INTRODUCTION TO INDUSTRIAL PHARMACY

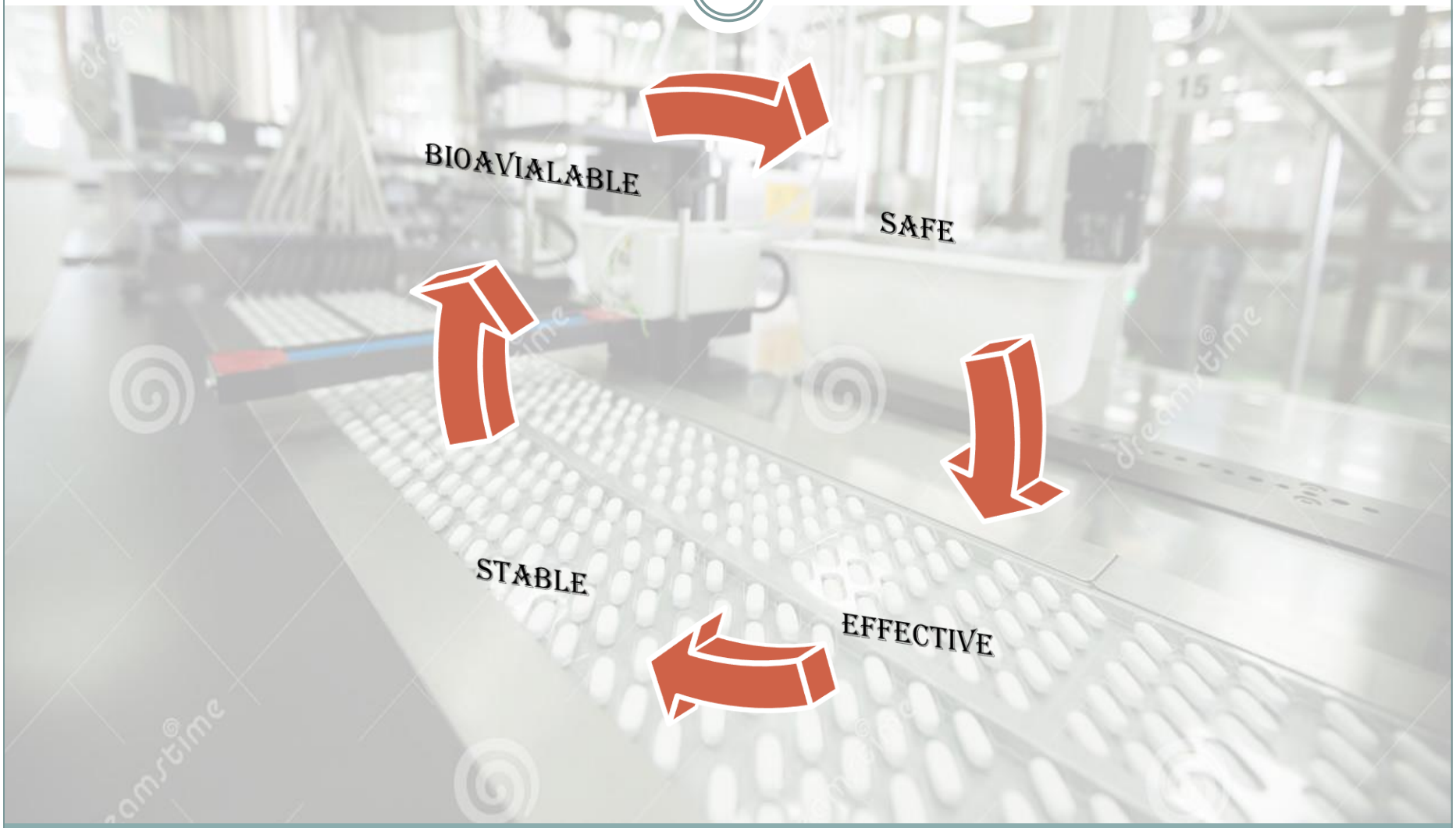
DEFINITION OF INDUSTRIAL PHARMACY

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

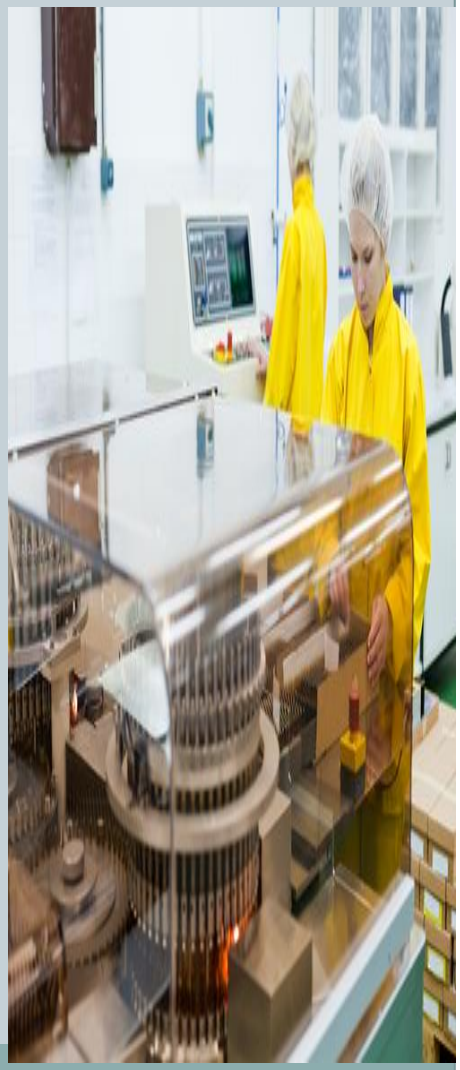
2- Production department

(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.

To ensure that products meets the requirements specified by the official monographs and to ensure that there is 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 Equipments

