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Industrial pharmacy- II lab

Course #: 512

LAB 5- Evaluation and quality control of tablet dosage form

UOBCOP

Department of pharmaceutics

Malathe Alshawi

-BSc. Pharm (Uni. of Basra College of Pharmacy);

-MSc. IPSci. (Brighton University, School of Pharmacy and Biomedical Sciences; UK)

Quality control, or **QC** for short, is a process by which entities review the quality of all factors involved in production. This approach places an emphasis on three aspects:[citation needed]

1. Elements such as controls, job management, defined and well managed processes,[1][2] performance and integrity criteria, and identification of records
2. Competence, such as knowledge, skills, experience, and qualifications
3. Soft elements, such as personnel, integrity, confidence, organizational culture, motivation, team spirit, and quality relationships.

Controls include product inspection, where every product is examined visually, and often using a stereo microscope for fine detail before the product is sold into the external market. Inspectors will be provided with lists and descriptions of unacceptable product defects such as cracks or surface blemishes for example.

The quality of the outputs is at risk if any of these three aspects is deficient in any way.

Quality control emphasizes testing of products to uncover defects and reporting to management who make the decision to allow or deny product release, whereas quality assurance attempts to improve and stabilize production (and associated processes) to avoid, or at least minimize, issues which led to the defect(s) in the first place.[citation needed] For contract work, particularly work awarded by government agencies, quality control issues are among the top reasons for not renewing a contract.[3]

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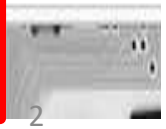


Q.C of tablets

- General appearance
- Shape and diameter,
- thickness,
- Weight variation
- Content uniformity
- Hardness,
- friability,
- disintegration time
- and dissolution characteristics.

Official test and non-official test

Official tests

- Weight variation
- Content uniformity
- Disintegration test
- Dissolution
- Friability

Non-official test

- Hardness test
- Thickness

Quality control test of tablets

1. General appearance:

''The tablet should be elegant.''

- The control of general appearance involves measurement of attributes such as:
  - The size and shape of tablet,
  - Organoleptic properties (color, presence or absence of odor, taste, surface texture and consistency)

A. The size and shape

- **The diameter and shape** is function of(depends upon) the die and punches. how?
  - tablets are discoid in shape,oval, oblong, round, cylindrical, or triangular.
  - The upper and lower surface may be concave and or tagged with logo.
  - The tablets might have a grove to facilitate breakage into smaller doses.
- the thickness depends upon the compression ***process:***
- The thickness is uniform if:
  - Consistent compression force.
  - Consistent particle size (uniform and same form batch to batch). May affect packing of powder during compression
  - Consistence filling process (good followability); otherwise it cause variation of weight from tablet to tablet

B. Organoleptic properties:

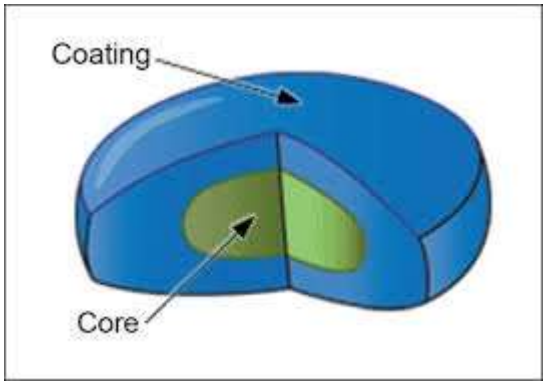
- **The colour:**
  - the tablet should be uniform in colour form tablet to tablet and from batch to batch.
  1. Color is an important mean of identification for many pharmaceutical tablets
  2. It is also usually important for consumer acceptance.
  - non uniformity in colour is called….??
  - Non uniformity in colour could be associated with:
    - Non uniformity in content
    - and poor product quality
- **The odour :**
  - important for consumer acceptance,
  - identification of drugs(; e.g., vitamins),
  - detection of a stability problem (e.g., ASA…etc.)
- **The taste:** is of a particular importance for ……???…….. tablet.

2. Weight variation test (Uniformity of mass).

- The weight variation test of tablet are used to confirm the tablet has the required amount of active drug.
- The amount of material in the die determines the weight of the tablets.
- Variation in die fill might be caused by:
  1. bad flow
     - How to improve?
  2. variation powder bed orientation
     - how to improve?
  3. the variation in particle size
  4. Variation in powder bed orientation or packing

Weight variation test

- This test is satisfactory only if both of the following are present:
  1. the tablet is uncoated or film coated tablet
  2. The % of active ingredients is 95% and more.
- However; it is one of the routine official test and has to be performed.

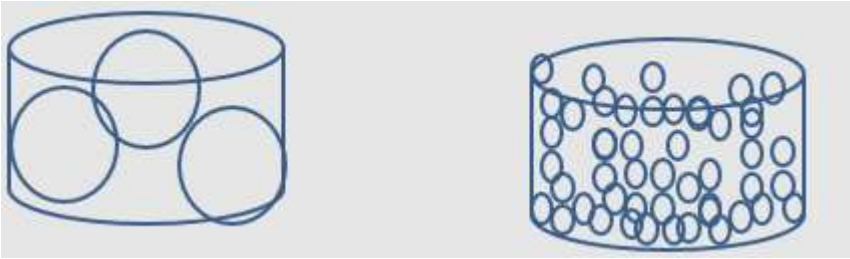


- Weigh 20 tablets and calculate the average mass.
- Limit: According USP, When each tablet weighed individually, less than 3 tablets are allowed to deviate more than the stated % of for the average mass listed in the table .

