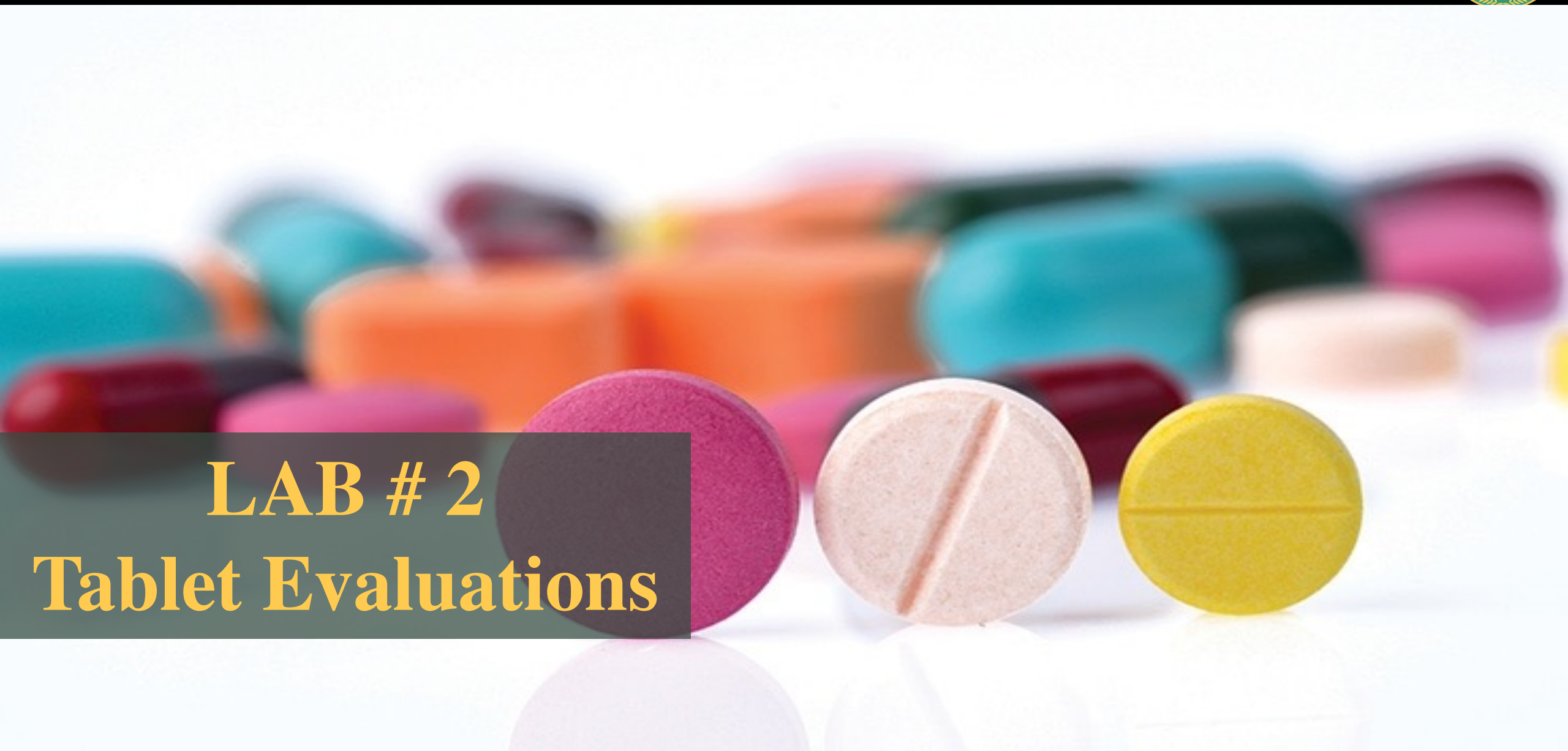


LAB # 2
Tablet Evaluations

General Appearance

- **General appearance**: its visual identity and overall "elegance" which is essential for:
- Tablet should be elegant, free of flaws and if it does contain debossed text should be clear and free of flaws.