(1) Sieves

Get uniform particle size

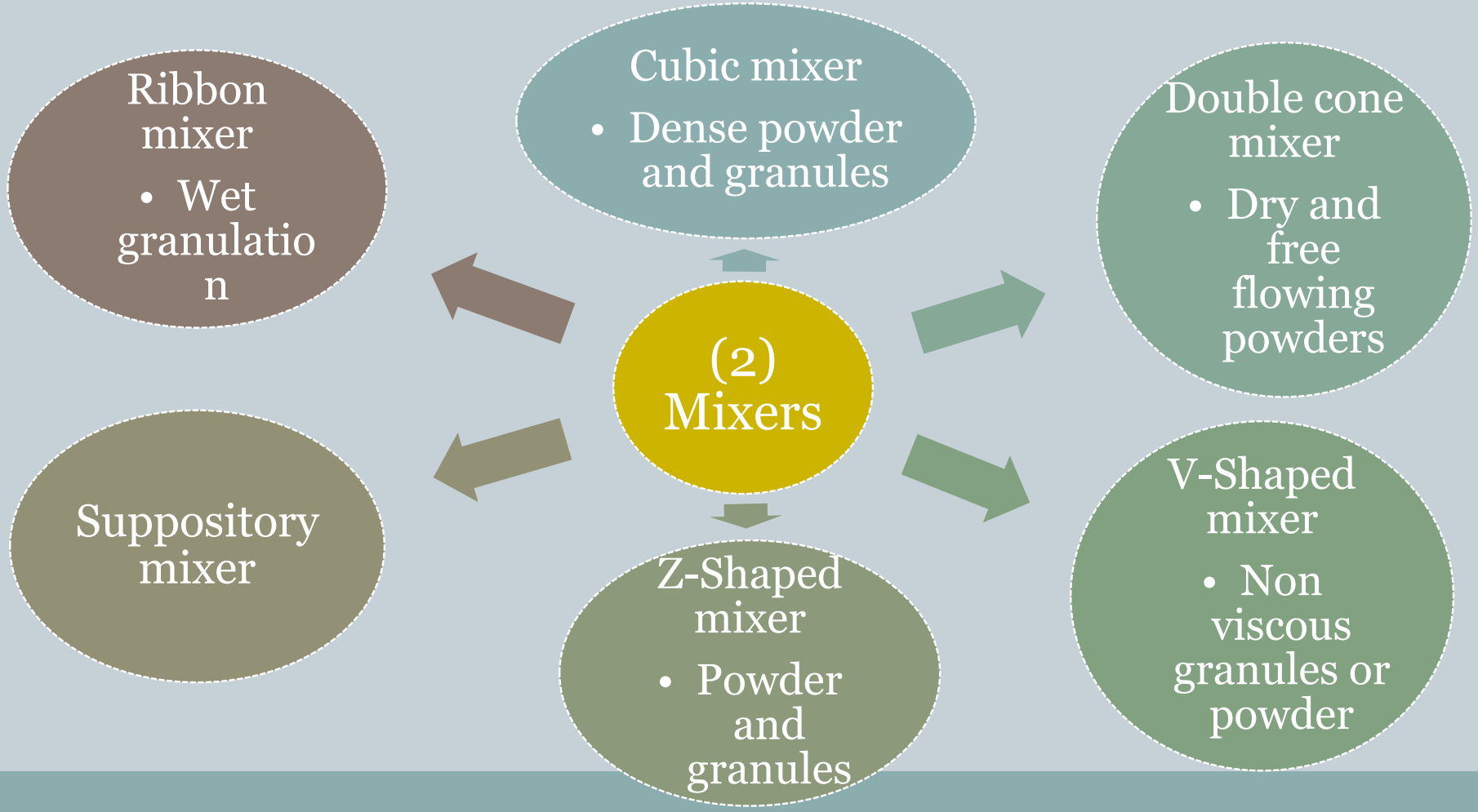
Coulter counter

Measure number of particles and size (< 1µm).

Sub-sieve sizer

Separate particles according to their size (0.2 to 50µm range).

2- Mixers


(2) Mixers
Cubic mixer
• Dense powder and granules
