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Research Article

Formulation And Characterization Of Sublingual Tablet With Natural Super Disintegrant For The Treamtent Of Anxiety

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ARTICLE INFO

ABSTRACT

In the event of some acute disorders, intervention must begin right away. Therefore, the most promising method of administration for a quicker and more direct absorption of the medicine into the systemic circulation may be sublingual drug delivery. The current study aims to minimize dose frequency, dose amount, enhance patient compliance and minimizing side effect by designing a fast dissolving tablet with natural superdisintegrants which can enhance therapeutic effectiveness as compared to synthetic super disintegrants. Using a flat face 8mm size punch, tablets were manufactured using direct compression. The tablets were then tested for hardness, thickness, weight fluctuation, friability, drug content, and dissolving, and all test results were determined to be within the pharmacopoeial limits. From improved life-cycle management to comfortable dosage for pediatric, young ones, and psychiatric patients with dysphagia, new sublingual technologies serve a wide range of pharmaceutical and patient demands. Being a natural product, it also reduces the possibility of any negative reactions or side effects when treating anxiety.

Keywords: Sublingual route, fast absorption, natural super disintegrants, first-pass metabolism, permeability, bioavailability.

INTRODUCTION

The brain, which is composed of a sizable mass of nerve cells that are covered by the skull, serves as the central nervous system's (CNS) command centre.The Latin term "anxietas" (to choke, throttle, bother, and disturb) is the root of the English word "anxiety," which refers to a range of behavioural, emotional, and cognitive reactions to perceived risk. [1].Anxiety is a typical human feeling. When anxiety is controlled, it can help people respond adaptively and predictably to difficult or stressful situations. When anxiety levels are too high, people become unstable and develop dysfunctional states. When anxiety develops in the absence of a challenge or stress, when its duration or intensity is out of proportion to the challenge or stress, when it causes a great deal of distress, and when it impairs one's ability to function in social, occupational, psychological, biological, or other domains, it is deemed excessive or pathological.

Sighns and symptoms

- Self- consciousness
- Excessive worry
- Sleeping issues
- Irrational fear
- Panic situation
- Self –doubt

Anti-anxiety drugs : An anxiolytic is a medication or other intervention that lowers anxiety (also called an antipanic or anti-anxiety agent). Conversely, anxiogenic drugs have the reverse effect of reducing anxiety[3]. Anisotropic substances or agents can be used to describe any of these categories of psychoactive drugs or

treatments. Numerous recreational substances, such as alcohol (technically called as ethanol), have been shown in studies to be anxiogenic even when they initially induce anxiolysis. Anxiolytic medications have been used to treat anxiety disorders and the associated mental and physical symptoms[4].

SUB-LINGUAL ROUTE OF ADMINISTRATION

The process of administering a drug via mouth is known as oral administration. Because many drugs are meant to have a systemic impact, meaning they travel through the blood stream to different regions of the body, they are taken orally. Typically, sublingual pills are flat, tiny, and just slightly crushed to maintain their softness. To enable the medication to be absorbed, the pills must disintegrate rapidly [5].Because it dissolves in a tiny amount of saliva, the patient must refrain from eating, drinking, smoking, and potentially talking for as long as the tablet is in the mouth beneath the tongue. The aim to provide pharmacological activity as soon as possible gave rise to systemic drug administration via the sublingual route [6]. Sublingual medications have been developed for a wide range of conditions, from mental illness (where patient compliance is critical for treating chronic indications including anxiety, depression, and schizophrenia) to migraines, for which a quick beginning of action is crucial.

