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COMPARISON OF DIFFERENT SUPERDISINTEGRANTS IN DESIGNING OF MOUTH DISSOLVING TABLETS OF DOMPERIDONE

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ABSTRACT

This research involves preparation of mouth dissolving tablets of of Domperidone by direct compression method using various concentrations of superdisintegrants sodium starch glycolate, croscarmellose and crospovidone (D1 – D9). The tablets were evaluated for parameters like thickness, hardness, friability, *In vitro* & *In vivo* disintegration time, wetting time, water absorption ratio, % drug content and *In vitro* drug release studies. Based on the results, formulation containing 6% superdisintegrants in combination (CCS, CP & SSG) (D-2) was identified as ideal and better formulation among all formulations developed for Domperidone Maleate tablets. *In vitro* release of optimized formulation of Domperidone Maleate Mouth dissolving tablets of D-2 was found to be 99.43% drug release within 10minutes and *in-vitro* disintegration time being ranges between 40 and 42sec. The final optimized formulation (D-2) was compared with marketed product of Domperidone Maleate tablets (DOMSTAL-MT) which shows 94.22% drug release in 10 minutes. It means the prepared formulation show quite satisfactory release with compared to Marketed Product.

Introduction:

Drugs are rarely administered in their original pure state due to various issues like stability, proper dose strength, etc. They are administered in various dosage forms after converting it into a suitable stable formulation [1]. The aim of dosage form is to administer a drug at a therapeutic concentration to a particular site of action for a specified period of time [2]. Oral routes of drug administration are widely used up to 50-60% of total dosage forms [3]. Several orally administered drugs have a less bioavailability due to their poor water solubility. In Biopharmaceutics classification system, drugs with decreased aqueous or water solubility, slow dissolution rate and increased membrane permeability are categorized as Class II drug [4].

Since for BCS class II drugs, rate determining step is release of drug from the dosage form and its solubility in the gastric fluid, so increasing the solubility leads to increases the bioavailability for BCS class II drugs

[5,6,7,8,9]. Solid dispersion is one of the many techniques available to enhance drug dissolution and bioavailability of poorly water-soluble drugs. Further, such formulations can be dispensed in the form of fast dissolving tablets which disintegrate and/or dissolve rapidly in saliva; thus may help in improving the bioavailability of such drugs.

When the solid dispersion comes in contact with the aqueous medium, the inert carrier or polymer dissolves quickly thereby releasing the drug, the increased surface area produces a higher dissolution rate thus increasing the bioavailability of the poorly soluble drug. Vomiting is the common problem for all the age groups. Domperidone, an antiemetic and prokinetic is one of the effectively used in vomiting / motion sickness, having less side effects, with half-life of 7.5 hours but poorly soluble in water and hence less bioavailable [10].

The purpose of this study is to prepare mouth dissolving tablets of Domperidone, an antiemetic drug, by using different superdisintegrants. The superdisintegrants will use in this study are croscarmellose sodium, sodium starch glycolate, crospovidone and Micro-crystalline Cellulose. Tablets will be prepared by direct compression Method and will be evaluated for uniformity of weight, thickness, hardness, friability, disintegration time (DT) and dissolution study. The effect of different superdisintegrants used in tablet formulation will be compared.

2. Materials & Methods:

2.1. Materials. Domperidone (API), Croscarmellose Sodium, Crospovidone, Mannitol, Aspartame, Microcrystalline Cellulose was obtained as a gift sample from Wockhardt Research Centre, Aurangabad, Maharashtra, India. Talc, Magnesium Stearate, Lactose were procured from R.S. Enterprises, Jaipur, India manufactured by Central Drug House (P) Ltd – CDH, New Delhi, India. All chemicals used were of analytical grade.

2.2 Methods:

Preparation of solid dispersions of Domperidone:

Solid dispersions (SDs) of Domperidone (DOM) prepared by fusion method with polymers PEG (4000 and 6000) and PVP (K30 and K90) in drug to polymer ratio 1:4 used for preparing mouth dissolving tablets [11,12].

Preparation of Mouth Dissolving Tablets of Domperidone Solid Dispersion by Direct Compression Method

Nine MDT formulations each weighing 200 mg, were prepared by using constant amount(10mg) of Domperidone Maleate, along with a mixture of Croscarmellose Sodium, Crospovidone, Sodium starch Glycolate at different concentrations viz. 3% and 6% as these superdisintegrants work best in between range of 2% to 8%. Batches were prepared using 3% of Superdisintegrant alone & in combination as well as 6% of Superdisintegrant alone & in combination.

Powdered blends, each weighing 200 mg, were then directly compressed using a single punch tablet machine equipped with convex shaped punches with a die diameter of 10 mm. Machine settings were adjusted to get the desired hardness value, which gives an intact tablet. Composition of the batches prepared is shown in Table 1.

