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Formulation and Evaluation of Mouth Dissolving Tablets

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Abstract

To improve patient compliance, Mouth Dissolving Tablets (MDT's) have emerged as an alternative to conventional oral dosage forms. Due to declaim in swallowing ability with age, elderly patients complain that it is difficult for them to administer some currently used dosage forms such as tablets and capsules. MDT's are solid dosage forms that dissolve or disintegrate rapidly in the oral cavity, resulting in solution suspension without need of water. Absorption starts from mouth. The main objective of this work is to formulate and evaluate Domperidone MDT's. It acts as an ant emetic used in the treatment of motion sickness. Different batches of tablets were prepared using higher and lower concentrations of superdisintegrants like croscarmellose sodium, crospovidone (C.P), sodium starch glycolate (SSG), while MCC was used as diluents. Tablets were prepared by slugging method. Different evaluations tests like Hardness, Friability, Wetting and disintegration times, % drug release were performed. Tablets containing along with crospovidone were disintegrate rapidly below 20sec and % drug release is 99% at 4th minute. Tablets with added patient benefits and increased consumer satisfaction.

Keywords: Formulation, Evaluation of Domperidone, Mouth Dissolving Tablets.

Introduction

The oral route of administration is the most important method of administering drugs for systemic effects. The most popular dosage forms being tablets and capsules, one important drawback of the dosage forms however is the difficulty to swallow. Dysphasia or difficulty in swallowing is seen to afflict nearly 35% of the general population. This disorder is also associated with number of medical conditions including stroke, Parkinson' s disease, AIDS, head and neck radiation therapy and other neurological disorders including cerebral palsy. Recent advances in Novel Drug Delivery System aim to enhance safety and efficacy of drug

molecule by formulating a convenient dosage form for better patient compliance. One such approach is MDT'S Domperidone, prepared by dry granulation method.

Orally disintegrating tablets contain a wide variety of pharmaceutical actives covering many therapeutic categories, and can be particularly good applications for pediatric and geriatric treatments. The time for disintegration of orally disintegrating tablets is generally considered to be less than one minute, although patients can experience actual oral disintegration times that typically range from 5-30 seconds. Orally disintegrating tablets are characterized by high porosity, low density, and low hardness. When administered, an in-situ suspension is created in the oral cavity as the tablet disintegrates and is subsequently swallowed. Nonetheless, orally disintegrating tablets have gained acceptance and market share, and have achieved reputable status amongst product life cycle management strategies

Materials and Methods

Formulation Designing

2^{nd} factorial design technique was used for formulation designing. In this "2" is factor i.e. combination of two super- disintegrants at a time and "n" indicates level i.e. higher and lower concentration. Twelve formulations were designed. Sodium starch glycolate was used in concentration of 2% and 8%, croscarmellose sodium 1% and 3%, crospovidone 2% and 5%, MCC was used as diluents.

Formulation composition-Table-I

S.No	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
1	Domperidone	10	10	10	10	10	10	10	10	10	10	10	10
2	Na starch glycolate	16	16	4	4	16	16	4	4	-	-	-	-
3	Croscarmellose sodium	6	2	6	2	-	-	-	-	6	2	6	2
4	Crospovidone	-	-	-	-	10	4	10	4	10	4	10	4
5	Mannitol	20	20	20	20	20	20	20	20	20	20	20	20
6	Micro. Cry. (Avicel)	142	146	154	158	138	144	150	156	148	154	152	158
7	Mg stearate	1	1	1	1	1	1	1	1	1	1	1	1
8	Aspartame	1	1	1	1	1	1	1	1	1	1	1	1
9	flavor	4	4	4	4	4	4	4	4	4	4	4	4

Evaluation of tablets

Weight variation:

Twenty tablets were selected at random and average weight was determined. Then individual tablets were weighted and the individual weight was compared with an average weight. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in table and none deviate by more than twice that percentage.

Hardness:
This is to force required to break a tablet in diametric compression. Hardness of the tablets is determined by stock's Monsanto hardness tester which consists of a barrel with a compressible spring. The painter moving along the gauze in the barrel at which the tablet fractures

Friability:
This test is performed to evaluate the ability to withstand abrasion in packing, handling and transporting. Twenty pre weighed tablets will be rotated at 25rpm for 4 minutes, then reweighed after removal of fines (using no 60 mesh screen), and the percentage weight loss was calculated accordingly.

