

Development of mouth dissolves tablets of Cinnarizine by Effervescent, Superdisintegrant addition and Sublimation Methods

Saleh Suliman Alsultan^{1*}, Abdullah Saeed Alasmari², Mohammed Ibrahim Abdullah alfayez³, Salamah Nasser Alkhamis⁴, Mohanad Ahmad Alghamdi⁵

^{1,2,3,4,5} Pharmacist at PSMCC, Riyadh KSA

Abstract - As a result of challenges associated with swallowing, there has been a recent uptick in the demand for tablets that may be dissolved in the mouth. This trend has been observed particularly among elderly and juvenile patients. Cinnarizine, an H1-receptor antagonist, is a common medication for treating motion sickness, vomiting, and vertigo. Cinnarizine tablets that dissolve in the mouth were made using effervescent, superdisintegrant addition, and sublimation processes respectively. Since the Superdisintegrant addition method resulted in the quickest disintegration time, it was selected for further study. For the next nine batches, we diluted model drug, carboxymethylcellulose salt, and L-HPC to various concentrations (B1-B9) The range of strengths covered was from 5% to 10%. It was determined how much each formulation varied in weight, how hard it was, how friable it was, how much active ingredient it contained, how long it took to disintegrate in vitro, how long it took to wet in vitro, and how well it dissolved in vitro. The formulation that contained 10% L-HPC exhibited a shorter disintegration time of 25.3 seconds and a shorter wetting time (29.1 seconds). In-vitro dissolving tests demonstrated that the whole dose of medication was released within just six minutes.

Keywords - Mouth dissolving tablets, Cinnarizine, Superdisintegrant, Treatment.

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1. INTRODUCTION

As a result of its convenience, compact size, and ease of manufacture, tablets have become the standard dosage form. However, elderly and young patients have trouble swallowing regular pills, which contributes to low patient compliance. Scientists have created novel medicine delivery technologies like "melt in mouth" or "mouth dissolve" tablets to address this shortcoming. Dissolving or dispersing in the mouth, these pills are a new innovation. Because of their convenient nature (for example, they may be taken without water, at any time of day or night), they are appropriate for use on both young and old patients. They are also appropriate for people with mental illness, those who are bedridden, and folks who are unable to obtain water easily. Tablets are widely used because of their many advantages over other dosage forms. These advantages include higher patient compliance, quicker start of action, greater bioavailability, and superior stability. [1]

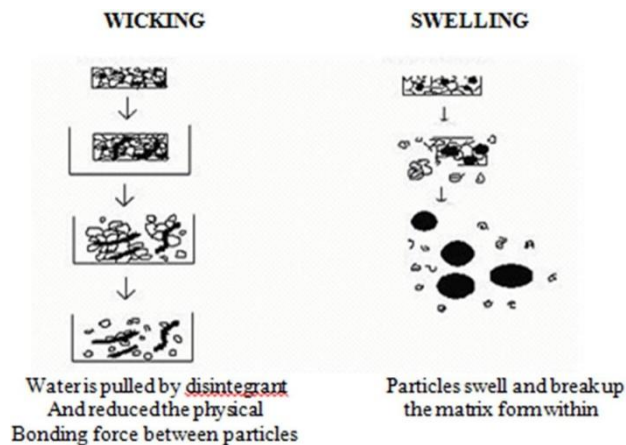
Cardiovascular medicines, analgesics, narcotics, antihistamines, and antibiotics are all possible options for this route of administration. Tablets that dissolve quickly are created using processes including tablet

moulding, spray drying, lyophilization, sublimation, and the inclusion of disintegrants.