Double cone mixer
• Dry and free flowing powders
V-Shaped mixer
• Non viscous granules or powder
Z-Shaped mixer
• Powder and granules
Suppository mixer
Ribbon mixer
• Wet granulation


ERWEKA

Dry granulator

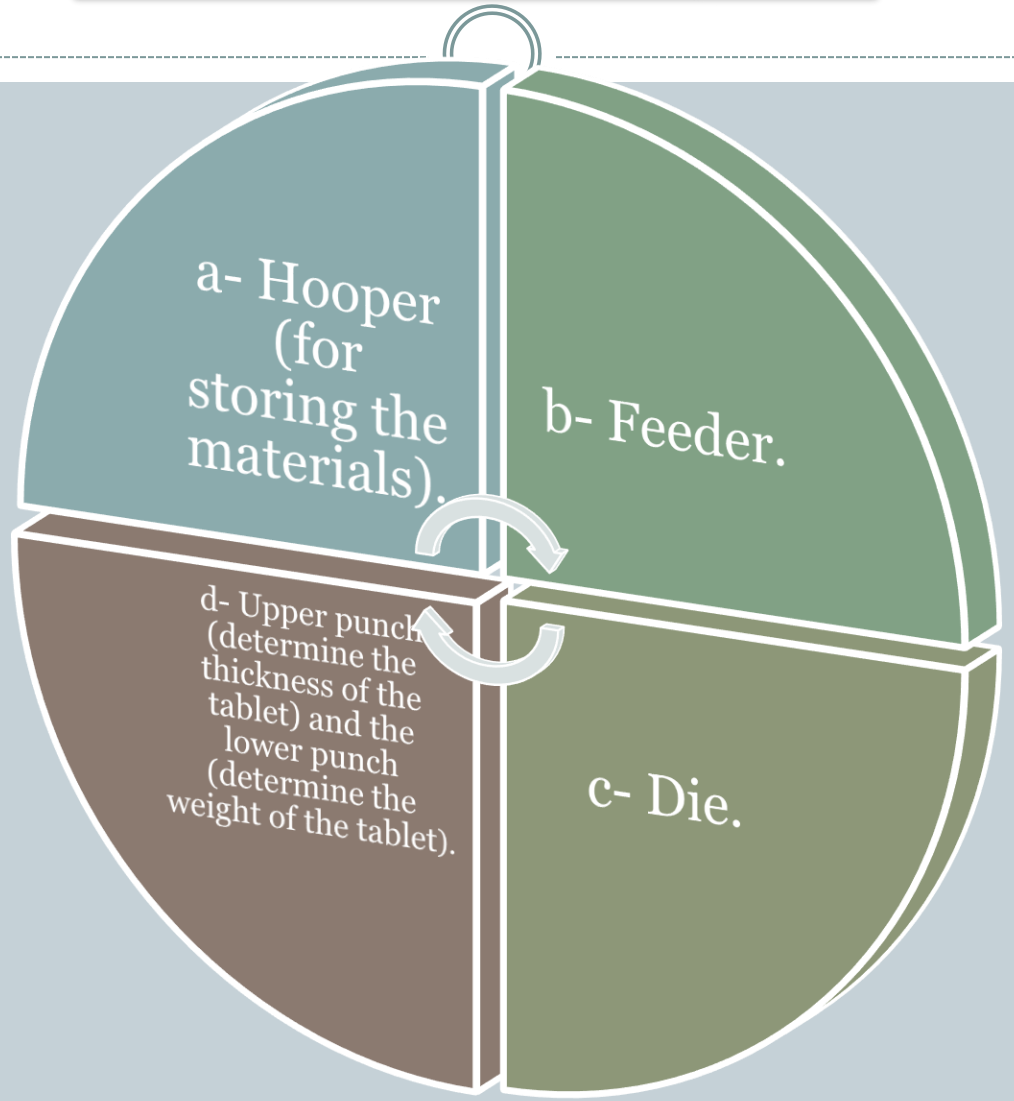
granulate slugs and pellets.

