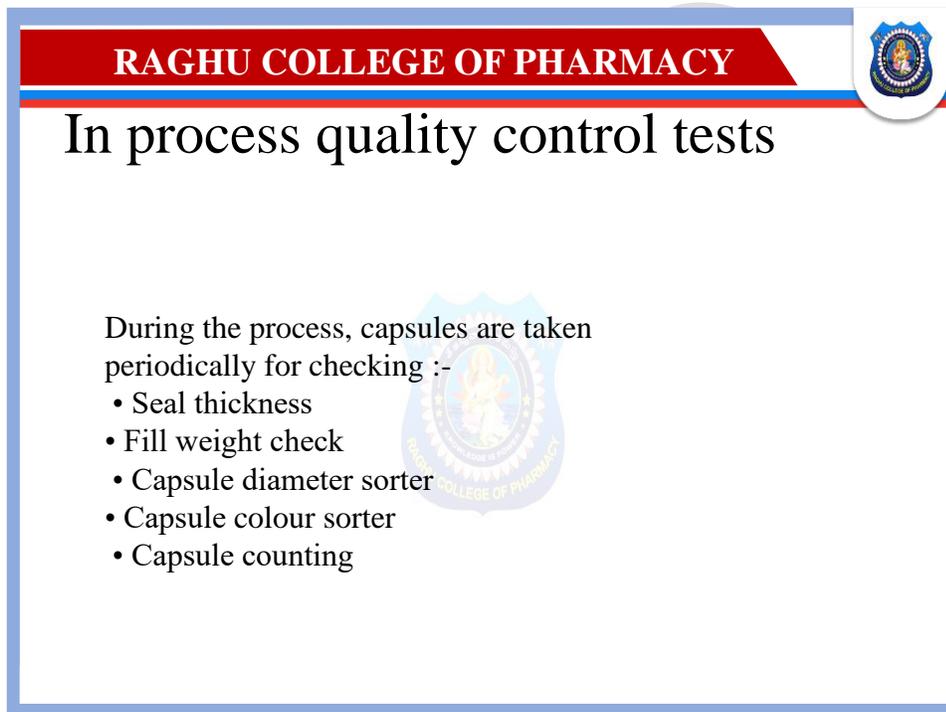


INDUSTRIAL PHARMACY-I**UNIT III-CAPSULES****CLASS:23****TOPIC in process and final product quality control tests**

RAGHU COLLEGE OF PHARMACY

In process quality control tests

During the process, capsules are taken periodically for checking :-

- Seal thickness
- Fill weight check
- Capsule diameter sorter
- Capsule colour sorter
- Capsule counting

Seal thickness

is measured under a microscope and changes in gelatin ribbon thickness, heat or pressure are made if necessary. Acceptable seal thickness is $\frac{1}{2}$ - $\frac{2}{3}$ of the ribbon thickness.

- Fill weight check :- are made by weighing the whole fresh capsule, slitting it open, and the contents are removed. The shell is then washed in a suitable solvent, and the empty shell is reweighed. If there is weight variation, then necessary changes are made in the pump that measure the weight of the material to be filled

- Capsule diameter sorter :- allows to sort and check the capsules are within the range of ± 0.020 inch of the theoretical diameter of the capsules. Overfills, underfills, or foreign capsules are discarded.

capsules are fed into the colour sorter automatically from the diameter sorter. Any capsule whose colour does not conform to the standard for that particular product is discarded, while other capsules that pass the test are accepted.

- **Capsule counting :- here the capsules are counted, and about 8000 capsules can be counted per minute. They are then, moved to further quality control tests of the finished product.**

Quality control tests

Capsules are subjected for following tests during quality control:-

Appearance

Weight variation tests

Disintegration tests

Dissolution tests

Content uniformity tests

Moisture permeation tests Soft gelatin

Weight variation testing conditions

Average net weight	Deviation (%)	No. of Capsules
Less than 300 mg	± 10	Min 18
	± 20	Max 2
300mg and more	± 7.5	Min 18
	± 15	Max 2

Disintegration test

Type of capsule	Disintegration medium	Temperature	Limit
Hard gelatin capsule	Water/ buffer	$37^{\circ}\text{C} \pm 2^{\circ}\text{C}$	30 min
Soft gelatin capsule	Water	$37^{\circ}\text{C} \pm 2^{\circ}\text{C}$	60 min
Enteric coated capsule	0.1 M HCl mixed phosphate buffer pH 6.8	$37^{\circ}\text{C} \pm 2^{\circ}\text{C}$	2 hr in HCl – no disintegration 1 hr in buffer - disintegrate