Absorption via the mouth cavity therefore avoids passing through metabolism first. The fraction taken through the sublingual blood vessels avoids the hepatic first pass metabolic processes, therefore the sublingual route often results in a speedier start of action than oral tablets. Children sometimes have difficulty swallowing due to immature muscles and neural systems; however, this may be readily remedied with the use of sublingual pills that dissolve quickly [7]

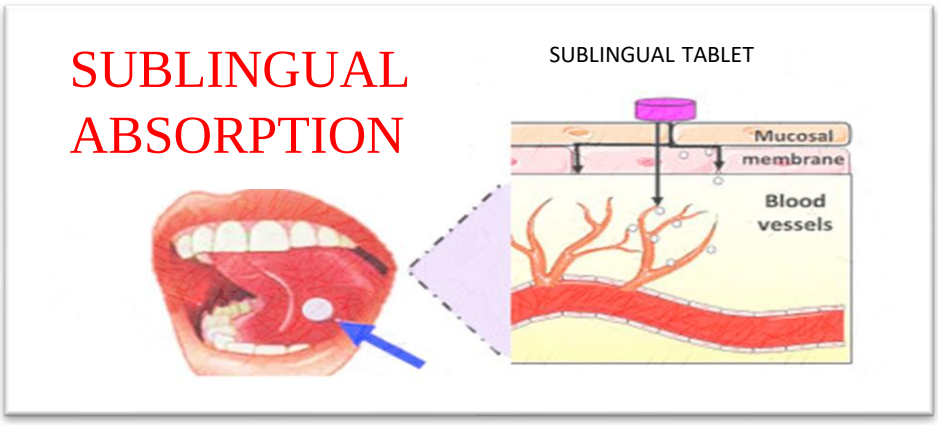


Figure 1: Sublingual absorption

MATERIAL AND METHOD

Propranolol, sodium starch glycolate, Mcc, magnesium steraete, talcum powder, mannitol, sachaline are obtained from dev bhoomi uttarakhand university Dehradun, uttarakhand, and banana powder was purchased from amazon online product. All chemicals were used of analytical grade

Preparation of Sublingual tablet by direct compression method

1. Weigh every ingredient using the amounts shown in Table No. 1.
2. Gather each component into a polybag after running it through sieve #80.
3. For fifteen minutes, combine a determined amount of propranolol, banana peeler, sodium starch glycolate, MCC, mannitol, and sodium saccharine in a polybag.
4. In a mortar and pestle, add the talc and magnesium stearate, and combine for five minutes.
5. Use a multiple rotatory compression machine from B-Tooling to compress the final mix using punches and dies that measure 6 mm in diameter.

Table 1: Composition of different batches of mouth-dissolving tablets of propranolol with comparison between natural and synthetic superdisintegrants

S.no	MATERIAL NAME	F1	F2	F3	F4	F5	F6
1	Propranolol Hcl	30mg	30mg	30mg	30mg	30mg	30mg
2	Sodium starch glycolate	40mg	55mg	70mg	-	-	-
3	Banana powder	-	-	-	40mg	55mg	70mg
4	MCC	80mg	65mg	50mg	80mg	65mg	50mg
5	Magnesium stereate	70mg	70mg	70mg	70mg	70mg	70mg
7	Mannitol	50mg	50mg	50mg	50mg	50mg	50mg
8	Sachaline	30mg	30mg	30mg	30mg	30mg	30mg
9	Total weight	300mg	300mg	300mg	300mg	300mg	300mg

EVALUATION PARAMETRE OF PREPARED SUB-LINGUAL TABLET

Pre-formulation studies:

1. **Bulk density:** The process of crystallization, milling, or formulation can have a significant impact on a compound's bulk density. By using a big funnel to transfer pre-screened grains toward the graduated cylinder, one may measure the weight and volume[8].
2. **Tapped density:** A mechanical tapper equipment is placed with a graduated cylinder carrying a particular mass of granules and is controlled for a predetermined no. of taps until a minimum volume is reached by the powder bed volume.
3. **Carr's index (CI):** The bulk density and tapped density readings are used to calculate Carr's index.
4. **Hausner's ratio**: It displays the powder's flow characteristics. The proportion of the tapped density to the bulk density of the granules or powder.
5. **Angle of repose;** Different angles of friction and response represent how stresses are transferred through a bead and how the bead reacts to applied tension. Pouring the powder over a conical funnel on a level, flat surface and measuring the included angle with the horizontal is how the angle of repose is found.
6. **Moisture content**: Gravimetric analysis was used to ascertain the excipients' moisture content. After the material was evenly spread out over 5 grams on the sample pan, the heating cycle was initiated. By heating the sample, the weight loss was used to quantify the percentage of moisture content.

