DESIGN AND TESTING OF OMEPRAZOLE TABLETS THAT DISSOLVE IN THE MOUTH

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Abstract:

Omelazole orally dissolving tablets are the focus of this research because of the rapid onset of action that would result from the drug's direct absorption into the systemic circulation via the buccal mucosa.Omelazole orally dissolving tablets are the focus of this research because of the rapid onset of action that would result from the drug's direct absorption into the systemic circulation via the buccal mucosa. They used the wet granulation process to make Omeprazole pills that dissolve in the mouth. Weighing and sieving the necessary amount of drug and other excipients through sieve no. 60 to obtain a homogenous mixer, we next made a damp mass of mixer with distilled water as the solvent. After passing this damp mass through sieve no. 10, we dried the granules at 50 °C until the moisture content was less than 2%.The current study effectively developed omeprazole mouth-dissolving tablets with an enhanced drug release profile. The formulation's satisfactory performance in measuring cumulative drug release, disintegration time, hardness, and friability led to its selection. This formulation's dissolving study demonstrated an increase in the cumulative percentage of drug release.

Keywords: Hepatic first pass metabolism, Omeprazole, Bioavailability, Mouth dissolving tablets.

1. Introduction:

Solid dose forms like mouth dissolving tablets have a nice flavor and dissolve or disintegrate in the mouth in about a minute, all without water. Fast-melting tablets, mouth melting tablets, or orally disintegrating tablets are some of the other names for MDTs. Commercialization of fast disintegrating dosage forms has been a success, and their increasing significance was recently brought to light when the European Pharmacopoeia adopted the phrase "Or dispersible tablets" to describe a kind of tablet that dissolves quickly in the mouth before ingesting [1,2]. The original intent of this method of administration was to help patients of all ages, especially those with swallowing difficulties, those with mental health issues or other diseases that make compliance challenging, and those with poor swallowing abilities. For a long time, MDT was considered its own dosage form because to its unique intended performance features, such as fast oral breakdown in saliva and the absence of chewing or liquid consumption required for ingestion [3,4].

1.1 Advantages of MDTs:

- Enhanced adherence by patients.By lowering side effects, pregastric absorption may increase bioavailability, lower dosage, and clinical performance.
- Easily given to people who have trouble swallowing.
- Suitable for use with children, the elderly, and those with mental health issues.
- Perfect for trips where running water isn't always an option

1.2 Ideal properties of MDTs [5,6] :

- First, they should melt or disintegrate in the mouth within a few seconds and don't need water for swallowing.
- Permit a high dosage of the medicine.
- Be well-tolerated by other excipients and flavor masking agents.
- Feel good in the mouth.
- after taking the medication orally, you should not leave any aftertaste in your mouth.
- Be sturdy enough to endure the handling that occurs during and after production.
- Show little reaction time to changes in temperature and humidity.
- Work well with what processing and packaging equipment is already available.
- Permit the inexpensive production of tablets using standard processing and packaging equipment.

2. Material anad methods:

Ingredientsforonetablet	**F_1 mg**	**F_2 mg**	**F_3 Mg**	**F_4 mg**	**F_5 mg**	**F_6 mg**	**F_7 mg**	**F_8 mg**	**F_9 mg**
DPC(equivalentto 75mgof Omeparazole)	377	377	377	377	377	377	377	377	377
Mannitol	51	46.5	37.5	51	46.5	37.5	51	46.5	37.5
Crosspovidone	9	13.5	22.5	-	-	-	-	-	-
Croscarmellosesodium	-	-	-	9	13.5	22.5	-	-	-
Sodiumstarchglycolate	-	-	-	-	-	-	9	13.5	22.5
Aspartame	4	4	4	4	4	4	4	4	4
MintFlavour	3	3	3	3	3	3	3	3	3

Magnesiumstearate	3	3	3	3	3	3	3	3	3
Talc	3	3	3	3	3	3	3	3	3
Totalweight	450	450	450	450	450	450	450	450	450

2.1 MANUFACTURING PROCEDURE:

- The first step in preparing the ODT was to employ an optimized batch of drug polymer complex, which included 75 mg of Omeparazole.
- The second step included passing each of the three ingredients—mannitol, crospovidone/croscarmellose sodium, and sodium starch glycolate—through a #40 mesh sieve.
- Thirdly, after sifting the excipients, combine them with the optimized DPC. Stir for three minutes. Finally, add the mint flavor and stir again.
- The fourth step was to pour in the magnesium stearate and talc, and then to stir the mixture for two minutes.
- The fifth step was to use a 10-millimeter concave punch to compress the powder mixture.
- **Bulk density:**
  The poured density is another name for it. The formula for this is the mass-to-volume ratio of powder. A 100 ml measuring cylinder was used to record the initial volume after 20 grams of powder, which had been passed through standard sieve #20, was poured into it. The term "bulk volume" describes this initial amount. Next, we use the formula to get the bulk density from this. You may find it as a concentration in g/ml by
  Db= M/ Vb
  Where, M is the mass of powder
  Vb is the bulk volume of the powder.
- **Tapped density:**
  It is the ratio of the powder's total mass to its tapped volume.We measured the volume by tapping the powder 750 times. If the difference between the two volumes is less than 2%, we consider it a successful measurement. Continue tapping for 1250 times and record the tapped volume if it's more than 2%. When using a bulk density equipment, tapping should continue until the volume difference between each subsequent measurement is less than 2%.It is provided by and is written as g/ml.
  Dt= M/ Vt
  Where, M is the mass of powder
  Vt is the tapped volume of the powder.
- **Angle of repose (θ):**
  The angle of repose is a measure of the friction forces in loose powder. It shows how the powder behaves when mixed with water.What follows is a formula for determining the maximum allowable angle between the powder pile's surface and a horizontal plane.
  tan(θ)=h/r