In order to help patients of all ages take cinnarizine for conditions like vertigo/disease, Meniere's nausea/vomiting, and motion sickness, researchers set out to create directly compressible orally disintegrating tablets of the drug with sufficient mechanical integrity, content uniformity, and acceptable palatability. When applied to other causes of vestibular dysfunction, it also proves beneficial. Inhibiting calcium channels is how cinnarizine slows down the contractions of vascular smooth muscle cells. Blood viscosity is lowered and erythrocytes are more malleable. It prevents the vestibular system from being stimulated. After taking cinnarizine orally, it is absorbed quickly into the body. Two to four hours after oral administration, the drug reaches its peak plasma concentration, and its half-life in plasma is between three and four hours. It has no flavour and is not soluble in water. It was chosen as a prototypical medicine to serve as a basis for developing orally disintegrating tablets. [2]

1.1 Criteria for tablets that dissolve in the mouth:

- Can be taken orally without the need of water, and they dissolve rapidly in the mouth.
- It needs to be tough enough to endure the stresses of production and subsequent handling.
- Should disintegrate completely, leaving behind no taste or aftertaste in the tongue.
- The degree to which an individual is affected by their surroundings should be relatively minimal (temperature and humidity).
- Tablets should be able to be made with standard processing and packaging machinery. [3]



1.2 The Manufacturing and marketing Factors Involve:

- All pharmaceutical companies, no matter how big or little, need to invest heavily in research and development of innovative drug delivery technologies and in applying such technologies to product development.
- Pharma companies frequently create new and enhanced dosage forms of a medicine as its patent term winds down.
- When a drug is introduced in a novel dosage form, the company gains additional opportunities for market dominance, product differentiation, etc.
- A company's reputation and brand value rise when a product arrives in a new, more convenient form to satisfy the needs of a previously underserved patient group. [4]

2. THE SUPERINTEGRATION MECHANISM

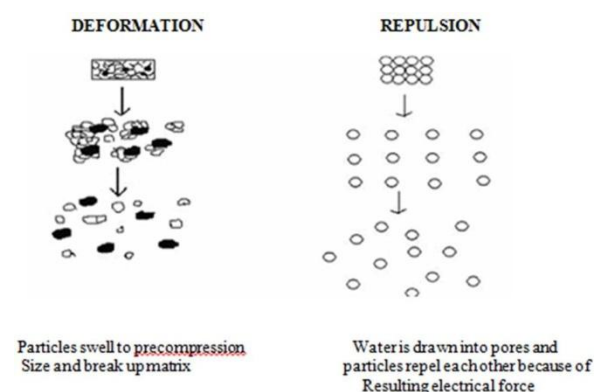
Disintegration of tablets typically occurs via the following four mechanisms:

i. Swelling: Most researchers agree that tablet disintegrating occurs mostly through the tablet's expansion. When there isn't enough swelling force to completely fill the pores of a tablet with a high porosity, the tablet might be difficult to disintegrate. On the other hand, the low-porosity tablet is subjected to a sufficient quantity of swelling force. [5]

ii. Porosity and capillary action: The initial phase in any disintegration process is capillary action. The intermolecular link is weakened and the tablet is broken up into tiny particles when it is placed in an aqueous media that is appropriate for the tablet. The tablet's ability to absorb water is affected both by the hydrophilicity of the medicine or excipient and by the tableting circumstances. By keeping its porous structure and low interfacial tension towards aqueous fluid, the disintegrant facilitates the creation of a hydrophilic network surrounding the drug particles, speeding up the disintegration process. [6]

iii. Due to dissolving particle: The swelling of tablets formulated with nonswellable disintegrants is explained by a different mechanism of disintegrant action. As we now know, the absence of a swelling particle is the root cause of tablet disintegration, Guyot-Hermann postulated a hypothesis of particle repulsion. Water is necessary for the disintegration mechanism that relies on electrostatic repulsion between particles. As the study's authors discovered, wicking plays a more significant role than repulsion. [7]

iv. Due to deformation: When particles are compressed into tablets, they become deformed, but when they come into contact with a watery medium, such water, they return to their original shape. Starch's swelling capability was improved in numerous experiments when the granules were severely deformed during compression. Broken tablets have particles that have grown in size due to distortion. [8]