Experimental method

Melting point determination

After taking a capillary tube, one end was heated to seal it. The medication powder was poured into the capillary tube to a height of 2-3 mm. The melting point device was placed inside the capillary tube, and the temperature was gradually raised. after the medication begins to melt, the temperature was recorded once again, and then again after the drug had entirely melted. [9].

UV Spectroscopy

A 1000µg/ml stock solution was created by weighing and dissolving 50 mg of propranolol powder in 50 millilitres of distilled water. A 10µg/ml dilution was then created using this stock solution. Ddistilled water was used for baseline correction, and the sample was processed in spectrum mode with a wavelength range of 200–400 nm[10].

Calibration curve

With a Shimadzu 1800 UV visible spectrophotometer, distilled water and a 6.8 pH phosphate buffer were used to produce the propranolol calibration curve. A precise 50mg of propranolol powder was weighed and then added to a 50ml volumetric flask with distilled water to create a 1000µg/ml propranolol stock solution. [11].

In vitro Dissolution

Turn the electric board's mains on. Heater knob for temperature adjustment and maintenance. Keep the water in the water bath at the correct level. Fill the dissolving vessel with 900 ml of buffer, then set the temperature between 36.5 and 37.5 ^{o}C. The lower edge of the blade is 23–27 mm from the interior of the vessel's bottom, and the shaft is positioned so that its axis is within 2 mm of the vessel's axis. Lower the paddle within the boat. In the vessel, place the tablet. Turn the device on right away and run it for 30 minutes at 50 rpm. Every five minutes, take five millilitres of the sample and replace it with the same volume of dissolving media. Utilising Whattman filter paper, filter the samples. Make the necessary dilutions and use a UV spectrophotometer set to analyse the samples at λmax 292 nm. Find the drug's concentration and release percentage. Turn off the apparatus's main and heating [12].

RESULT AND DISSCUSSION

A sublingual propranolol pill was created. For the sublingual tablet formulations F1 through F3, six batches of artificial superdisintegrants such as sodium starch glycolate were made, whereas the formulations F4 through F6 used natural superdisintegrants, such as banana powder. The desired outcome was obtained by using the direct compression approach. Every formulation was put through an assessment process.

The weight range of the tablets was 300 mg. Out of all the formulations, formulation F2's taped density was the greatest (table 3). Friability readings for each pill ranged from 0.5 to 0.8. The pharmacopoeial standards for the weight variation and drug content uniformity tests were met by all manufactured tablets (batch F1 to F6). Table 3 displays the results of the test, hardness, friability, disintegration time, and wetting time.

The pills' average hardness, as determined by a hardness test, ranged from 2.8 to 3.9 kg/cm2. All formulas had a percentage of friability less than 1%, which suggests that the friability is within the allowed bounds. Batch F5, made with natural superdisintegrants such as banana powder, had the lowest disintegration time of all the batches, with a disintegration time of 53.67±2.309 s. The batch F5 has the lowest wetting time of all the batches in Table 4 at 28.66±0.577 s.

TABLE 2: Evaluation parameter of capillary property of powder (drug excipient mixture)

Characterization	F_1	F_2	F_3	F_4	F_5	F_6
Bulk Density	0.105	0.100	0.96	0.105	0.100	0.120
Tapped Density	0.117	0.123	0.117	0.117	0.117	0.111
Carr's index	14.25	20.00	18.80	10.25	14.76	15.49
Hausner's ratio	0.18	1.35	1.20	1.14	1.17	1.11
Angle of repose	27.92	26.66	28.36	27.09	25.92	29.63

TABLE 3: Evaluation of physio-chemical properties of sub-lingual tablet

Batch	Hardness(kg/cm)±SD	Friability(%)±SD	Thickness(mm)±SD	Weight varation(mg)±SD
F_1	3.843±0.051	0.843±0.0052	1.9±0.196	128.33±2.081
F_2	3.9±0.00	0.726±0.0155	1.63±0.047	116.33±0.577
F_3	3.66±0.057	0.863±0.0125	1.83±0.125	119.53±1.327
F_4	3.76±0.185	0.856±0.0157	1.79±0.115	114.16±2.01
F_5	3.46±0.059	0.683±0.015	1.83±0.185	111.60±1.134
F_6	2.833±0.057	0.580±0.010	2.7±0.099	123±3.04

