

In-process Quality Control Tests For Coated Tablets

Experiment No. 8

Date :

Aim : To evaluate sugar/film coated tablets for in-process quality control tests.

Theory

A variety of tests are conducted on sugar coated and film coated tablets in order to make sure that the manufactured tablets are of the best possible quality. From the point of production of tablets, quality control tests are classified into two categories.

<i>In-process quality control tests</i>	<i>Finished product quality assurance tests</i>
Appearance	Dissolution rate
Dimensions	Uniformity of content
Hardness	Stability studies
Disintegration time	Content of active ingredient and confirmation of all the tests reported in in-process quality control
Adhesion test	
Resistance to abrasion	

In-process quality control tests are the tests conducted when the tableting and coating are under process. These tests should be able to be completed quickly, without halting the process for a long time. In this experiment, in-process quality control tests are performed on sugar coated/film coated tablets.

In-Process Quality Control Tests

Appearance (unofficial test) : The tablets should be free from cracks, depressions, pinholes, etc. The colour, surface roughness, and polish of the tablet should be uniform on whole surface.

Dimensions (unofficial test) : The dimensions of the tablets are thickness and diameter. Thickness and diameter of a tablet are measured using a vernier calipers or screw gauge.

Weight variation test : This is not performed for sugar coated tablets and is applicable only for film-coated tablets.

Hardness (unofficial test) : *Hardness* (diametral crushing strength) is a force required to break a tablet across the diameter.

The hardness of a tablet is an indication of its strength. The tablet should be stable to mechanical stress during coating, handling, and transportation. The degree of hardness varies with different manufactures and with different types of tablets.

The force is measured in kilograms. It is tested by using hardness testers such as Monsanto tester, Pfizer tester, Erweka tester, Schleuniger tester, and Strong Cobb tester.

This is a valuable test, which might influence the dissolution rate of the active ingredient. Depending on the type and concentration of the binding agent (for example, acacia mucilage, starch paste, sugar syrup, methyl cellulose dispersion etc) and the type of coating, the hardness of a tablet varies.

Disintegration (official test) : *Disintegration* is defined as that state in which any residue of tablet, except fragments of insoluble coating, remaining on the screen of the test apparatus consisting of a soft mass having no palpably firm, unmoistened core. This test can be determined quickly with greater ease. This is the only in-process quality control test that is more related to the performance of the tablet. Unless the coating is intended to control drug release, the coating should have minimum effect on tablet disintegration.

TABLE 5
Specifications for Disintegration for Coated Tablets

Type of dosage form	Vehicle	Time of disintegration	State of disintegration	Remarks
Coated tablets	Water	One hour	Complete	Passes
	if failed, 0.1 N HCl	One hour	Complete	Passes
Enteric coated tablets	0.1 N HCl	2 hours	No complete disintegration	Passes
	mixed phosphate Buffer, pH 6.8	60 min	Complete	Passes

Adhesion test (unofficial test) : This is measured using tensile strength testers. Here the force required to peel the film from the tablet surface is measured. In this practical it is not tested.

Resistance to abrasion : The ability of coatings to remain stick to the tablet surface is tested. Any mistake in the formulation of coating solution can be tested here.

Finished product quality assurance tests are not tested in this practical class.

Procedure

Appearance : The tablets are visually observed for the following parameters.

Test	Observation	Inference
Chipping	Absent / Present	Passes / Does not pass
Cracks	Absent / Present	Passes / Does not pass
Depressions	Absent / Present	Passes / Does not pass
Pinholes	Absent / Present	Passes / Does not pass
Colour	Uniform / Ununiform	Passes / Does not pass
Polish	Uniform / Ununiform	Passes / Does not pass
*Twinning	Absent / Present	Passes / Does not pass
Non drying coatings	Absent / Present	Passes / Does not pass
Blooming	Absent / Present	Passes / Does not pass
*Sweating	Absent / Present	Passes / Does not pass
Sticking/Picking	Absent / Present	Passes / Does not pass
Surface roughness	Smooth / Irregular	Passes / Does not pass
Bridging/Filling	Absent / Present	Passes / Does not pass

Dimensions : The thickness and diameter of five tablets are measured using vernier calipers or screw gauge. The thickness and diameter of the tablet is accurately calculated using the following formula.

$$T.R. = P.S.R. + [(C.H.R \pm Z) \times L.C.]$$

The terms given in the equation are already explained.

Zero correction : If zero reading of headscales coincides with main line of pitch scale, then zero correction is not required. If zero reading of headscales lies above the main line of pitch scale, then number of divisions of headscales is noted and this number is deducted. If zero reading of headscales lies below the main line of pitch scale, then number of divisions of headscales is noted and this number is added (see Figure 8).

Thickness					
Trial	PSR	CHR	Z	LC	TR
1					
2					
3					
4					
5					

TR	Average	Difference	Per cent difference	Permitted difference	Inference
				5 %	Passes / does not pass

Diameter					
Trial	PSR	CHR	Z	LC	TR
1					
2					
3					
4					
5					

Tablet Sl. no.	Hardness in kg/cm ²

Average hardness of tablets:kg / cm².
 Batch of tablets passes / does not pass for hardness test.

Disintegration : Disintegration is carried out first using water as the medium. If the test fails, then process is repeated with fresh 6 tablets using 0.1 N HCl as medium. The disintegration time is noted when all tablets pass through the sieve. Generally the disintegration time for coated tablets is 60 minutes.

Test	Observation	Inference
Water is placed in the disintegration apparatus. The temperature of the medium is maintained at 37°C. Sugar coated tablets are placed, one in each of the six tubes of the basket. Then the plastic weights are placed over each tablet to prevent the tablet coming outside of the tubes of the basket. The basket is allowed to operate.	Time required for complete disintegration of all the six sugar coated tablets is min	Batch of sugar coated tablets passes / does not pass for disintegration test

Disintegration time for sugar-coated tablets (unless stated in IP) is 30 minutes.
 Batch of tablets passes / does not pass for disintegration test.

Resistance to abrasion:

Test	Observation	Inference
Sugar-coated tablets are rubbed on a white paper.	Resilient films should remain intact and no colour should be transferred to the paper.	Batch of tablets passes the test.
	Very soft coatings are readily 'erased' from the tablet surface to the paper.	Batch of tablets does not pass the test.

Number of tablets having soft coatings is
 Batch of tablets passes the test / does not pass the test.

Summary of Observations

Sl. No.	Test	Observation	Inference
1	Appearance		
2	Tablet thickness		
3	Tablet diameter		
4	Hardness		
5	Disintegration		
6	Resistance to abrasion		

Report :

QUESTION BANK

1. Define the terms 'Quality Control' and 'Quality Assurance'.
2. Describe the procedure for the disintegration tests of the following tablets:
 Uncoated tablets, Sugar coated tablets, Enteric coated tablets
3. List the official and unofficial quality control tests for coated tablets.
4. What is the objective of conducting hardness test for tablets?
5. What is the importance of disintegration test in the evaluation of tablets?
6. Mention the pharmacopoeial limits for the weight variation test of coated tablets.
7. Why is friability test not required for coated tablets?