- **Carr's index (or) % compressibility:**
  It shows how powder moves through a fluid. Presented as a percentage, it is:
  $$I = \frac{Dt - Db}{Dt} \times 100$$
  Where, Dt is the tapped density of the powder and
  Db is the bulk density of the powder.
- **Relationship between % compressibility and flowability:**

S.No	%Compressibility	Flow ability
1.	5-12	Excellent
2.	12-16	Good
3.	18-21	Fair Passable
4.	23-35	Poor
5.	33-38	Very Poor
6.	<40	Very Very Poor

3. RESULT AND DISCUSSION:

3.1 PREFORMULATION STUDIES:

Generate helpful information to the formulator on producing mass-produced, stable, and bioavailable dosage forms; this is the overarching goal of pre-formulation research.

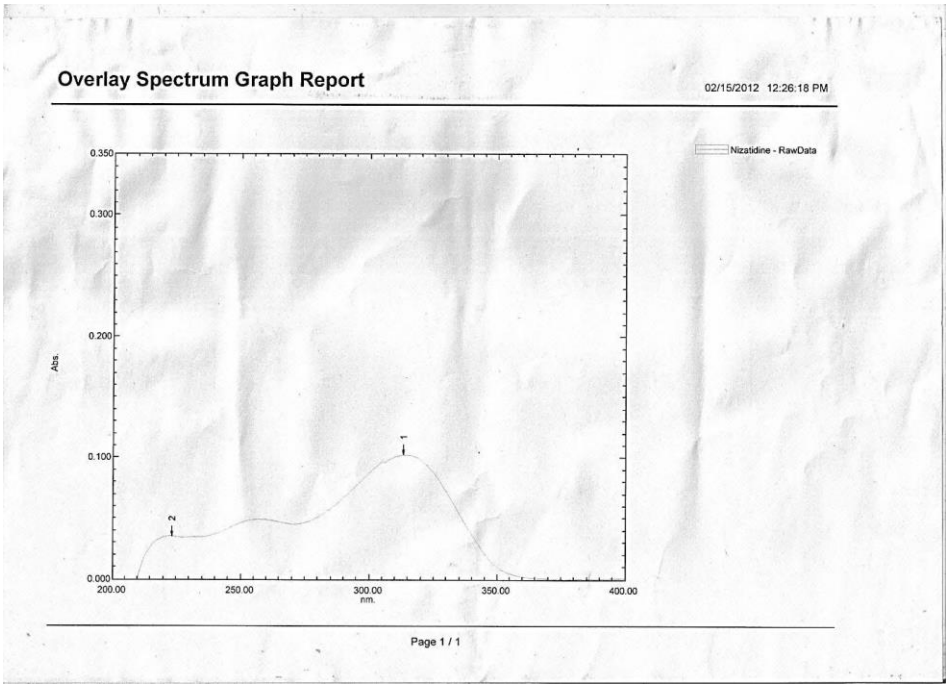
3.2 Omeparazole melting point determination:

The legal limitations are satisfied using the capillary technique, which confirmed that the melting point of omeparazole is 132.70C.

3.3 Finding the maximum analytical wavelength (λmax) of omeparazole:

With water serving as a blank, a UV-Spectrophotometer was used to scan a solution of omeparazole in water from 200 to 400 nm. A strong peak was seen at 315 nm, indicating that the analytical wavelength is 315 nm. As illustrated in Figure 6, the determined value falls within the official monograph's specified range.