Tablet size and Thickness
The size and thickness of the tablets were measured by using Vernier Caliperse scale

Wetting time:
This test is especially meant for MDT's A piece of tissue paper (10cm diameter folded twice will be placed in small Petridis containing 6 ml of simulated saliva pH-9, a tablet will put on the paper, and the time for complete welting was measured

Water absorption ratio:
A piece of tissue paper folded twice was placed in a small Petri dish containing 6ml of water. A tablet was put on the paper and the time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio R, was determined using following equation,

$$R = 100X W_a - W_b / W_b$$

Where W_a = weight of tablet after absorption
W_b = weight of tablet before absorption

***In vitro* dispersion time:**
It will measure by dropping a tablet in a measuring cylinder containing 6ml of pH 6.8 (simulated saliva fluid). In – vitro dispersion time was measured.

Disintegration Time:
For this purpose, a Petridis (10cm diameter), filled with 6ml of 6.8 P^h buffer, will taken and then randomly selected tablet will be carefully put in the centre of the Petri dish and the time for the tablet to completely disintegrate into fine particles was noted.

Dissolution study:
This was done by USP type II dissolution apparatus is used. For this paddle was used. The speed of the paddle was 100rpm. The dissolution medium was 250ml of 0.1N Hydrochloric acid at a temperature of 22^0c. The time of sampling was every 30sec up to 5mts and final sample was taken at 10^{th} minute. 5ml of sample was withdrawn and an equal amount of 0.1NHcl was replaced to maintain sink conditions, and directly analyzed the samples by using U.V Spectro photometer without any dilution. Concentration of the drug was calculated from standard

equation obtained from standard curve. Cumulative percentage drug release and percentage drug unreleased was calculated and respective graphs were plotted.

Results

Tablets were obtained of uniform weight due to uniform die fill, with acceptable variation as per I.P. specifications, i.e. below 7.5%. Hardness of the tablets for each formulation was 2-3 Kg/cm^2. Friability below 1%was an indication of good mechanical resistance of the tablets. Water absorption ratio, which is important criteria for understanding the capacity of disintegrates to swell in presence of little amount of water, was calculated. It was above tablet weight i.e. above 200mg. In – vitro dispersion time was less for formulations containing crospovidone compare to other super – disintegrates. Drug release was found to be 99% at 4th minute. While conventional marketed tablet require more time for same amount of drug to be released.

Evaluation of Tablets-Table-II

S.No	Test	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
1	Wt.variation	4.5	5	4	4.5	5.1	4.1	5.5	4.1	3	6	3.5	3
2	Hardness	3.1	3.8	2.3	3.8	3.1	2.3	3	3	2.1	3.1	3.1	3.1
3	Friability	0.6	0.7	0.6	0.8	0.8	0.6	0.8	0.5	0.6	0.8	0.8	0.6
4	Thickness	4.3	4.3	4.3	4.3	5	4.9	5	5	5.2	5	5.1	5
5	Wetting time	120	60	60	180	20	25	28	26	15	15	18	15
6	Water absorption ratio	198	197	206	132	222	233	178	179	202	211	218	179
7	Disintegration time(sec)	78	122	16	180	12	18	17	20	12	10	10	10
8	In–vitro dispersion time(sec)	76	120	14	178	14	16	15	18	10	13	10	19
9	Diameter(cm)	1	1	1	1	1	1	1	1	1	1	1	1
10	%drug release	75	76	88	51	115	79	81	60	92	99	97	82

Discussion

Tablets were evaluated for weight variation, hardness, friability, in – vitro dispersion time and dissolution study. Tablets were having uniform weight. Hardness and friability data indicates good mechanical resistance of the tablets. Formulations containing Crospovidone shows better results. Super –disintegrates were used in various combinations at higher and lower concentration. At lower level also excellent disintegration time is obtained. Hence there is no need to use higher concentration. Mannitol, Aspartame and flavor enhance the organoleptic properties.

Conclusion

Formulations without crospovidone were showing higher disintegration time. Formulations containing combination of croscarmellose sodium and crospovidone shows lower disintegration timings i.e. below 20sec, higher water absorption ratio and 99% drug release was found at 4th minute compare to formulations containing combination of sodium starch glycolate and crospovidone, except formulation containing both higher concentration of SSG and C.P. Final conclusion is formulations 5, 10 and 11 showing excellent results i.e. lower disintegration, wetting timings and 99% drug release was found at 4th minute.

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