2.1 Methods for the preparation of mouth dissolving tablets:

Following is a brief overview of some of the most popular recent decades' worth of cutting-edge technologies:

i. Lyophilization or Freeze-Drying: After the product has been frozen, the water is removed by sublimation in a process known as freeze drying. When compared to other solid forms, freeze-dried

items dissolve more quickly in the body. Lyophilization improves the formulation's dissolving properties by giving the bulking agent and, in certain cases, the medication, a glossy amorphous structure. Here we describe a typical production process for MDT utilising this method. The pharmaceutical ingredient is suspended in a polymer or carrier that has been dissolved in water. Blister packs are prefabricated, and the mixture is weighed and placed into the walls. The medication solution or dispersion is frozen by passing the trays containing the blister packs through a liquid nitrogen freezing tunnel. The freeze-drying process is then continued by storing the blister packs in cold storage. The aluminium foil backing is put on a blister-sealing machine after the product has been freeze-dried. At last, the blisters are wrapped and sent on their way. Freeze-drying has been shown to boost bioavailability and improve absorption. [9]

ii. Tablet Molding : There are two basic kinds of moulding processes: the solvent technique and the heat method. The wetted mass is formed by compressing the powder mixture at low pressures in moulded plates using the solvent technique (compression molding). Air drying then eliminates any remaining solvent. The resulting tablets have a more porous structure that speeds up dissolving and are less compact than compressed tablets. Preparing a solution of a medicine, agar, and sugar then pouring the suspension into the blister packing wells, allowing the agar to solidify at room temperature to create a jelly, and finally drying at 300C under vacuum, constitutes the heat moulding process. To what extent can moulded tablets withstand mechanical stress is of significant concern. Increase the tablets' mechanical stability by including binding agents. A further issue with this technique is that it can hide flavours. It is simpler to mass-produce tablets using the moulding method than the lyophilization method. [10]

iii. The Cotton Candy Method: The cotton candy process, sometimes called the candy floss process, employs centrifugation to form a crystalline phase equivalent to that of flossing in order to produce fast-dissolving tablets. Matrix in this technique is made from saccharides or polysaccharides by a shear foam process, which turns them into an amorphous floss. Matrixes can be cured and processed to provide a flowable, compactible, and highly soluble filler. The formation of porous, three-dimensional structures that encapsulate the active ingredients is what causes the rise in surface area. When the product is put in the mouth, it instantly dissolves and spreads out. Flash Dose is a trademark owned by Fuisz Technology for this particular invention. [11]

iv. Sprays-Drying: Hydrolyzed or non-hydrolyzed gelatin was used for the matrix, mannitol was used as a bulking agent, and sodium silicate polyethylene glycol or croscarmellose were used as disintegrants. Incorporating an acid (like citric acid) or

an alkali facilitated the breaking down and dissolving processes (such as sodium bicarbonate). In order to obtain the porous powder, we first spray dried the aforementioned mixture and then compacted it into tablets. As demonstrated in an aqueous solution, the disintegration period of tablets made using this technique is 20 seconds. [12]

v. Sublimation: Sublimation can be used to remove a subliming substance like camphor from crushed tablets, leading to a high porosity as numerous holes form in their stead. The high porosity of the compressed mannitol tablets can be attributed to the presence of many pores formed at the areas where camphor particles had existed before they were sublimated. They dissolve rapidly in the mouth because to the tablets' high porosity (about 30%). (within 15 seconds). Camphor was removed from the dried granules that had been produced using a wet granulation technique by use of a vacuum. Traditional methods include dry granulation, moist granulation, and direct compression. [13]

2.2 Advantages of mouth dissolving tablets:

- Patients who are unable to or should not swallow, such as those with renal failure, or who refuse to swallow, such as those in the paediatric, geriatric, or mental health populations, can get their medications with no effort.
- Patients who are unable to get up from their beds, persons who are always on the go, and those who simply do not have the time to drink water before bed have a lower compliance rate.
- Possessing a pleasant mouthfeel is a The oral dissolving pill is a game-changer in the way people think about taking medication.
- New opportunities for profit can be found in the areas of diversification strategy, brand extensions, management software, promotional exclusivity, and patent life extension.
- Useful when instant relief is needed, including in situations of motion sickness (kinetosis), an allergic reaction, or a cough. [14]

3. OBJECTIVES

- To study development of mouth dissolves tablets of cinnarizine.
- To learn about cinnarizine, superdisintegrant addition, and sublimation.