Average mass of tablet	Deviation %
<80 mg	±10.0
80 -250 mg	±7.5
>250 mg	±5.0

3. Content uniformity:

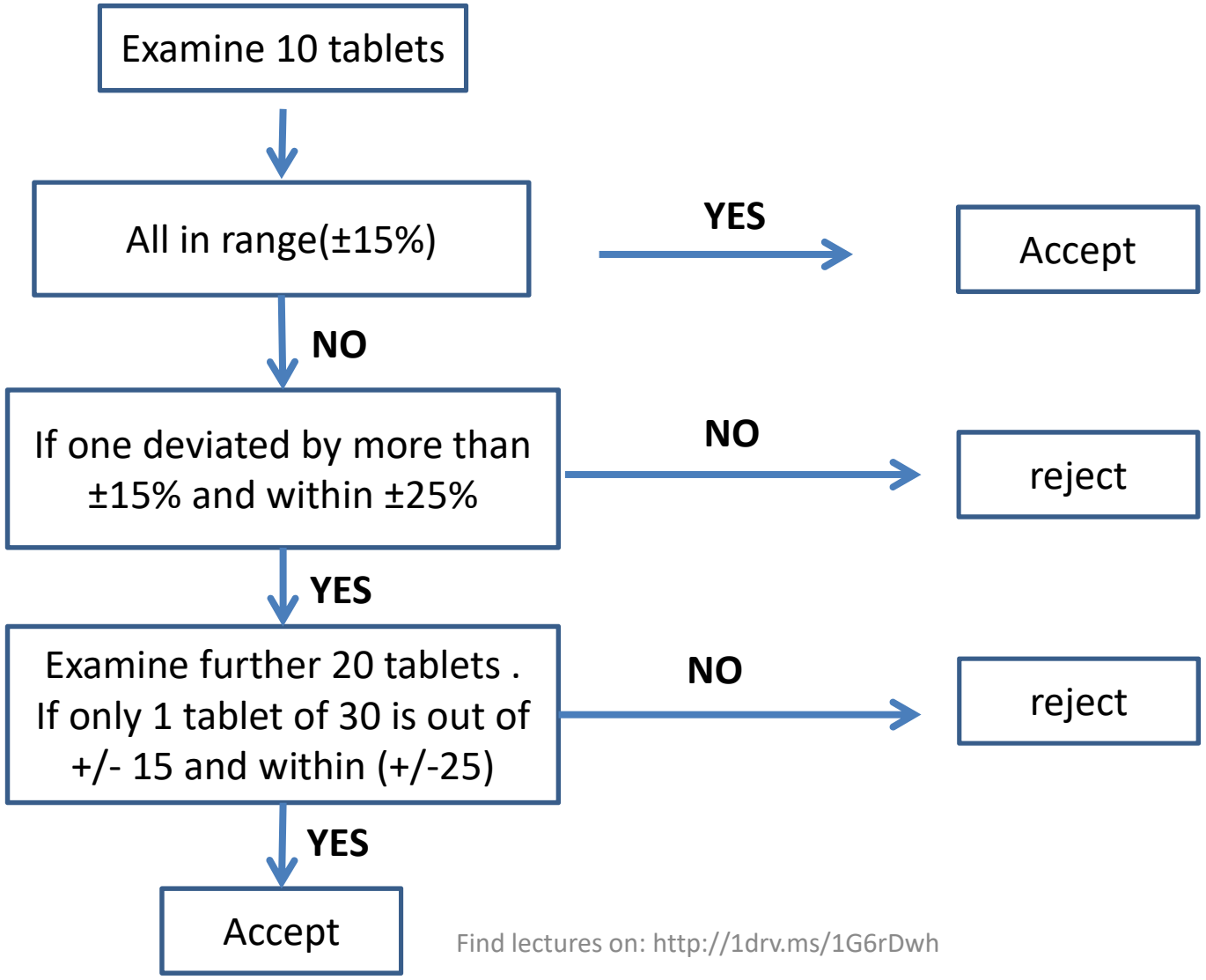
- 10 tablet is assayed individually for their content according to the method prescribed in the individual monograph.
- **<u>factors that may cause content uniformity variation in tablets:</u>**
- Insufficient mixing (Non-uniform distribution).
- Segregation.
- Bad flowability
- Packing of powder which might result of variant particle size.



Aim of measuring the content unifotmity

- Variations in content uniformity cause more problems in low dose drugs than in high dose drugs. For e.g.:
  - ± 0.1mg of 500mg-paracetamol tablet
    - →(%) variation
    - which is significant, OR not Significant
  - ±0.1mg of 0.2mg-misoprostol tablet
    - → (%) variation
    - which is significant OR not Significant.

General procedure for measuring the content uniformity in USP



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4.Disintegration test for tablets

- Disintegration measures the time that is required for a tablet to break up into a small particles at certain conditions (temp, media).
- Disintegration test is indicated for all tablets except :
  - Chewable tablets,
  - those tablet should dissolve slowly such as lozenges, glycerine trinitrate
  - some types of sustained release products. WHY SOME???

find study materials on link: :
www.goo.gl/KBOm0R

Disintegration test end point

- Complete disintegration is defined as that state in which any residue of the unit, except fragments of insoluble coating or capsule shell, remaining on the screen of the test apparatus or adhering to the lower surface of the discs, if used, is a soft mass having no palpably firm core.