(3) Homogenizer [Granulator]

Wet granulator

granulate suspensions, emulsions and dispersions.

(4) Tablet machine



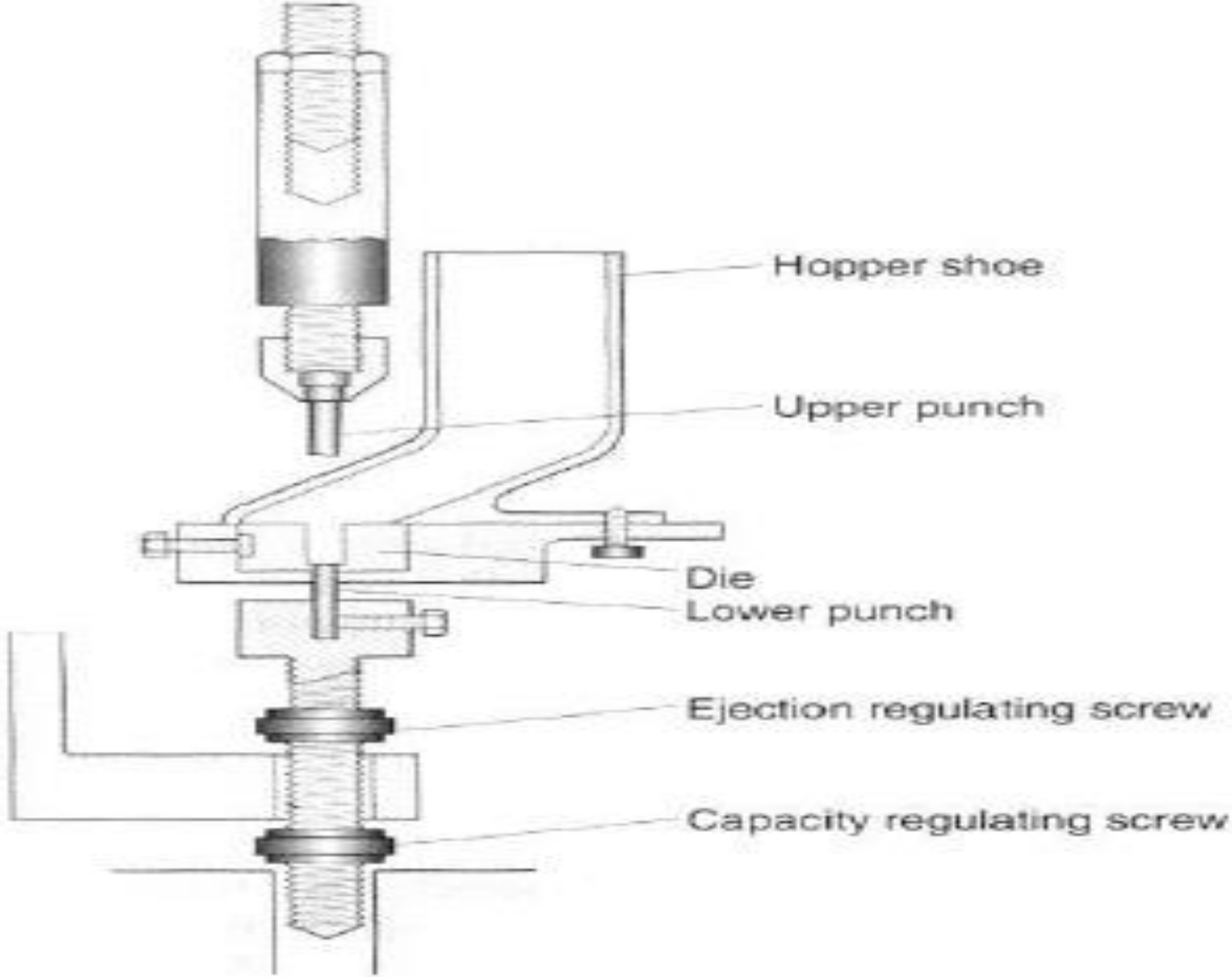
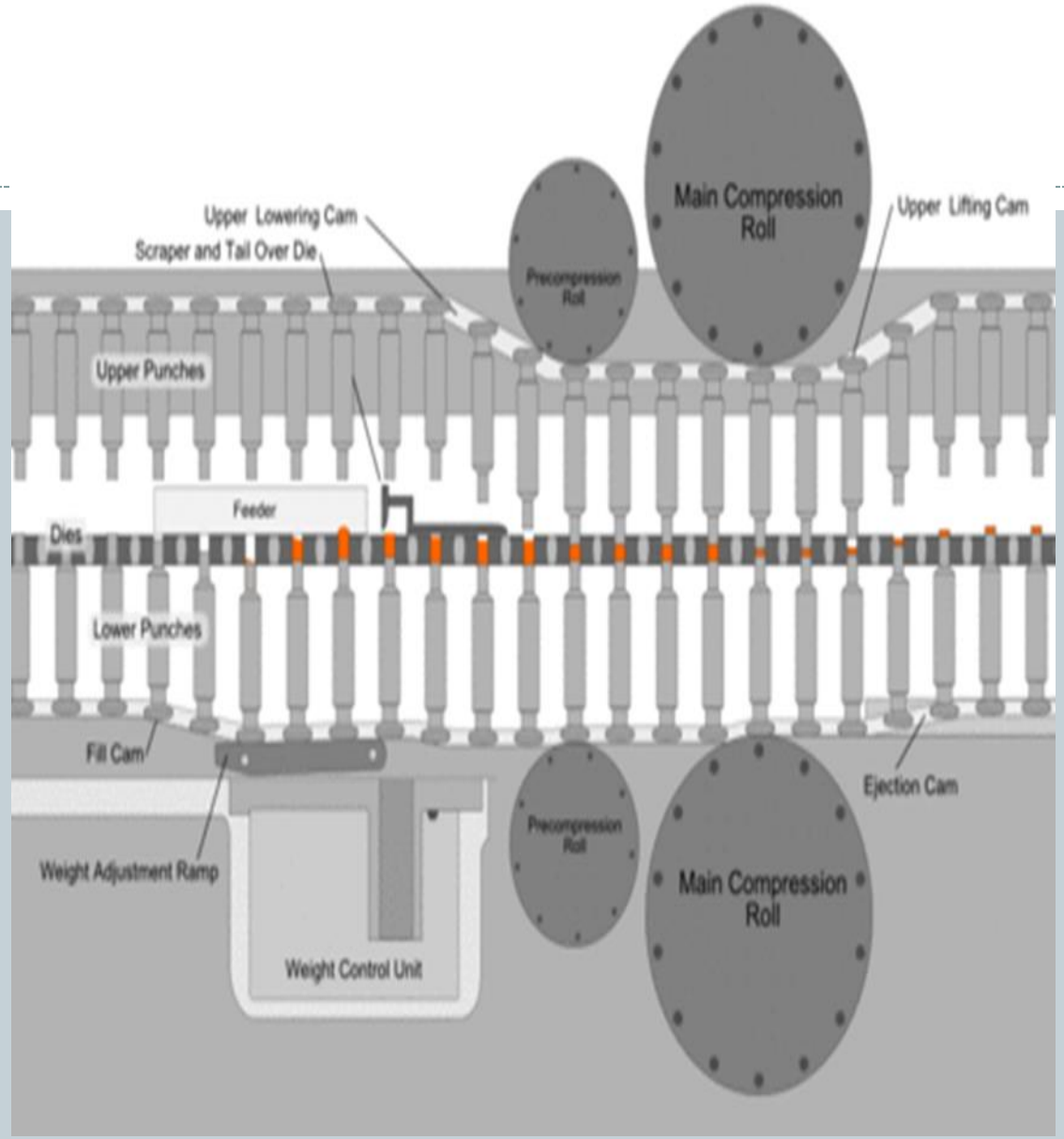


Fig. 27.2 A single-punch tablet press.