Table 1: Composition and codes of SD P414 mouth dissolving tablets

Ingredient (mg)	Formulation Codes								
	D1	D2	D3	D4	D5	D6	D7	D8	D9
Domperidone Maleate	10	10	10	10	10	10	10	10	10
Croscarmellose Sodium	2	4	6	-	-	12	-	-	-
Sodium Starch Glycolate	2	4	-	6	-	-	12	-	-
Crospovidone	2	4	-	-	6	-	-	12	-
Mannitol	80	80	80	80	80	80	80	80	80
Talc	5	5	5	5	5	5	5	5	5
Magnesium Stearate	5	5	5	5	5	5	5	5	5
Microcrystalline Cellulose	30	30	30	30	30	30	30	30	30
Lactose q.s.	64	58	64	64	64	58	58	58	70
Total Weight (mg)	200	200	200	200	200	200	200	200	200

3. Evaluation of Powder Blends: All formulation powder bland batches were evaluated for precompression studies viz. angle of repose, bulk density, tapped density, Carr's consolidation index, and Hausner's ratio as per the official methods [13, 14, 15].

4. Evaluation of Compressed Tablets

4.1 Tablet Thickness:

From each batch ten tablets were taken of and their thickness was recorded using Eureka Thickness Tester. The data is shown in Table 5.

4.2 Hardness:

Hardness of the MDT of each batch was determined using Monsanto hardness tester. It is expressed in kg/cm^2. The data is shown in Table 5.

4.3 Weight Variation:

All the batches of compressed MDT's were subjected to weight variation test, as per IP-2010 [16]. Twenty tablets were taken and weighted individually; their average weight was calculated and compared with the individual tablet weight to notice the variation in tablet weights. The data is shown in Table 5.

4.4 Friability:

Friability of tablets was determined using Roche friabilator. Sample of 20 pre-weighed MDTs were placed in a friabilator and revolve at a speed of 25 rpm for 4 min [17]. Now dust removed from the tablets, weighed again, and percentage weight loss (friability) was calculated.

$$\% \text{ Friability} = \{1 - \frac{Wo}{W}\} \times 100 \quad \text{.....Eq.1}$$

Where, W_0 is initial weight of the tablets before the test and W is the weight of the tablets after test. Results are presented in Table 5.

4.5 Wetting Time:

Five circular tissue papers were placed in a petridish of 10 cm diameter. Ten milliliters of phosphate buffer pH 6.8 containing a water-soluble dye (Amaranth), was added to the petridish to check complete wetting of the tablet surface. A tablet was cautiously placed on the surface of the tissue paper in the petridish containing dye solution at 25°C and wetting time was noted using a stopwatch as the time required for dye solution to reach the upper surface of the tablets and to completely wet. These results were carried out in repetition of three [18,19]. The data is shown in Table 5.

4.6 *In vitro* Disintegration Test [20,21]:

Bi et al. recommended the use of a modified dissolution apparatus (a paddle method), in place of the conventional disintegration apparatus [20]. The disintegration time of MDTs is determined by means of the disintegration test for conventional tablets that is described in the official monographs.

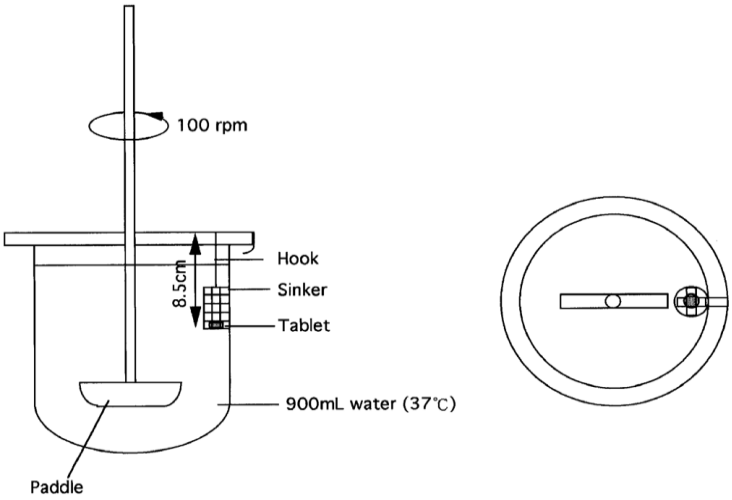

FIGURE 1: MODIFIED DISSOLUTION APPARATUS FOR DISINTEGRATION OF MDT'S [20]

In this study, 900 ml of phosphate buffer pH 6.8 maintained at 37°C was used as the disintegration fluid and a paddle at 100 rpm used as stirring element. Disintegration time was noted when the tablet disintegrated and passed completely through the screen of the sinker (height 3–3.5 mm, width 3.5–4 mm and submersed at a depth of 8.5 cm from the top with the help of a hook).

