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PRE AND POST COMPRESSION PARAMETERS OF TABLET AND MANUFACTURING DEFECTS

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ABSTRACT

Tablets are defined as solid unit dosage form of medicaments intended for oral use. They became most popular as they were easy in preparation compared to any other type of dosage forms. But the major drawback exists in its manufacturing. Pre and post compression parameters are important since chemical breakdown or interactions between tablet components may alter the physical tablet properties and greatly affect the bioavailability of the tablet system. These are various standards that have been set in the various pharmacopoeias tablets. These include the angle of repose, hausner's ratio, compressibility index, bulk density, tapped density, void volume, diameter, size, shape, thickness, weight, hardness, disintegration and dissolution character. An industrial pharmacist usually encounters number of problems during manufacturing. Majority of visual defects are due to inadequate fines or inadequate moisture in the granules ready for compression or due to faulty machine setting. Functional defects are due to faulty formulation. In this article we will discuss the imperfections found in tablets along–with their causes and related remedies.

KEYWORDS: Tablet, Pre-compression parameters, Manufacturing defects, Remedies, Dissolution.

INTRODUCTION[1]

Tablets are most widely used solid dosage form of medicament in which one usual dose of a drug has been include. They may be oblong, round, convex, flat, and engraved with an

identifying symbol. They are prepared in coated, uncoated, uncoloured, coloured, 1, 2 or 3 layered. Evaluation of tablets is carried out by pre and post compression parameters of tablet. In the pre compression parameter angle of repose, hausner ratio, % compressibility is carried out to evaluate flow characteristics of powder, furthermore bulk density and tap density are measured. In the post compression parameters hardness test, friability test, weight variation, disintegration time, and dissolution time are evaluated. Above mentioned all pre and post compression parameters are carried out to avoid common tablets defects such as weight variation, friability, sticking, capping, and mottling.

Pre Compression Parameters[2]

Angle of repose

Angle of repose defined as the maximum angle possible between surface of pile of powder and horizontal plane. It is characteristic related to inter particulate friction or resistance movement between particles.

$\Theta = \tan^{-1} h/r$

Where,

Θ = Angle of repose

h = Height of pile

r = Radius of pile

Hausner's Ratio

Hausner's ratio is correlated to the flowability of a powder or granular material. If it is greater than 1.25 is considered to be indication of poor flowability.

H = Dt/Ddb

Where,

Dt: Tapped density;

Dbd: Bulk density

% compressibility

Percent compressibility of powder mix was determined by carr's compressibility index.

Carr's index (%) = TTBD – LBD / TBD x 100

Where, BD: Bulk density

TD: Tapped density

Table 1: Relationship between angle of repose, hausner's ratio, percent compressibility and flow property.

Flow characteristics	Angle of repose	Hausner's ratio	Percent compressibility
Excellent	25-30	1.00-1.11	1-10
Good	31-35	1.12-1.18	11-15
Fair	36-40	1.19-1.25	16-20
Passable	41-45	1.26-1.34	21-25
Poor	46-55	1.35-1.45	26-31
Very poor	56-65	1.46-1.59	32-37
Extremely poor	>66	>1.60	>38

Bulk density

Bulk density is defined as the mass of the powder divided by the bulk volume and is expressed as gm/cm^3. Specific bulk volume or reciprocal of bulk density is called bulkiness or bulk.

Db = M / vb

Where,

Db=Bulk density

M=Weight of sample in gm

Vb=Bulk volume

Tapped density

It is the ratio of total mass of the powder to the tapped volume of the powder. It is expressed in g/ml and is given by;

Dt = M / vt

Where,

Dt = Tapped density

M = Mass of powder

Vt = Tapped volume of powder

Void volume[3]

The volume of spaces is known as the void volume "V" and is given by formula

V = vb - vt

Where,

Vb = bulk volume

Vt = true volume.

Post Compression Parameters For Tablets

Hardness test[4]

Hardness is define as the resistance of tablet against the applied force till to breaks it. Tablet hardness and strength essential to the tablet can shock with the stress during manufacturing, and transporting. It is expressed in kg/cm^2.

Factor affecting hardness

a) Amount of binder.

b) Granulation preparing method.

c) Compressive force.

Table 2: Types of tablets and standard hardness values.[5]

Type of tablets	Standard hardness values (kg/cm^2)
Uncoated tablets	3-5 kg/cm^2
Coated tablets	3 kg/cm^2
Fast dissolving tablets	3.0-4.2 kg/cm^2
Conventional tablets	2.5-5 kg/cm^2
Extended release tablets	5-7.5 kg/cm^2
Chewable tablets	2.25-2.5 kg/cm^2
Sustained release tablets	10-20 kg/cm^2

Friability test

It is a phenomenon in which surface of tablet are damaged or braked, due to mechanical shock. It is tested by using Roche friabilator which rotated 25 rpm for 100 revolution.

