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DISINTEGRATION TIME – NEED IN AYURVEDIC PHARMACEUTICS – A REVIEW

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ABSTRACT

Introduction: Though the Ayurvedic formulations are time tested for their promising and reliable therapeutic efficacy there is a need for standardization of the same in the current era to meet the global standards followed by global acceptance. A formulation needs to pass all the analytical tests before it enters the market irrespective of the system of medicine and dosage form for the safe use of the drug. **Aim And Objectives:** The main aim of the study is to emphasize the importance of the Rate of Disintegration in Ayurvedic dosage forms and the Role of the Rate of Disintegration in Drug absorption. **Materials And Methods:** Concept of Disintegration, Instrumentation and SOP of Disintegration test, Mechanism of Disintegration, Factors influencing Rate of Disintegration, Need of Disintegration test in Ayurvedic dosage forms. **Discussion:** Though designing a formulation is the prime step in developing pharmaceutics, the analytical standardization of the designed formulation encourages the further movement of the product. The rate of disintegration is influenced by many factors like size, excipients, buffer media etc., which may increase or decrease the time. **Conclusion:** This test is very important and necessary for all the tablets (coated or uncoated), capsules to be swallowed because the dissolution rate depends upon the time of disintegration which ultimately affects the rate of absorption of the drug.

Keywords: Disintegration [1], Absorption, Pharmaceutics.

INTRODUCTION

Though the Ayurvedic formulations are time tested for their promising and reliable therapeutic efficacy there is a need for standardization of the same in the current era to meet the global standards followed by global acceptance. A formulation needs to pass all the analytical tests before it enters the market irrespective of the system of medicine and dosage form for the safe use of the drug. There are various sets of analytical parameters for every formulation based on dosage forms. And these parameters serve as key factors in Pharmacodynamics and pharmacokinetics. Rate of Disintegration is one such analytical test where it serves as a benchmark in various dosage forms by its role in drug absorption.

Aim and Objectives:

- The main aim of the study is to emphasize the importance of the Rate of Disintegration in Ayurvedic dosage forms.
- Role of Rate of Disintegration in Drug absorption.

Materials and Methods:

- Concept of Disintegration.
- Instrumentation and SOP of Disintegration test.
- Mechanism of Disintegration.
- Factors influencing Rate of Disintegration.
- Need of Disintegration test in Ayurvedic dosage forms.

Concept of Disintegration:

Disintegration is the time required for the tablet to break into particles in a particular media. Disintegration is defined as the state in which no residue of the tablet or capsule remains on the screen of the apparatus or, if a residue remains, it consists of fragments of disintegrated parts such as insoluble coating of the tablet orcapsule shells, or any melted fatty substance from the pessary or suppository or is a soft mass with no palpable core. Solid dosage forms are the largest dosage form which is abundantly produced and marketed among all other dosage forms because of their unique advantages. This test is essential for tablets intended for administration by mouth, except those intended to be chewed before being swallowed or those that should dissolve slowly in the mouth, e.g., lozenges or effervescent tablets. For such dosage forms disintegration is an official test for deciding the fitness of the tablet for both marketing and consumption. The performance of a drug is primarily influenced by the disintegration and dissolution behaviour of the powder compact. Thereby it has its influence on other parameters like dissolution and rate of absorption. The disintegration process is an integral step in ensuring, indeed maximising the bioavailability of the active principles from the majority of solid dosage forms.

INSTRUMENTATION AND SOP OF DISINTEGRATION TEST:

FIGURE 1: DISINTEGRATION TEST APPARATUS

FIGURE 2: APERTURE MESH

The apparatus consists of a basket-rack assembly, a 1-litre beaker, a thermostatic arrangement for heating the fluid and a mechanical device for raising and lowering the basket in the immersion fluid at a constant frequency rate.

BASKET-RACK ASSEMBLY: six cylindrical glass tubes, 77.5 ± 2.5 mm long, 21.5 mm in internal diameter and with a wall thickness of about 2 mm. Two superimposed transparent plastic plates, 90 ± 2 mm in diameter and 6.75 ± 1.75 mm thick perforated by six holes having the same diameter as the tubes as shown in figure 01. Attached to the underside of the lower plate is a woven stainless steel wire cloth with 2.0 ± 0.2 mm mesh apertures and a wire diameter of 0.615 ± 0.045 mm. The upper plate is covered with a stainless-steel disc perforated by six holes as shown in figure 02, each about 24 ± 2 mm in diameter, which fits over the tubes and holds them between the plastic plates. A standard motor-driven device is used to move the basket assembly containing the tablets up and down at a constant frequency of between 28 and 32 cycles per minute through a distance of 50 to 60 mm. The change in stroke direction should be smooth and not abrupt.

Discs: A cylindrical disc for each tube, each 20.7 ± 0.15 mm thick in diameter and 9.5 ± 0.15 mm thick, made of transparent plastic with a relative density of 1.18 to 1.20, and pierced with five holes, each 2 mm in diameter. Four equally spaced grooves are cut in the lateral surface of the disc in such a way that at the upper surface of the disc they are 9.5 mm wide and 2.55 mm deep.

Perforated plastic discs are placed on top of the tablets to impart an abrasive action to the tablets. They are useful for tablets that float.

