



School of Pharmacy & Life Sciences

Campus BHUBNESWAR Batch : A2

Code : DCPY1107 Subject : PHARMACEUTICS-I Date : 7.11.19

Applied and Action Learning

(Learning by doing and discovery)

Name of the Experiment : Quality control test for marketed paracetamol tablet.

SKETCH

AIM OF THE EXPERIMENT :-

To perform the quality control test for the marketed paracetamol tablet.

Material, Tools & Equipment Required (if any)

Sl.No.	Name	Specification	Qty..
	marketed paracetamol tablet, electronic balance, sieve gauge, Roche friabilator, disintegration apparatus, Monsanto tester, Pfizer hardness tester.		

PROCEDURE

70

Observations, Calculations, Graph

Safety Precaution:

Application & Inference:

REPORT:-

The quality control test for given marketed paracetamol-tablet (calpol) was performed. The product passes the quality control test.

ASSESSMENT

MARKING PROCEDURE		Full Mark	Marks Obtained	Remarks
Accuracy & Process	Sketch	10		
	Sequence of Operation	10		
	Use of Tools & Equipment	10		
	Safety Observation	5		
Report	Observations, Calculations, Graph	25		
Inference		30		
Viva		10		
Total		100		

Signature of Faculty

Signature of Student: *BITTU - DEY*

Name: BITTU - DEY

Regn. No: 181517100038

• THEORY:-

The various quality control test are conducted for the marketed paracetamol tablet are:-

- (i) Appearance
- (ii) Thickness and diameter (Diameter)
- (iii) weight variation test
- (iv) Hardness test
- (v) Friability test.

• PROCEDURE:-

1. Appearance:-

The tablets are examined externally under a biconvex lens for surface, colour, polish, etc. The tablets should be free from cracks, depression, pinholes etc.

Test	Observation	Inference.
surface roughness	Smooth	passes
cracks	Absent	passes
depressions	Absent	passes
pinholes	Absent	passes
colour	uniform	passes
polish	uniform	passes.

2. Dimension:-

The thickness and diameter of 5 tablets are measured by using vernier calliper or screw gauge.

Formula:- $TR = MSR + (CSR \times LC)$

where TR = Total Reading
 MSR = Main scale reading
 CSR = Circular scale reading
 LC = least count = 0.001.

* THICKNESS

Tablet no	MSR	CSR	LC (cm)	TR	Average
1	5	38	0.001	5.038	5.041 cm
2	5	42	0.001	5.042	
3	5	43	0.001	5.043	

* Diameter

Tablet no	MSR	CSR	LC (cm)	TR	Average
1	13	64	0.001	13.064	13.054 cm.
2	13	63	0.001	13.063	
3	13	62	0.001	13.062	

3. ~~Weight variation test~~ :-

20 tablets are weighed individually. Calculate the average weight and compare the individual tablet weight with the average weight.

The % deviation is calculated by using the following formula.

$$\% \text{ deviation} = \frac{\text{individual weight} - \text{average weight}}{\text{average weight}} \times 100$$

Total weight of 20 tablets is 3.94 g.

Average weight of tablets is 0.197 g.

Tablet No	Individual weight of tablet	deviation from the average weight	percentage weight-
1.	0.19	0.007	3.55
2.	0.18	0.017	8.62
3.	0.21	-0.013	-6.59
4	0.19	0.007	3.55
5	0.20	-0.003	-1.52
6	0.18	0.017	8.62
7	0.18	0.007	8.62
8	0.19	0.007	3.55
9	0.19	-0.003	3.55
10	0.20	-0.003	-1.52
11	0.20	0.007	-1.52
12	0.20	0.007	-1.52
13	0.19	-0.003	3.55
14	0.19	-0.003	-1.52
15	0.20	0.017	-1.52
16	0.20	0.007	8.62
17	0.18	0.007	3.55
18	0.19	0.007	8.62
19	0.19	0.017	8.62
20	0.18	0.007	3.55

Hardness test^o-

The hardness of the tablet is tested the hardness tester. The tablet is placed across the diameter in between the spindle and the anvil. The knob is adjusted to hold the tablet in position. The reading of the pointer is adjusted to zero. The pressure is increased slowly to break the tablet.

Tablet no	Hardness Kg/cm ²
1.	5.4 Kg/cm ²
2.	5.4 Kg/cm ²
3.	5.9 Kg/cm ²

• Friability test :-

Roche friabilator is used to measure the friability of the tablets. It rotates at a rate of 25 rpm. 10 tablets are weighed collectively and placed in the chamber of the friabilator. In the friabilator, the tablets are exposed to rolling, resulting from free fall of tablet within the chamber of the friabilator. After 100 rotation (4 min), the tablets are taken out from the friabilator and intact tablets are again weighed collectively.

percentage friability is determined using the following formula %

$$\% \text{ friability} = \frac{w_1 - w_2}{w_1} \times 100$$

where w_1 = weight of the tablet before test

w_2 = weight of the tablet after test

weight of 10 tablet (w_1) before the test = 1.96 g

weight of 10 tablet (w_2) after the 100 rotation = 1.95 g

$$\% \text{ friability} = \left[\frac{w_1 - w_2}{w_1} \right] \times 100$$

$$= \frac{1.96 - 1.95}{1.96} \times 100 = 0.51\%$$

So, friability = 0.51%

• Disintegration test :-

The disintegration test apparatus consist of basket rack assembly containing six open-ended glass tube. They are held vertically and the bottom of tube is covered with 10 mesh screen. By the use of a motor, the basket raises and lowers in the immersion fluid at a frequency of 29 to 32 cycle per minute. The wire screen is always maintain below the level of the fluid. The fluid temperature is maintained at $37 \pm 2^\circ\text{C}$ through the test.

Test	Observation
<p>water (or specified med^m) is placed in the disintegration apparatus. The temp of the med^m is maintained 37°C. A tablet is placed in each of the six tubes of the basket. Then the plastic disc (weights) are placed over each tablet to prevent the tablet coming outside of the tube of the basket. The basket is allowed to operate</p>	<p>Time required for complete disintegration of all the six tablets is <u>16 min</u></p>

• summary of observation :-

Sl. no	Test	Observation	Inference
1	Appearance	smooth - surface roughness Absent - cracks, depressions uniform - colour, polish	Passes
2	Tablet thickness	5.041 mm	Passes
3	Tablet diameter	13.054 mm	Passes
4	uniformity of weight	—	Passes
5	Hardness	5.56 kg/cm ²	Passes
6	Friability	0.51%	Passes
7	Disintegration	16 min	Passes.

~~Handwritten signature~~