The general appearance is important for:

1. Patient acceptance.
2. Control lot to lot uniformity.
3. General tablet to tablet uniformity.
4. Monitor trouble free manufacturing

Lab Work for General Appearance

- Record your notes about tablet formulation (A, B and C):

1. Make a table and list your notes
2. Record color, packaging quality.
3. If your tablet contains an imprint or marking record your noted about quality and clarity of printing.
4. **Record your noted about tablet visual flaws:**

- Is there is any chips, cracks, contamination from foreign body (example: hair, oil drops and dirt).
- Surface texture ("smooth" versus "rough") .
- Appearance ("shiny" versus "dull").

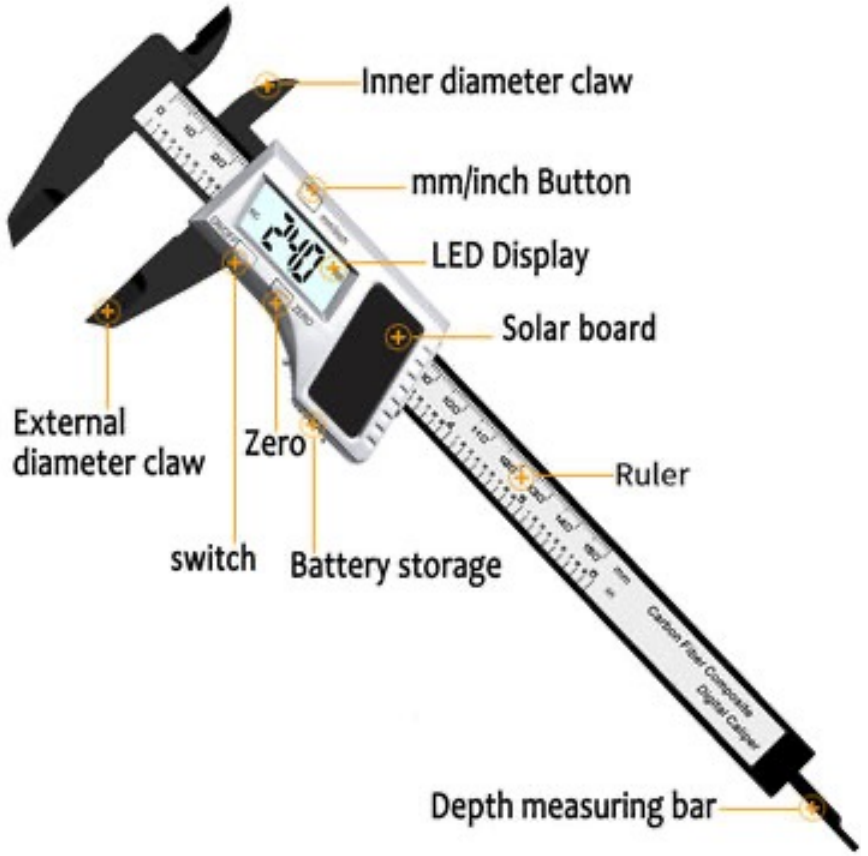
- **DO NOT** record smell or taste and if you ever need to hold the tablet, wear cloves.

Lab Report Example

Formula	Packaging Quality	Tablet color	Does tablet contains imprint	Quality of Imprint	Any Tablet Flaws?	Tablet surface texture	Tablet Appearance
A, B, C Or drug name (if available	Good, Bad, Average	White, Yellow, …	Yes /NO	Good, Bad, Average	Ex, **Yes**: tablet contains chips, or **No**: tablet looks good and free of flaws	Smooth/ rough	Shiny/dull