Medium:

The volume of liquid is such that the wire mesh at its highest point is at least 25 mm below the surface of the liquid, and at its lower point is at least 25 mm above the bottom of the beaker. At no time should the top of the basket rack assembly become submerged. There is a thermostatic arrangement for heating the liquid and maintaining the temperature at 37° ± 2°C

If 1 or 2 tablets fail to disintegrate, repeat the test on 12 additional tablets; not less than 16 of the totals of 18 tablets tested.

Table 1: Showing Disintegration time of various dosage forms

SL.NO.	DOSAGE FORM	DISINTEGRATION TIME
1	Uncoated Tablet	NMT 15 min, in water with Disc 37°C ±2°C
2	Coated Tablet	NMT 30 min, in water with Disc for Film Coated Tab, and NMT 60 min Other than Film-coated tablet
3	Enteric Coated Tab	According to IP Intact for 2 hr in 0.1 M HCl (Simulated gastric fluid) & disintegrate within 60 min in Mixed 6.8 Phosphate buffer (Simulated Intestinal Fluid)
4	Dispersible/Soluble	Within 3 min in water at 25°C ± 1°C
5	Oro dispersible	within 1 min
6	Effervescent Tab	5 min in 250 ml water at 20-30°C
7	Buccal& Sublingual	Not Applicable but dissolve within 15-30 min.

MECHANISM OF DISINTEGRATION:

Disintegration time is an integral part of analytical tests of Ayurvedic dosage forms like Vati Kalpana [2], Guggulu Kalpana [3], Varti Kalpana [4] etc.,

The mechanism of Disintegration follows

1. **WICKING (CAPILLARY ACTION) – LIQUID PENETRATION**

Interarticular bonds which hold the solid particles together to maintain the structural integrity of the Dosage form is disrupted. Thus, wicking (liquid penetration) is one of the main steps in disintegration.

The liquid penetration is directly proportional to the pore size of the compact and hydrophilicity of excipients.

2. SWELLING:

Particles swell Omni-directionally pushing the other components apart resulting in matrix breakage.

3. STRAIN RECOVERY:

During tablet making, the disintegrant particles are deformed when in contact with water the disintegrant tends to go back to its previous structure, recovering its original shape.

4. INTERRUPTION OF PARTICLE–PARTICLE BONDS:

During tabletting bonding occurred by solid bridges, mechanical interlocking or intermolecular forces – it is proposed that the interruption of these binding bonds is one of the disintegration mechanisms.

FACTORS INFLUENCING RATE OF DISINTEGRATION:

1. Tablet composition or formula
2. Size of the tablet/granule
3. Weight of the tablet/granule
4. Tablet hardness
5. Binders
6. Lubricants
7. Disintegrating agents
8. Temperature
9. Humidity
10. Type of hopper feed during tablet making
11. Compression force during tablet compression
12. P^H of gut fluids – gastric/intestinal
13. $P^H$of buffer media

NEED OF DISINTEGRATION TEST IN AYURVEDIC DOSAGE FORMS:

As Disintegration time[5]is the time required for the tablet to break into particles in a particular media, irrespective of the system of medicine majority of the solid dosage forms need to undergo disintegration time test for its acceptance for therapeutic utility in major populations. Even in Ayurveda, we have our own Kalpana's like vati and Guggulu which can be correlated to solid dosage forms of modern pharmaceuticals for which this test is a must. The mode of action of both vati and Guggulu will be different this difference can be drawn even based on the parameters like disintegration time. The disintegration of vati will be faster compared to Guggulu because the vati will not have any coating of gum resin except some excipients like sugar coating, film coating and enteric coatings whereas even Guggulu will have all these coatings concerning the intended action but Guggulu (gum resin) itself acts as a coating by which the disintegration time prolong. As the disintegration time is less for the Guggulu than vati their dissolution time will be more, and the rate of absorption will be slower which inevitably affects the therapeutic action of the drug. Instead of considering this as a lacuna, we can consider Guggulu as a sustained release dosage form of ayurvedic pharmaceutics hence the time of disintegration plays a major role in the standardization of Ayurvedic formulations.

DISCUSSION

Though designing a formulation is the prime step in developing pharmaceutics, the analytical standardization of the designed formulation encourages the further movement of the product. Different dosage forms will have different sets of analytical parameters which a product has to undergo, disintegration time is one such analytical test in which all the solid dosage forms like tablets and capsules which are leading dosage forms of the pharmaceutics also need to undergo the test for their approval. This test gives direct information regarding the drug dissolution followed by drug absorption which are the key factors in drug action. Different dosage forms will have different times of disintegration time concerning different media as shown in table no 1. Because the disintegration time will be different for acidic media which is a gastric environment and disintegration time in alkaline media will be different which is the enteric environment of the human body. Hence disintegration time assessed in a neutral buffer media is considered as a standard for comparing both acidic and alkaline media.

The rate of disintegration is influenced by many factors like size, excipients, buffer media etc., which may increase or decrease the time. Hence during the

test, the factors influencing the disintegration time need to be focused on.

CONCLUSION

This test is very important and necessary for all the tablets (coated or uncoated), capsules to be swallowed because the dissolution rate depends upon the time of disintegration which ultimately affects the rate of absorption of the drug. All the Ayurvedic formulations need to undergo various analytical tests to meet the global standards for global acceptance.

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