4. METHODOLOGY

Super disintegrants are used in the manufacturing of mouth dissolving tablets.

The superdisintegrant croscarmellose sodium and L-hydroxyproline, together with croscarmellose sodium and L-hydroxyproline, was utilised in the production of these formulations. Cinnarizine, mannitol, Avicel 102, super disintegrants, aspartame, talc, and magnesium stearate were the only substances that reached the required gramme weight and sieve size (60 #).

4.1 Analyzing a Powder Mixture

i. Bulk Density (Db): The whole mass of the powdered split by the powder's total density is the formula for calculating the bulk powder density. Powder that had been sieved through a No. 20 standard sieve was weighed and then poured into a measuring cylinder, where its original weight was recorded. They referred to this initial amount as the bulk volume. The following formula was then used to derive the bulk density from these measurements. Its value, reported in grammes per millilitre, is

$$Db = M / Vb$$

Powder mass (M) and powder bulk volume (Vb) are entered into the equation.

ii. Tapped Density (Dt): To find the density of a powder, we divide its total mass by its tapped volume. Tapping the powder 750 times yielded a volume reading, which was recorded if there was less than a 2% discrepancy between the measured and tapped volumes. If the percentage is more than 2%, tapping will continue for another 1250 cycles, at which point the total volume tapped will be recorded. Once there was less than a 2% discrepancy in volume between each subsequent reading, tapping stopped. Its value, in grammes per millilitre, is calculated as follows:

$$Dt = M / Vt$$

Powder mass (M) and powder tapped volume (Vt) are used here.

iii. Angle of Repose (q): The funnel was opened so that the powder mixture could fall freely onto the work area below. Measuring the powder cone's diameter and using the data in the following equation allowed us to calculate the angle of repose.

$$\tan (q) = h/r$$

Where h and r stand for the height and radius of the powder cone, respectively.

iv. Carr's index (or) % compressibility: It is a representation of the powder's rheological characteristics. It is a percentage value provided by

$$I = Dt - Db/Dt \times 100$$

Where Dt is the density at the tap and Db is the density at the bulk.

v. The ratio of Hausner: Powder flow difficulty can be inferred indirectly using the Hausner ratio. The following formula was used to arrive at the result.

$$\text{Hausner ratio} = Dt / Db$$

Where Dt and Db stand for the tapped and bulk densities.

4.2 Evaluation of Orally Disintegrating Tablets

i. Friability (F): The Roche friabilator was used to test the tablet's friability. This apparatus rotates a tablet in a plastic container at 25 revolutions per minute while lowering it from a height of 6 inches with each revolution, subjecting it to abrasion and stress. In the friabilator, a preweighed sample of tablets was exposed to 100 rotations. After being wiped off with a clean muslin towel, the tablets were re-weighed. The formula yields friability (F).

$$F = \frac{W_{\text{initial}} - W_{\text{final}}}{W_{\text{initial}}} \times 100$$

ii. Wetting time: A square of double-folded tissue paper was dropped into a Petri dish of water holding 6 millilitres. The number of seconds it took for the tablet to get completely wet after being set on the paper was recorded. By keeping the water at 37 degrees Celsius, the procedure was slightly adjusted. Wetting time is proportional to the amount of time it takes for the pill to dissolve when held still on the tongue.

iii. In-Vitro drug release study: Researchers used a Paddle equipment to determine the rate of Cinnarizine release from a mouth dissolving tablet in vitro. Since the solution needed to be shielded from light, the dissolving apparatus was coated with black polythine. The dissolving test was performed in 37 + 0.50C, 50 rpm 0.1 N HCl. At 2, 4, 6, 8, and 10 minutes, 5 ml samples of the solution were taken out of the dissolving equipment and replaced with new dissolution medium. The percentage of Cinnarizine released was determined.