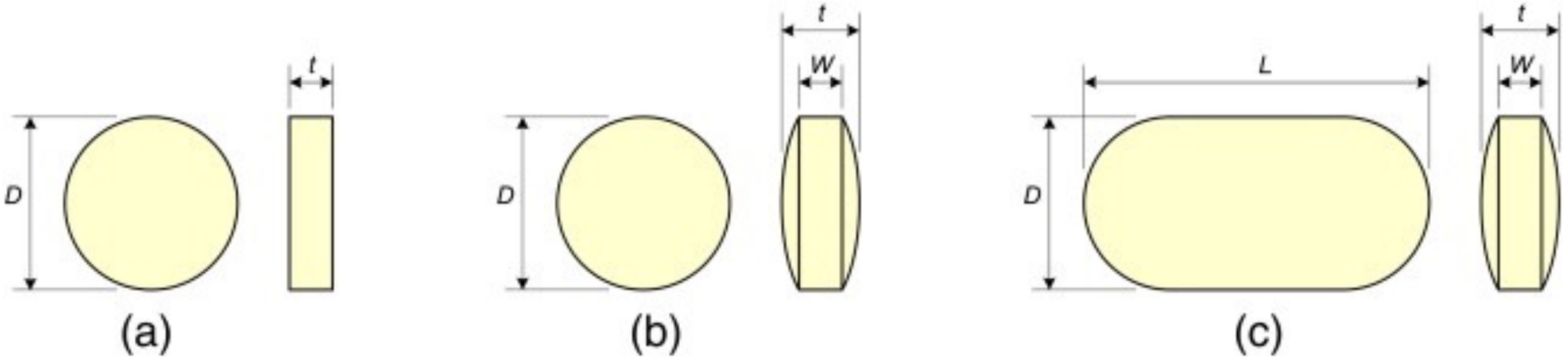
Tablet Thickness (Non-Official)

- Tablet size and shape is determined by punched and die.
- Tablet thickness is variable depending of filling and distance between upper and lower punches and compression forces.
- Tablet thickness is evaluated to assess tablet to tablet uniformity and quality of our product.
- Its measured using vernier caliper
- As a general rule tablet thickness should not variate by more than 5 % in both direction.



Measurements guide

- D: Diameter
- **t: Thickness**
- W: Width



Hardness Test (Non-Official)

- **NO** official limit for this test.
- This test will give us an idea about how our tablet can withstand mechanical pressure during manufacturing, storing and handling.
- It will give us an idea about the time for tablet disintegration.
- Usually conventional tablet requires 4-8 kg.
- Chewable tablet will require less than 3 kg to break.
- Its recommended to use minimum 6 tablet for this test.
- Lozenges will require > 10 kg