F = Initial wt. – Final wt. / Initial wt. x 100

Weight variation[6]

This test is performed to check the out the uniformity of weight of tablets. The tablets are selected randomly from every system and weighed for to the weight variation. Not more than two of the individual weight deviate from average weight by more than % given in pharmacopeia. IP, BP and USP has given the limits for tablet weight variant given below.

Table 3: % deviation in weight variation.

USP	Max.% difference allowable	IP/BP
130 mg > or less	±10%	80 mg > or less
130 mg – 324 mg	±7.5%	80 mg – 250 mg
324 mg < or less	± 5 %	0 < or more

Disintegration time

DT Apparatus

Study of *in-vitro* disintegration time of tablet is determined by using disintegration test apparatus as per USP. Apparatus consist of 6 glass tubes.

Mesh aperture: 2 mm, cycles: 28-32 cycles/min, 50-60 mm distance from top and bottom, temperature of water $37^0C \pm 2^0C$. If 1 or 2 tablets fail, repeat test for another 12 tablets.

Place one tablet in every tube disc upload in each tube and apparatus run the by using PH 6.8. Temperature maintained at 37 ± 2^0 C. in 1000 ml vessel.

Table 4: Standard disintegration time for various types of tablets.[7]

Type of Tablet	Time (min)	Comment	Solvent used
Uncoated tablets	NMT 15	$37\ ^0C \pm 2\ ^0C$	Water
Dispersible / Soluble tablets	3	$25\ ^0C \pm 1\ ^0C$ (IP), $15 – 25\ ^0C$ (BP)	Water
Orodispersible tablets	Within 1 min		
Effervescent tablets	5, 5	$20- 30\ ^0C$ (IP), $15- 25\ ^0C$ (BP)	250 ml water, 200 ml water
Chewable tablets	5		
Sugar coated tablets	60		Water
Coated tablets (Film coated tablet)	NMT 30		
Coated tablets (Other than film coated tablet)	NMT 60		
Enteric coated tablets	120, 60		0.1 N HCl Phosphate buffer solution, pH 6.8
Delayed-release tablets	120, 60		0.1 N HCl Phosphate buffer solution, pH 6.8
Buccal & Sublingual	15-30		

Dissolution[8]

It is a standardise method for measuring rate of drug of release from a dosage from. The extent of drug and rate release from the tablet. it is determined by dissolution test.

Table 5: Classification of dissolution apparatus in different pharmacopoeia.

	IP	USP	BP	EP
Type 1	Paddle apparatus	Basket apparatus	Basket apparatus	Paddle apparatus
Type 2	Basket apparatus	Paddle apparatus	Paddle apparatus	Basket apparatus
Type 3		Reciprocating cylinder	Flow through cell apparatus	Flow through cell apparatus
Type 4		Flow through cell apparatus		
Type 5		Paddle over disk		
Type 6		Cylinder		
Type 7		Reciprocating holder		

Challenges in dissolution testing

- Failure of the performances evolution of the apparatus or product.
- In vitro in vivo correlation.
- Lack of objectivity in setting or selecting experimental condition.

Common Tablet Defects[9]

Weight variation

Friability

Hardness

Sticking

Capping

Mottling.

The above defect arise from:

-Problem with unit upstream.

-Problem with the tablet press.

-Poor quality raw material.

Capping

Capping happen when a fracture occurs at a top of tablet and or cap, separate from body of solid tablet. Poor formulation as well as bad processing practice can cause capping.

Steps to eliminate capping

Punch penetration

Pre compression

Slow press down

Slowing tableting rate

Sticking

Sticking is formed when the granules of formulation stuck to the face of the press punch.

Steps to eliminate sticking

Adjusting the compression force

Increase the pressure

Polishing

Proper lubricant mix

Mottling

Mottling is an unequal distribution of colour on a tablet with light or dark areas standing out in an otherwise uniform surface.

To overcome this difficulty:

Change binder system

Reduce the drying temperature

Grind to small particle size

CONCLUSION

Pre and post compression parameters of tablets such as angle of repose, hausner's ratio, % compressibility, bulk density, tap density, void volume and hardness, friability, weight variation time, disintegration time, dissolution time were studied respectively. In addition common tablets defect viz. weight variation, friability, hardness, sticking, capping and mottling were studied.

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CONFLICT OF INTEREST

The authors declares no conflict of interest.

ABBREVIATIONS USED

BD: Bulk density; TD: Tapped density; DT: Disintegration test; Kg: Kilogram; gm: Gram; NMT: Not more than; Mg: Milligram, rpm: Revolution per minute.

SUMMARY

This review summarizes the pre and post compression parameters of tablets. The effect of precompression parameters on the manufacturing of tablets and possible defects during tablet manufacturing are also given. Remedies for tablet manufacturing defects are included in this review.

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