Evaluation of Tablet DF

Quality control (QC)

- Generally, we have:

1) In-processing QC 2) After-processing (finished) QC

In-processing QC (In production unit)

Includes different tests for row materials characterizations and evaluating the processing steps involved within the tablets production like mixing, milling, drying, granulation, compression, coating and packaging.

All these tests are important for obtaining good (after processing QC) tests.

- These tests may involve validation of equipment that are needed within production processes.
- As evaluation tests for coated tablets, we have (adhesion test) using tensile-strength testers which measure the force required to peel the film layer from the tablet surface.
- Particle sizes or (granules sizes) and flow properties are important to be measured for different causes related to in-processing and after processing QC tests. (???)

After processing QC tests

- Are generally classified into official (Compendial) and non official (Non-compendial) tests, preformed into separated unit (QC unit).
- Official tests are found and registered into pharmacopeia and give the final decision about accepting or rejecting the batch of tablets.

Non-official tests

1) Observation of organoleptic properties (inspection): like color, size, appearance (tablets defects), surface roughness (specially for coated types) and thickness. These test are preformed visually or by certain testers.

2) Evaluation of mechanical properties like:

- Friability test: give idea about the tendency of tablet surfaces toward chipping or friability in presence of movement.
- Hardness test : Give idea about the tablet crushing strength, may be preformed for coated tablets.

Official tests

1) **Weight variation test**
2) **Content uniformity test**
3) **In vitro disintegration test**
4) **In vitro dissolution test (T100% and release profile)**
5) **In vivo bioavailability tests:** Using animals or human volunteers depending on the drug development phase.
6) **Stability tests: may be for short term or long term, includes physical, chemical and microbiological types**

- The term "shelf life" of a drug slightly differs from a drug's "expiration date." The shelf life generally relates to a drug's quality over a specified period of time, whereas the expiration date relates to both quality and safety of a medication at a specific point in time.

You must know:

- Hardness limits of chewable, sublingual, dispersible and extended-released tablets.
- Disintegration of coated tablets.
- Differences between type I and type II dissolution apparatus.
- Factors affecting dissolution of tablets.
- Factors affecting stability of tablets DF.
- Climatic zone of Iraq.
- ICH (International Conference on Harmonisation)