Equipment

- https://youtu.be/q7PFpwa_hg4

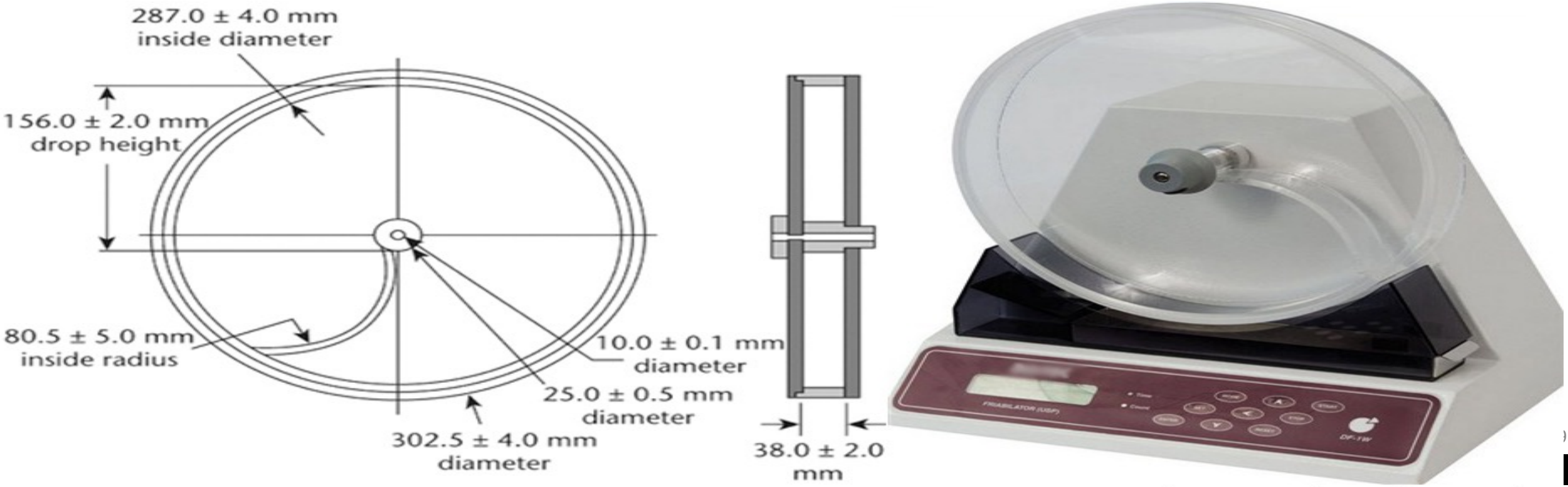
Erweka Hardness and thickness tester

Monsanto Hardness tester

Pfizer Hardness tester

Tablet Friability (USP)

- Tablets that tend to powder, chip, and fragment when handled lack elegance and consumer acceptance.
- The laboratory friability tester is known as the **Roche friabilator**.
- Tablets are preweighed and are tested run for 4 min at 25 rpm.
- Conventional compressed good tablet will loss less than 1% of their weight.



Weight Variation (USP)

- **Weight variation**: weight of the tablet being made is routinely measured to help ensure that a tablet contains the proper amount of drug.
- For the uncoated tablets, 10 tablets are collected, weighed individually and average weight is calculated as follow:

- $$Average\ weight = \frac{Weight\ of\ 10\ tablets}{10}$$

Then % variation is calculated from the following equation:

- $$\%\ variation\ of\ individual\ tablet = \frac{Individual\ weight - Average\ weight}{Average\ Weight} * 100\%$$

Weight variation

Formula or name	A		B		C	
Tablet No.	Individual weight	% variation	Individual weight	% variation	Individual weight	% variation
1						
2						
Average		----------		----------		----------

Weight Variation Test (USP)

- To pass weight variation test:

1. **No more than 2 tablets** are allowed to be outside the variation limit in the table below and **NO** one tablet differs by more than 2 times the percentage limit.

Average weight of Tablets (mg)	Maximum Percentage Difference Allowed
130 or less	10 %
130- 324	7.5 %
More than 324	5 %

Content Uniformity Test (USP)

- In this test tablet is dissolved in suitable solvent and drug content is quantified using appropriate analytical method.
- In this test, **30** tablets are randomly selected.
- Then 10 tablets of these 30 tablets are analyzed individually for drug content using various analytical methods such as HPLC.
- At least the contents of 9 of these 10 tablets must be within **85%-115%** of the theoretical drug contents and only **one tablets** is allowed to be within **75%-125%.**
- If this is not met the remaining 20 tablet is analyzed and **no one should** be out of 85%-115%.

Disintegration Test (USP)

- Disintegration is the process of tablet breakdown into smaller particles or granules.
- It will help us to predict the bioavailability of our formulation.
- The disintegration test can be performed using the USP disintegration apparatus.
- It consists of a rack contain 6 open tubes that contain mesh on one end. This rack moves up and down in a 1 litter beaker that contain water or other simulated gastric fluids at 28 to 32 cycle per minute frequency.
- 16 tablet is selected to perform the test and 6 are tested at each stage and run at specific time.
- All 6 tablet should completely disintegrate within that time.
- If not the other 12 is tested and all of them should completely disintegrate.
- Generally, tablet disintegration time is about **30 min**. coated tablet is required to stay intact at least for **one hour** in the apparatus.

Equipment for Disintegration

- https://youtu.be/YxumOXqH824

Next Week Report

- Each student will submit an individual report, you may include the following:
- Student name, group, lab date
- A brief description for the importance of evaluation of the general appearance, tablet thickness variation, and weight variation of tablet formulation.
- Calculation and result for each experiment.
- A conclusion of whether the tablet formulation under evaluation can be considered as an accepted formulation (based on these evaluations) and why?

- Answer the following question:
- What is the content uniformity test of tablet dosage form.
- Can weight variation evaluation is used as an evaluation for content uniformity of tablet formulation? give an example.