iv. Assay: After accurately weighing tablets from each lot, the powdered equivalent of 100 mg Cinnarizine was placed into a 100 ml amber coloured volumetric flask, stirred, and 10 ml pipetted out before being diluted to make up the remaining 90 ml. We transferred the standard solution from its original container to a fresh amber volumetric flask and diluted it to 100 ml with a new 10 ml pipette. After filtration, the resultant solution was measured at 253.5 nm to establish the cinnarizine concentration.

v. Fast Dissolving Tablet Stability Testing: The formulation of the pills was shown to be stable in

both conditions after thirty days of testing at room temperature and at forty degrees Celsius. The medication concentration, wetting time, in vitro dissolution rate, and in vitro disintegration time are some of the criteria tested to establish how stable the formulations developed are. The purpose of this examination is to determine the stability of the formulations.

5. RESULTS

5.1 Dissolving tablets containing super disintegrants:

In an effort to develop mouth dissolving pills, crospovidone, croscarmellose sodium, and L-HPC were all evaluated and evaluated. Five, seventy-five, and ten percent of the superdisintegrant concentration were taken. The angle of repose, the Hausner ratio, and the percent compressibility of the powder mix were all measured. After the tablet was manufactured, it underwent testing to determine its physical parameters.

5.2 Examining a Powder Mixture:

i. The angle of repose, denoted by (q):Ingredients including crospovidone, croscarmellose sodium, and L-HPC were tried out in the development of mouth dissolve tablets. Five, seventy-five, and ten percent superdisintegrant solutions were sampled. They tested the powder's compressibility, measured the angle of repose, and calculated the hausner ratio. Physical features, wetting time, in vitro disintegration time, assay, and in vitro drug release were all measured for the manufactured tablet.

ii. Compressibility Index:After doing some math, we found that the compressibility index can be anywhere from 11.86 percent to 19.18 percent. All formulations demonstrated good flow properties except the one with L-HPC 7.5% and 10%.

iii. Hausner ratio:It was discovered that the Hausner ratio fell somewhere in the range of 1.13 to 1.23, and this finding suggested that every formulation had acceptable flow qualities.

5.3 Physical Parameters

i. Weight variation:Because the percentage weight fluctuation was within the IP limitations of 7.5% of the weight, every single tablet that was created (B1 to B9) was successful in passing the weight variation test. It was discovered that the weights of all of the pills were consistent, exhibiting low values of standard deviation. The weight variation test can be passed using the formulation that has been developed.

ii. Thickness:The formulation was tested to a maximum thickness of 2.62 mm. It was determined

that 2.53mm is the bare minimum thickness for this formula. It was determined that 2.58mm is the mean thickness across all formulations.

iii. Friability test:We measured a maximum friability of 0.8% for this formulation. Friability tests showed that a value of 0.65% was required for the formulation to be considered friable at all. All tablet formulations were mechanically stable since the friability percentage was less than 1%.

iv. Drug content:It was determined that the entire formulation had a maximum drug content of 101.05% and a minimum drug content of 98.14%. Both of these figures are expressed as a percentage of the total. The findings fell within the permissible range as outlined by the IP.

v. Disintegration evaluation in vitro:In vitro The time required for disintegration was measured to fall anywhere between 25.3 and 59.4 seconds. The B9 formulation has the quickest disintegration time of all the possible options. Because of its gelling qualities, croscarmellose sodium causes disintegration to take significantly longer in formulations where it is present.

vi. Stability Study:The improved formulation underwent a stability test in accordance with the ICH guidelines for one month at temperatures ranging from 2 to 8 degrees Celsius (for the controlled sample), room temperature, and 40 degrees Celsius. According to the findings, there was not a discernible shift in the tablet's physical or chemical parameters during the course of the study; as a consequence, the formulation was determined to be stable.