Main Compression Roll
Upper Lowering Cam
Scraper and Tail Over Die
Precompression Roll
Upper Lifting Cam
Upper Punches
Feeder
Dies
Lower Punches
Fill Cam
Ejection Cam
Weight Adjustment Ramp
Precompression Roll
Main Compression Roll
Weight Control Unit

(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 powder mixture.
- (B)**Flame photometer**: measure the concentration or amount of ions such as K and Na.
- (C) **Hardness tester**: measure the hardness of the tablet

HARDNESS TESTER:

Manual hardness tester

such as Monsato hardness tester.

Electrical hardness tester

such as Erweka hardness tester.

1- very friable tablet

crack rapidly.

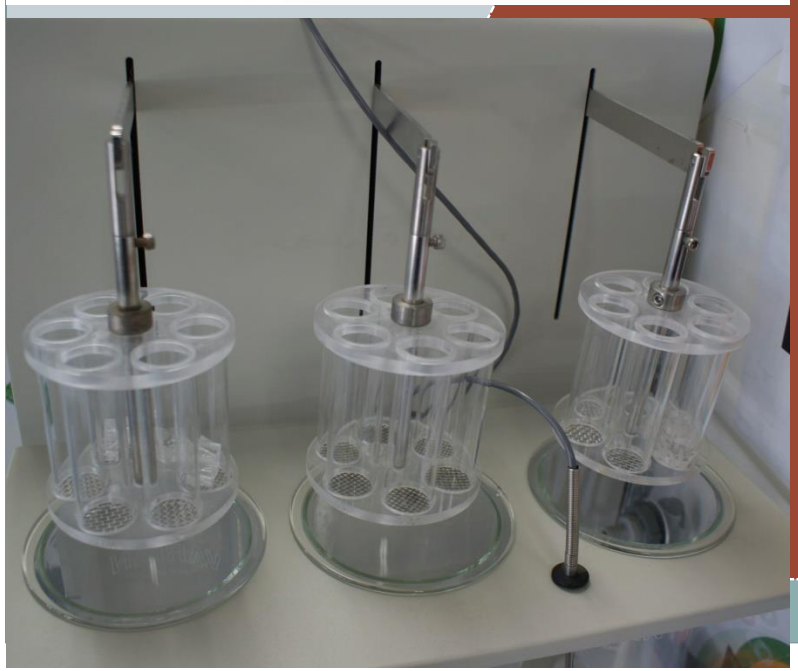
(D)

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.

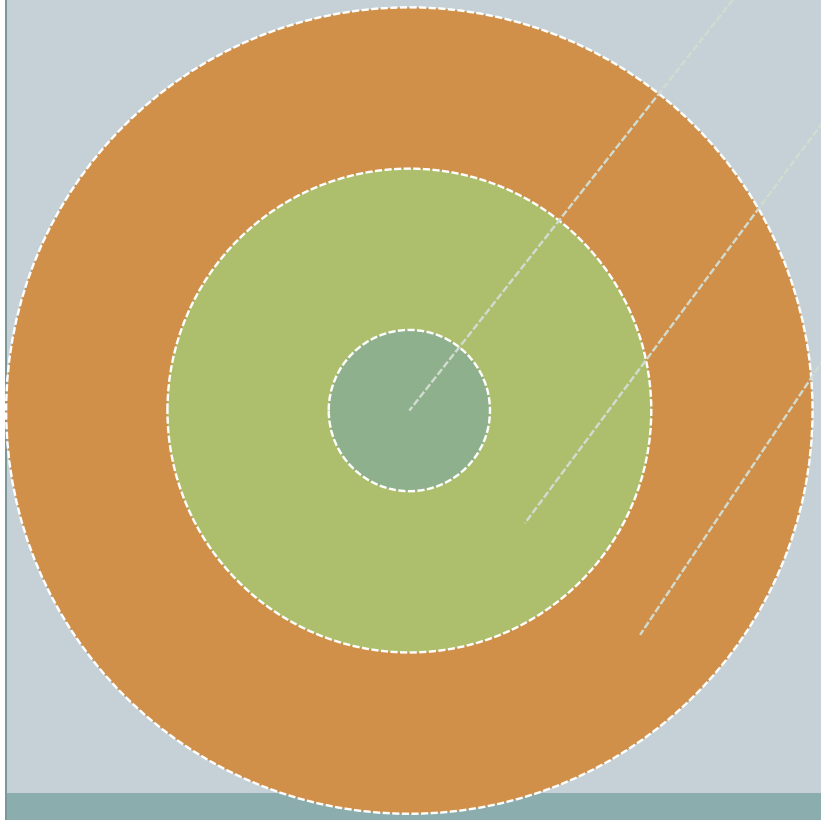
EXCEPTION: (Hard tablet) with higher quantity of binder will require > 30 min. to disintegrate.