4.7 Content Uniformity [22]:

Randomly selected twenty tablets from each trial batch were weighed and then powdered in a glass mortar with pestle. The weight equivalent to 10 mg of powdered DOM was taken and dissolved in 10 ml of methanol in volumetric flask. The volume was then adjusted to 100 ml with phosphate buffer pH 6.8. An aliquot of 2.5 ml of the above solution was taken and diluted to 10 ml with phosphate buffer pH 6.8 in separate volumetric flask. The absorbance of above sample was determined spectrophotometrically at 284 nm and drug content was determined using calibration curve. The mean value and standard deviation of all the formulations were calculated.

% Drug Content = Sample Absorbance/ Standard Absorbance x 100.....**Eq.2**

4.8 *In vitro* Release study [23,24]:

The *in vitro* release studies of all the formulations were carried out using USP type II dissolution test apparatus. The tablets were placed in dissolution bowls containing 900 ml of phosphate buffer pH 6.8

maintained at 37ºC ± 0.5 and stirred at 50 rpm. Samples (5 ml) were collected by manual programming at different time intervals (1, 2, 4, 6, 8, 10, 15 min) and replaced with fresh dissolution medium. The absorbance was determined spectrophotometrically at 284 nm. Comparison of dissolution profiles were constructed as shown in fig. 2 to 5. Cumulative drug release was calculated on the basis of mean amount of DOM present in the respective tablet by the formula:

$$\text{Amount released (mg)} = \frac{\text{Concentration} \times \text{Bath volume} \times \text{Dilution factor}}{1000} \quad \textbf{.....Eq.3}$$

$$\text{Percent drug release (PDR)} = \frac{\text{Amount released}}{\text{Drug content}} \times 100 \quad \textbf{.....Eq.4}$$

5. Result & Discussion:

5.1 Pre-compression Evaluation:

The results of bulk density and tapped density ranged from 0.416 to 0.441 and 0.501 to 0.527 respectively. The results of angle of repose (22.62 to 29.36) indicated good flow properties which were further supported by Carr's index (14.84 to 18.82). Results are shown in table.

5.2 Post-compression Evaluation:

Average tablet thickness (Table No. 2) was found to be consistent throughout the batch. Tablet thickness ranges between 2.01mm to 2.05mm. As these tablets are rapidly disintegrating. Tablet hardness ranges between 2.23 kg/cm^2 to 2.69 kg/cm^2. Uniformity of weight of the MDTs was assessed and the average weight for all formulations was found to be between 198-203 mg which was within in the prescribed limits i.e. ±7.5% (185 to 215 mg).

The wetting time in all the formulation was very good. It ranges between 33 to 43 seconds which is depend on the concentration of superdisintegrants in the tablets.

The friability of all formulations was found to be less than 1.0%. Disintegration time of prepared MDTs was in the range of 25-49 seconds. As the concentration of superdisintegrants in the formulations was increased the disintegration time was found to decrease. Based on the results, formulation containing 6% superdisintegrants in combination (CCS, CP & SSG) (D-2) was identified as ideal and better formulation among all formulations developed for Domperidone Maleate tablets.. Drug content of all the formulations was found to be within the limits.

All the nine formulations were subjected for the in vitro dissolution studies using tablet dissolution tester USP type II. The samples were withdrawn at different time intervals (1, 2, 4, 6, 8, 10 & 15min) and analyzed at 284nm. Cumulative drug release and cumulative % drug retained were calculated on the basis of mean amount of Domperidone present in the respective tablet.

The results obtained in the in vitro drug release for the formulations D1 to D9 & marketed product Domstal-MT is tabulated in Table No. 2 & 3 & shown in Fig. The rapid drug dissolution was observed in D2, 99.43% in just 10 minutes, this might be due to fast breakdown of particles and rapid absorption of drug. The drug release was completely achieved in a shorter duration of time. In all the formulations the drug release was nearer to 100% within 15 minutes.