Fig .1

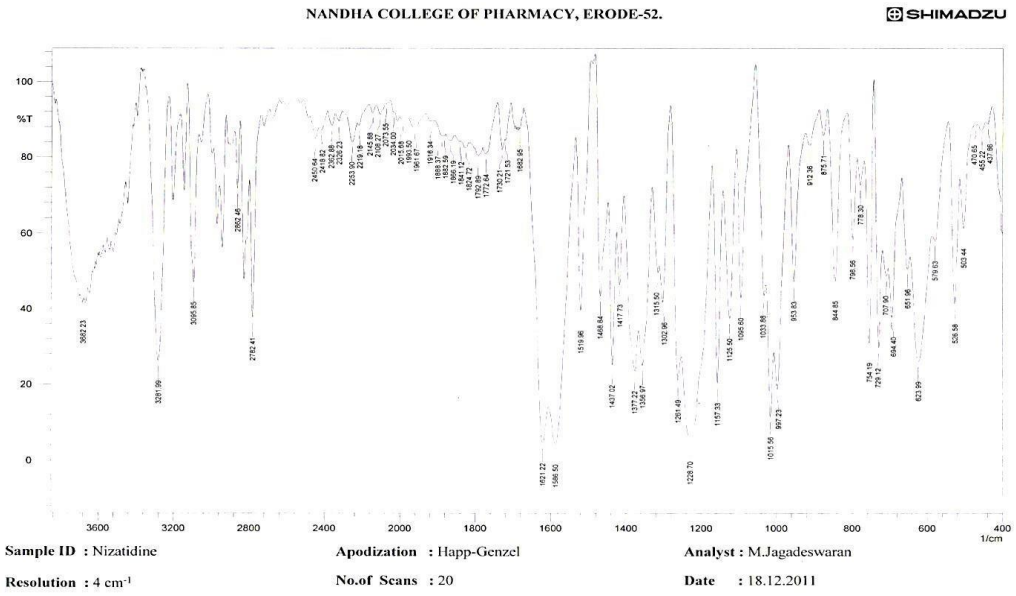


3.4 Physical compatibility studies of drug and excipients:

A visually-based physical compatibility analysis of the medicine and excipients is essential for the development of a stable and effective solid dosage form. Since there was no alteration to the physical description, the research concludes that the medication, polymer, and other excipients were physically compatible.

3.5 Chemical compatibility studies by FTIR:

Figures 2 show the results of an infrared spectrum analysis of the excipients (Omeparazole, polymer, etc.) performed using the KBr pellet technique. Both the pure Omeparazole and its physical combination display all of the typical peaks, suggesting that there is no interaction between the two.



4. CONCLUSION:

The design of omeprazole ODTs aimed at improving patient compliance, especially for those who have difficulty swallowing conventional tablets. The study would conclude that a stable, effective formulation of omeprazole ODTs was successfully developed. The tablets were tested for their disintegration time and dissolution profile. A key conclusion is likely that the tablets dissolved quickly in the mouth, typically within seconds or minutes, allowing for fast onset of action without the need for water. If the study included bioavailability testing, it might conclude that the ODT formulation maintained the bioavailability of omeprazole similar to conventional oral dosage forms. Additionally, the stability of the ODTs would be confirmed, ensuring that the formulation was resistant to degradation under various storage conditions. Since ODTs dissolve in the mouth, taste is an important factor. The conclusion would likely address that taste-masking techniques were effectively incorporated, resulting in a palatable formulation with high patient acceptability.

5. FUTURE PROSPECT:

Although the study may have successfully incorporated basic taste-masking strategies, future work could explore more advanced and cost-effective methods to further enhance the patient experience.

6. REFRENCES:

1. H Seager. Drug-delivery products and the Zydis fast-dissolving dosage. J Pharm Pharmacol 1998;50:375-82.
2. SS Biradar, ST Bhagavati, IJ Kuppuasad. Fast dissolving drug delivery system: a brief overview. Internet J Pharmcol 2006;4:467-76.
3. W Habib, R Khankari, J Hontz. Fast-dissolve drug delivery system. Crit Rev Ther Drug Carrier Syst 2000;17:61-72.
4. SR Parakh, AV Gothoskar. A review of mouth dissolving tablet technologies. J Pharm Pharmacol 1998;50:375-82.
5. BS Kuchekar, AC Badhan, HS Mahajan. Mouth dissolving tablets: a novel drug delivery system. Pharm Times 2003;35:7–9.
6. S Nail, L Galtin. Freeze drying: principles and practices. In: KE Avis, HA Lieberman. Eds. Pharmaceutical dosage forms-parenteral medication, Marcel Dekker Inc., New York; 1993. p. 163-233.
7. R Bogner, F Meghan. Fast dissolving tablets, US Pharmacist; 2005. p. 27.
8. M Gohel, M Patel, R Agarwal, A Amin, R Dave, N Bariya. Formulation design and optimization of mouth dissolving tablets of nimesulide using vacuum drying technique. AAPS PharmSciTech 2004;36:5.
9. M Adel, M Semreen, K Oato. Superdisintegrants for solid dispersion to produce rapidly disintegrating tenoxicam tablets via camphor sublimation. Pharm Technol 2005;13:241-7.
10. J Remon, S Corveleyn. Formulation and production of rapidly disintegrating tablets by lyophilization using hydrochlorothiazide as a model drug. Int J Pharm 1997;152:215–25.

11. G Gregory, J Peach, J Mayna. Article for carrying chemicals. United States Patent 1983;4:371, 516.
12. D Gole, R Levison, J Carbone. Preparation of pharmaceutical and another matrix system by solid-state dissolution. United States Patent 1993;5:215, 756.
13. KG Van Scoik. Solid pharmaceutical dosage in tablet triturates form and method of producing the same. United States Patent 1992;5:882, 667.
14. K Masaki. Intrabuccally disintegrating preparation and production thereof. United States Patent 1995;5:466-4.
15. W Pebley, N Jagar, S Thomnson. Rapidly disintegrating tablets. United States Patent 1994;5:298, 261.