Table 1: mouth-dissolving pill formulation using several techniques

Ingredient	Method		
	Effervescen t	Superdisintegrantaddition	Sublimation
Cinnarzine	25	25	25
AvicelPH102	50	60	-
Sodiumbicarbonate	20	-	-
Citricacid	16	-	-
Crospovidone	-	15	-
Camphor	-	-	40
Aspartame	2	2	2
Talc	4	4	4
Mgstearate	2	2	2
Mannitolupto...	200	200	200

Table 2: making mouth-dissolving tablets with several super disintegrants

Ingredient	B1	B2	B3	B4	B5	B6	B7	B8	B9
Cinnarizine	25	25	25	25	25	25	25	25	25
Croscopovidone	10	15	20	-	-	-	-	-	-
Croscarmellose sodium	-	-	-	10	15	20	-	-	-
L-HPC	-	-	-	-	-	-	10	15	20
Avicel102	60	60	60	60	60	60	60	60	60
Aspartame	2	2	2	2	2	2	2	2	2
Talc	4	4	4	4	4	4	4	4	4
Mgstearate	2	2	2	2	2	2	2	2	2
Mannitolupto...	200	200	200	200	200	200	200	200	200

Table 3: The powder blend's evaluation

Batch code	Bulk density	Tapped density	Angle of repose	%compressibility	Hausnerratio
B1	0.58	0.68	25.61	14.71	1.172
B2	0.56	0.67	25.07	16.42	1.196
B3	0.55	0.64	24.68	14.06	1.164
B4	0.53	0.62	24.50	14.52	1.170
B5	0.52	0.59	23.82	11.86	1.135
B6	0.50	0.57	23.49	12.28	1.140
B7	0.58	0.70	30.05	17.14	1.207
B8	0.58	0.71	30.64	18.31	1.224
B9	0.59	0.73	31.45	19.18	1.237

Table 4: Components of an Orally Disintegrating Tablet

Batch code	Weight Variation	Thickness (mm)	Hardness (Kg/cm ²)	Friability (%)	In-Vitro Disin. Time (Sec)	Wetting Time (Sec)	Assay (%)
B1	pass	2.56	2.5	0.73	48.3 ± 1.53	69.8 ± 1.04	98.14
B2	pass	2.57	2.5	0.76	34.0 ± 1.00	35.0 ± 0.95	99.02
B3	pass	2.60	2.5	0.79	28.6 ± 1.22	32.4 ± 1.15	100.51
B4	pass	2.63	2.5	0.74	59.4 ± 2.42	89.0 ± 0.85	98.91
B5	pass	2.65	3.0	0.78	32.6 ± 1.25	66.0 ± 1.35	100.04
B6	pass	2.66	2.5	0.80	36.6 ± 2.12	70.4 ± 1.48	99.86
B7	pass	2.51	3.0	0.69	59.7 ± 2.46	67.8 ± 0.35	98.92
B8	pass	2.52	2.5	0.65	33.5 ± 0.50	41.7 ± 1.45	101.05
B9	pass	2.54	2.5	0.66	25.3 ± 0.58	29.1 ± 1.05	100.34

Table 5: Drug release profiles for batches B1 through B9, in percentages

Cumulative %drug release									
Time (min)	B1	B2	B3	B4	B5	B6	B7	B8	B9
2	52.49	66.50	70.15	46.85	49.19	56.89	50.91	69.53	83.20
4	80.96	86.74	88.94	63.64	67.63	86.39	71.34	88.25	96.02
6	95.36	97.37	99.84	88.96	77.84	99.01	86.91	95.38	99.86
8	97.82	98.93	100.38	98.15	100.21	99.48	97.74	101.00	100.19
10	98.08	99.06	100.50	98.27	100.06	99.67	98.76	101.05	100.17