Table 2: Evaluation of Post-compression/Tablet parameters

Form. Code	Uniformity of Thickness (mm) (n =10)	Diameter (mm) (n = 3)	Hardness (kg/cm^2) (n=3)	Weight Variation(mg) (n = 20)	Wetting time (s) (n=5)	Drug Content Uniformity (n = 10) (%)
D1	2.04 ± 0.02	10.02 ± 0.01	2.69 ± 0.02	202 ± 3.34	35-38	96.56
D2	2.02 ± 0.01	10.05 ± 0.02	2.25 ± 0.03	201 ± 2.60	37-40	99.71
D3	2.03 ± 0.01	10.00 ± 0.01	2.47 ± 0.01	203 ± 3.70	33-35	95.04
D4	2.01 ± 0.03	10.04 ± 0.01	2.53 ± 0.03	202 ± 2.95	40-42	98.85
D5	2.01 ± 0.02	10.02 ± 0.01	2.29 ± 0.01	204 ± 3.67	36-39	102.29
D6	2.00 ± 0.06	10.03 ± 0.02	2.45 ± 0.04	201 ± 3.12	32-35	99.62
D7	2.02 ± 0.04	10.03 ± 0.03	2.23 ± 0.02	200 ± 2.15	37-39	98.47
D8	2.03 ± 0.02	10.04 ± 0.01	2.62 ± 0.03	202 ± 1.82	34-36	97.33
D9	2.05 ± 0.01	10.01 ± 0.03	2.51 ± 0.02	201 ± 2.16	40-43	99.24

Table 3: The *in vitro* drug release of various batches of DOMPERIDONE formulations

Time (mins)	Formulation Codes									
	D_1	D_2	D_3	D_4	D_5	D_6	D_7	D_8	D_9	DS
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1	38.45	45.82	25.77	43.36	35.18	44.59	35.59	48.27	24.55	42.55
2	61.17	71.03	42.28	62.42	58.70	68.57	64.83	61.63	41.45	57.10
4	76.23	79.19	61.33	80.77	77.84	74.67	74.60	73.84	61.32	63.55
6	84.84	84.54	79.26	84.49	84.00	87.36	76.65	80.38	74.34	71.27
8	92.26	95.64	87.47	90.68	92.23	92.34	87.71	90.64	78.43	86.79
10	94.40	99.43	92.86	92.40	93.96	97.34	95.14	98.91	80.50	94.22
15	99.41	99.98	96.23	96.99	95.29	98.69	97.30	99.85	85.85	98.01

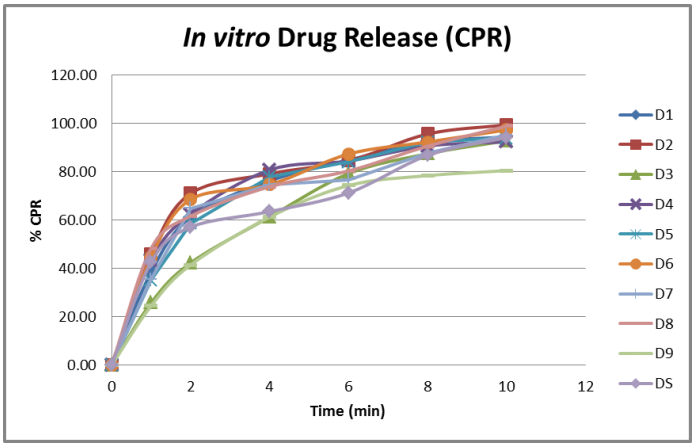

Fig. 2: Comparison of *in vitro* drug release of all prepared formulations (D1 to D9) with marketed product Domstal-MT

6. Conclusion

Mouth dissolving tablets of Domperidone were formulated using different super disintegrants. Domperidone was selected for the research work, due to less central nervous system (CNS) side-effects and better pharmacokinetic properties (low dose, low bioavailability, and longer half-life) that are well suited for its formulation as MDT. Nine batches of Mouth dissolving tablets of Domperidone Maleate were successfully prepared using sodium starch glycolate, croscarmellose and crospovidone by direct compression method. (D1 – D9). The tablets were evaluated for parameters like thickness, hardness, friability, *In vitro* & *In vivo* disintegration time, wetting time, water absorption ratio, % drug content and *In vitro* drug release studies. Based on the results, formulation containing 6% superdisintegrants in combination (CCS, CP & SSG) (D-2) was identified as ideal and better formulation among all formulations developed for Domperidone Maleate tablets. *In vitro* release of optimized formulation of Domperidone Maleate Mouth dissolving tablets of D-2 was found to be 99.43% drug release within 10minutes and *in-vitro* disintegration time being ranges between 40-42sec. Though formulation D-8 also showed good release (98.91%) which might be due to 6% Crospovidone but using only crospovidone made the preparation costly that's why the combination of all the superdisintegrants was the good alternate. The final optimized formulation (D-2) was compared with marketed product of Domperidone Maleate tablets (DOMSTAL-MT) which shows 94.22% drug release in 10 minutes. It means the prepared formulation show quite satisfactory release with compared to Marketed Product. From this observation it was concluded that the formulated tablets of Domperidone Maleate (D-2) were superior, economic and effective in achieving patient compliance.

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