(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).

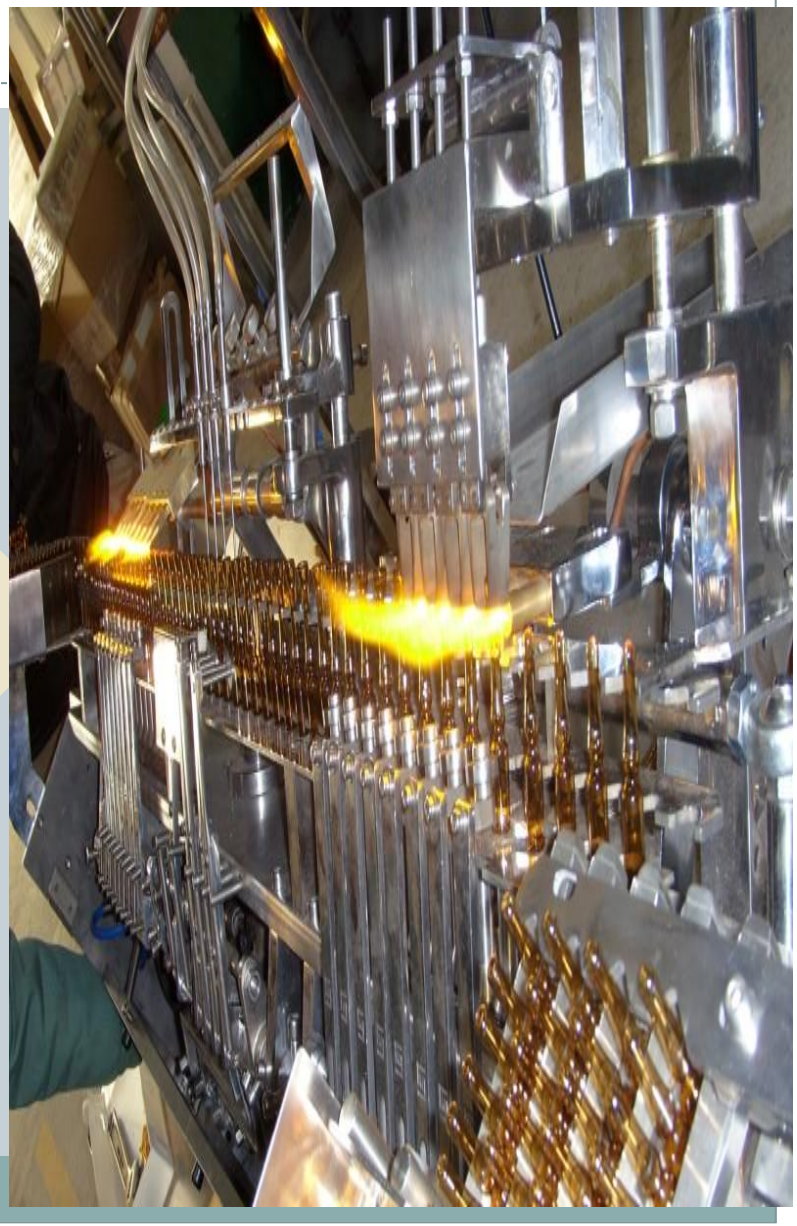
3rd: Ampoules equipment:

(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.

