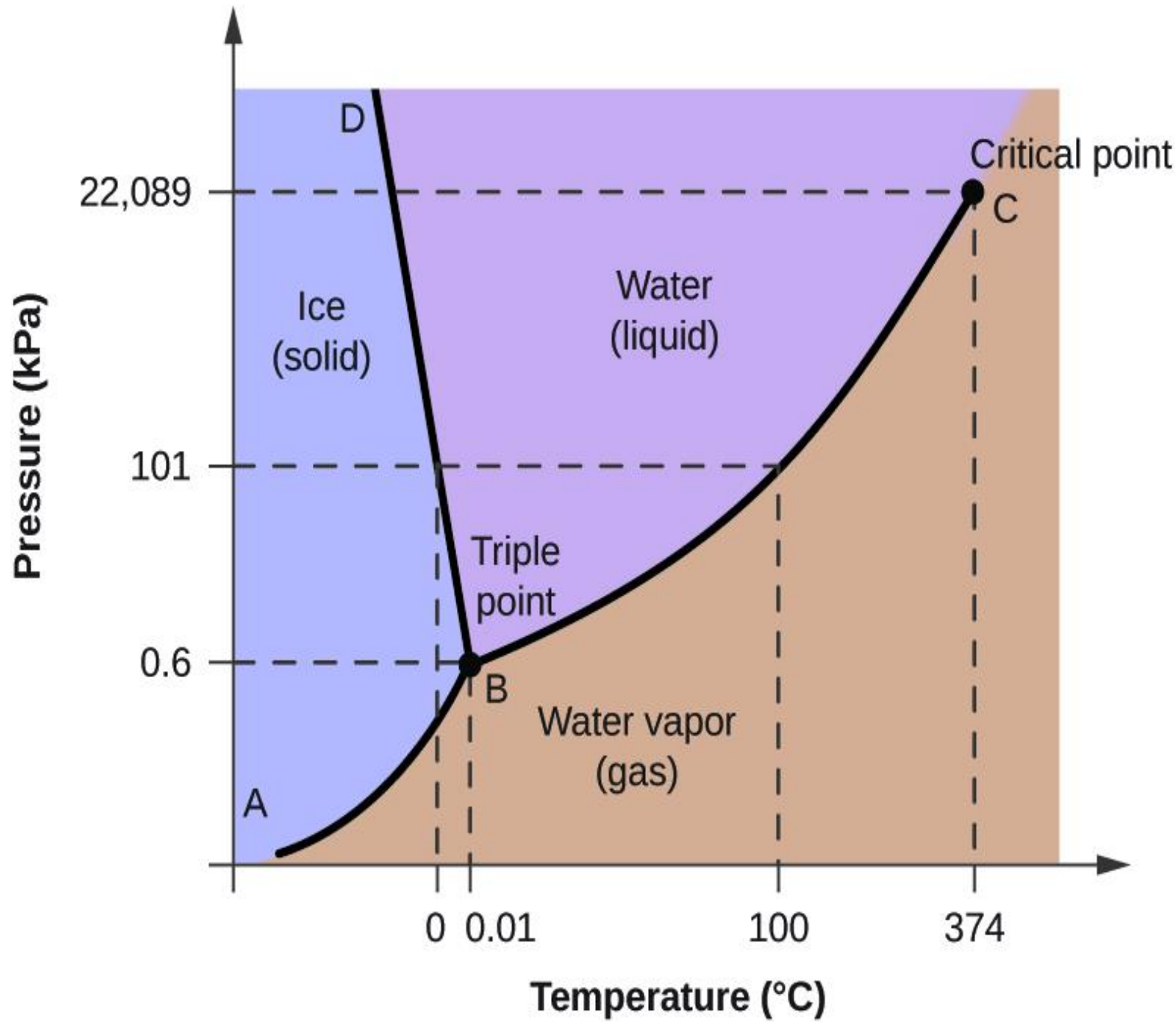
Temperature	Pressure	Time for sterilization
121° C	15 PSI	15 minutes
184° C	30 PSI	3 minutes

Tray dryer

Which operates by passing hot streams of air.

Freeze dryer

For substances affected by heat or moisture especially hormones.







Spasibo

Gracias

شكر

Obrigado

Spasibo

Dank U

Dziękuję

Grazie

Merci

Thank You

Ngiyabonga

Dank U

Thank You

Diolch

Ngiyabonga

Obrigado

Tack

Merci

Danke

Dziękuję

Danke

Grazie

Merci

Dank U

תודה

Terima Kasih

Diolch

Grazie

Merci

Tack

תודה

Tack

Ευχαριστώ