TABLE 4: Other Parameters

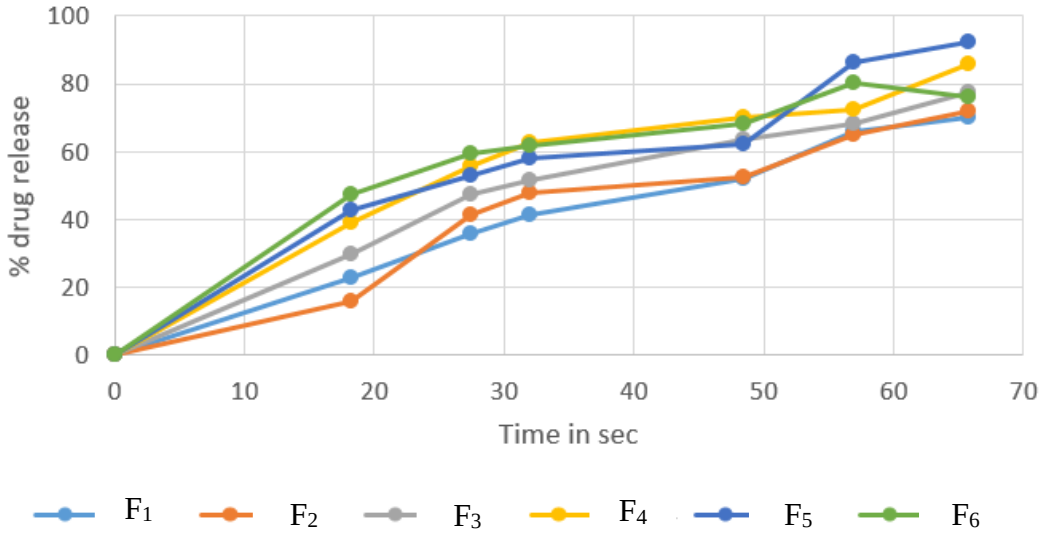
Batch	Drug content uniformity	Water absorption ratio	Wetting time (sec)	Disintegration time (sec)
F_1	91.33±2.816	51±2.445	44.32±4.021	105±6.92
F_2	88.66±1.5773	48.33±0.577	32±3.505	78.66±3.214
F_3	93.66±3.285	43.66±4.173	52.31±1.527	62.66±1.527
F4	95±3.6085	49±3.08	36±4.682	65±3.01
F_5	98.33±0.573	40±1	28.66±0.557	53.67±2.309
F_6	96±2.635	42.33±2.309	32.33±2.596	79±3.604

Optimization of formulation:

In comparison to previous formulations, Formulation F5 demonstrated superior performance in terms of drug content homogeneity, with a minimal disintegration time of 53.66±2.309 and a wetting time of 28.66±0.577. Based on the previously mentioned characteristics, additional testing including UV, FTIR, and drug release were performed on the optimised formulation (F5).

Figure 2: Prepared sublingual formulation (F5)

In vitro drug release study



CONCLUSION

The present work aimed to develop a fast-dissolving propranolol tablet by using natural super disintegrants, such as banana powder, to accelerate the release of medicine. In this work, we created and effectively tested multiple batches of propranolol fast-dissolving tablets by varying the sodium starch glycolate and banana produce through direct compression and by examining their physical properties, drug release rate, and other quality attributes.

In conclusion, the fast-dissolving propranolol pills injected with novel superdisintegrants are showing promising outcomes. The time required for breakdown was greatly reduced by the formulation F5 including banana powder, allowing for rapid pharmaceutical release and dissolution. The results suggest that the F5 formulation tablet has a great deal of potential to improve an individual's cooperation, particularly for those who have trouble swallowing regular tablets. Being a natural product, it also reduces the possibility of any negative reactions or side effects when treating anxiety.

The concepts underlying the development of the propranolol rapid dissolving tablet offer a practical, workable means of accomplishing the targeted objectives of speedier breakdown and solubility difficulties.

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