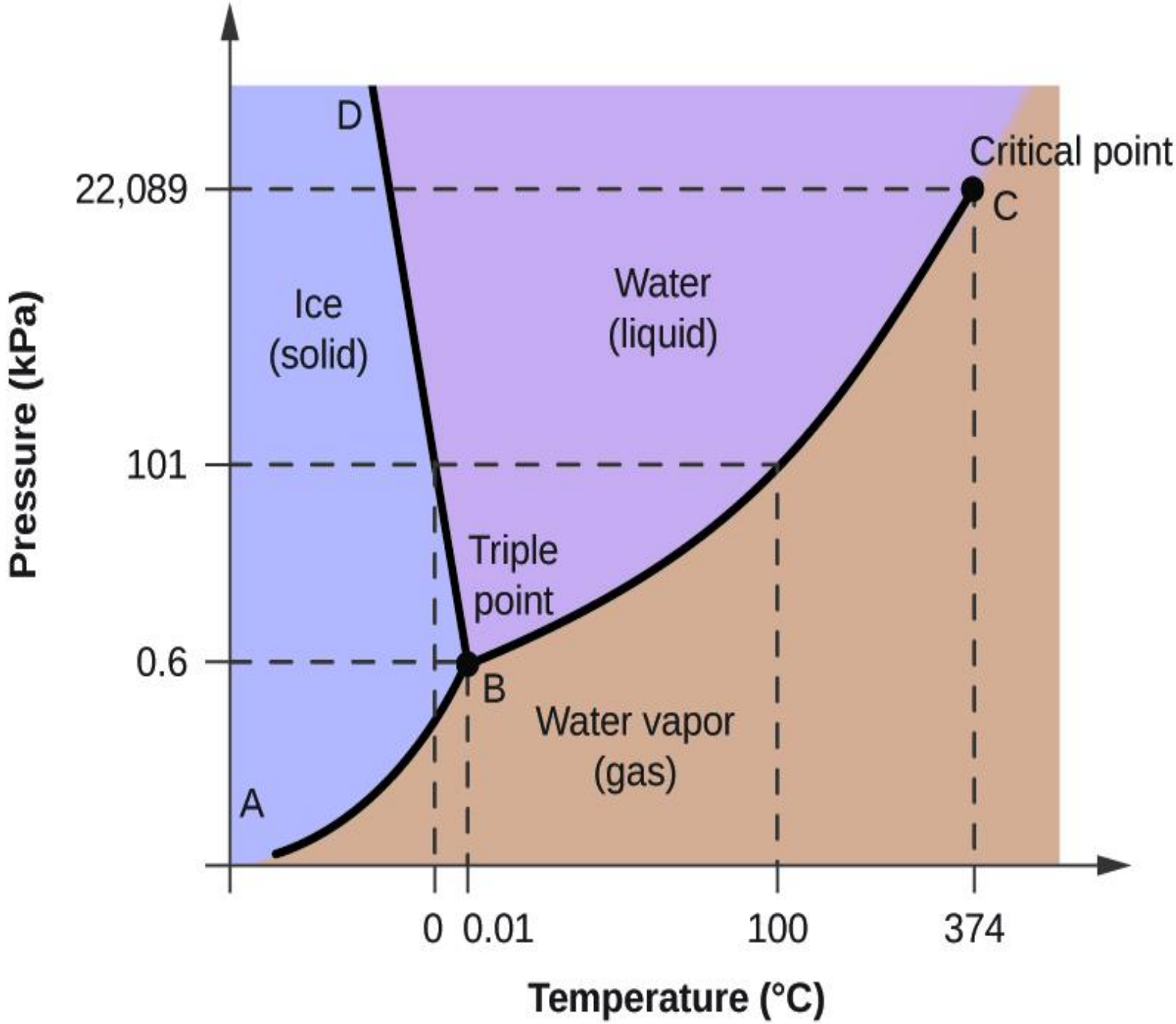
Temperature	Pressure	Time for sterilization
121° C	15 PSI	15 minutes
184° C	30 PSI	3 minutes

Tray dryer

which operates by passing hot streams of air.

Freeze dryer

for substances affected by heat or moisture especially hormones.


D
Critical point
22,089
C
Ice
(solid)
Water
(liquid)
Pressure (kPa)
101
Triple
point
0.6
B
Water vapor
(gas)
A
0
0.01
100
374
Temperature (°C)


Спасибо
Gracias
شكرا
Obrigado
Спасибо
Dank U
Grazie
Ευχαριστω
Danke
Ευχαριστω
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Merci
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Thank You
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Grazie
Terima Kasih
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