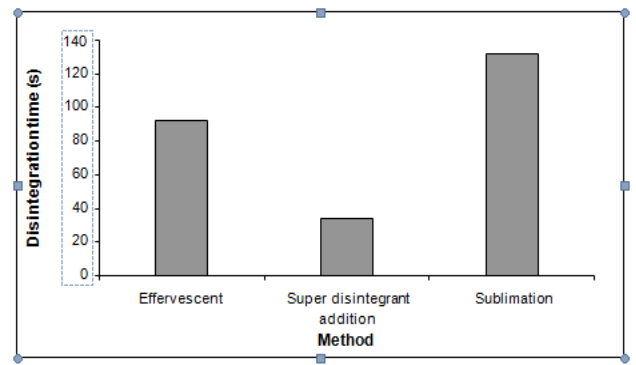


Fig.1: Column graph showing mouth-dissolving tablet disintegration times

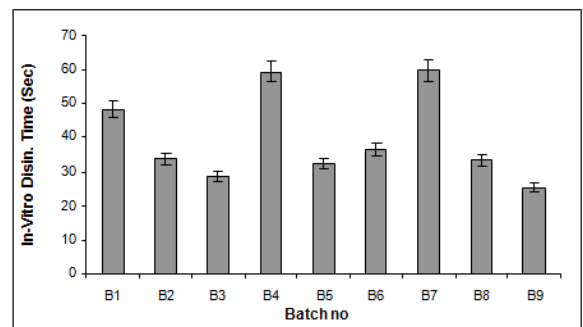


Fig. 2: Disintegration time (Sec) column graph for several batches

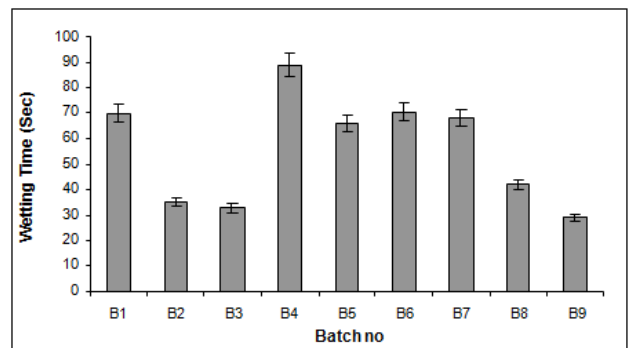


Fig. 3: Column graph showing several batches' wetting times in seconds

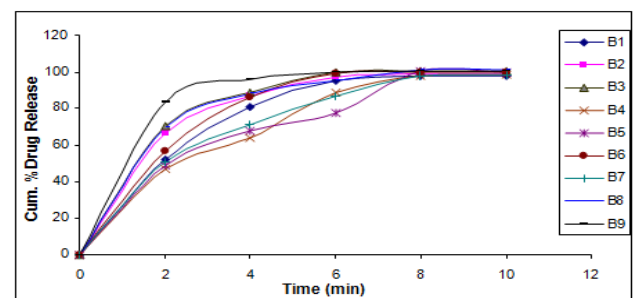


Fig. 4: Cumulative percent medication release profile for lots B1 through B9



After 5 Seconds

After 25 Seconds

Fig. 5: images of in vitro disintegration Duration of Formulation B9's Oral Dissolving Tablet

6. CONCLUSION

Tablets that dissolve in the mouth have seen increased demand over the past decade, particularly among the elderly and young children who have trouble swallowing. As an H1-receptor antagonist, cinnarizine is prescribed often to patients suffering from nausea, vomiting, and dizziness brought on by motion sickness. Effervescent, superdisintegrant addition, and sublimation processes were used to create cinnarizine tablets that dissolve in the mouth. This can be achieved by taking a standard dosage form at a certain dose on a regular basis. Therefore, the medication can be given by several methods and in numerous dose forms. Many medications are given orally. Most medications that are taken orally are swallowed whole, but there are a small number that are designed to dissolve in the mouth. The most common and well-tested method of medicine administration is by mouth. It has a number of advantages over other medication administration methods, including being more benign, simple, convenient, safe, and easy to produce and administer. Children frequently experience difficulties with swallowing since their muscles and nerves are not fully matured.

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Corresponding Author

Saleh Suliman Alsultan*

Pharmacist at PSMMC, Riyadh KSA