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Research Article

Formulation and Evaluation of Orodispersible Tablets of Domperidone

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ABSTRACT

The present study aimed to formulate orodispersible tablets of domperidone to increase its solubility and to enhance the patient compliance, provide a quick onset of action, as compared to marketed formulations. Dispersible tablets are easier to administer or swallow than capsule/conventional tablets for paediatrics, uncooperative, and those with conditions of motion sickness sudden episodes of allergic attacks or coughing. Domperidone is indicated for relief of nausea and vomiting. Orodispersible tablets were prepared by direct compression technique using β-cyclodextrin (CD) with 3 different super disintegrants like as crospovidone, croscarmellose sodium and sodium starch glycolate in various concentration. The prepared powder mixtures were subjected to both pre and post compression evaluation parameters including; IR spectroscopy, tablet hardness, friability, wetting time, disintegration time and *in vitro* drug release. IR studies indicated that there was no interaction between the drug and excipients. Tablet hardness and friability indicated good mechanical strength of tablets. Wetting time decreased from 47.40±0.07 to 30.05±0.05 sec by increasing the super disintegrants concentration from 4 % to 8 % w/w of tablets. The formulation F2 which was prepared by using the 4% of crospovidone showed maximum drug release rate from 47.95±0.02 to 99.5±0.05% after 10 min. The formulation F2 with disintegration time 26.54 sec and dissolution rate 99.5±0.04 was selected as best formulation. Formulation F2 compared with conventional marketed formulation and F2 formulation was found to be superior.

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INTRODUCTION

The European Pharmacopoeia (Suppl. 4.1, IV and Ed.) adopted the word "Orodispersible Tablet" as a tablet that disperses rapidly before swallowing when it is placed in the mouth before ingestion". Domperidone is poorly water-soluble drug; its dissolution is disintegration dependent (1-2). Domperidone was used as model drug in the present study because it's a dopamine receptor blocking activity at both chemoreceptor trigger zone and at the gastric level. It has strong affinity for the D2 and D3 dopamine receptors, which was found in the chemoreceptor trigger zone, located just outside the blood brain barrier, which amount other regulate nausea and vomiting (3). Among all the other routes, the oral drug delivery has been most widely utilized route of administration, which has been explored for the systemic delivery of drugs via various pharmaceutical products. Oral route is the most important route of drug administration compared with other route and it is considered as self-medication, ease of administered and avoidance of pain compared to parenteral route (4, 5). Oral route achieved good popularity may be in part attributed to its ease of administration. Therefore, a fundamental understanding of various disciplines, including GI physiology, pharmacokinetics and pharmacodynamics and formulation design are essential approach to the successful development of pharmaceutical dosage forms (6-7). As a site for drug delivery, oral cavity offers advantages over the conventional gastrointestinal route and the parenteral. It provides direct entry into the systemic circulation thereby avoiding the hepatic first pass effect, ease of administration. Dissolution within the oral cavity also permits intra-oral absorption, thus bypassing first-pass effect (8). To achieve goal of any drug delivery system is the successful delivery of the drug, in which 90% of the drugs are administered to the body for the treatment of various disorders and diseases as it is regarded as the safest, convenient and economical method of drug delivery having the highest patient compliance (9-11). The orodispersible tablets (ODTs) has been enhanced demand for more friendly patient compliance dosage forms, from the past three decades. The ODTs is dissolved or swallowed and then enters into the systemic circulation to produce the desired effect and to remove the adverse effect (12-14). The researcher's activities have been focused and emerging to develop the ODTs which disintegrate rapidly in the oral cavity within 1 min. According to European pharmacopeia 7.0, ODTs should be disintegrated in less than 3 minutes,

which is ease of administration for patients who are mentally ill, disabled, un-cooperative, paediatric and geriatric population. Dispersible tablets are uncoated tablets that are dissolved in water before being administered, resulting in a uniform dispersion. Bitter drugs are more acceptable to different groups of people when the tablets dispersed with a good taste and flavour. When put in water, the tablets must be able to form an adequate dispersion that is uniform and stable. The main advantage is that the absorption and onset of clinical effects are faster (15-18). There are various drug delivery system, but recent advances in novel drug delivery system (NDDS) aim to enhance the safety and efficacy of drug molecules by formulating a convenient dosage form for administration and to achieve better patient compliance. One such approach is lead to ODTs (19-21). The objective of the present research work was preparation of ODTs of domperidone using water soluble polymers having acceptable mechanical properties and faster dissolution to achieve faster onset of action, to increase the bioavailability of domperidone using various superdisintegrants to overcome the difficulties like swallowing, vomiting and also to bypass the first pass metabolism.

MATERIALS AND METHODS

Domperidone and β-cyclodextrin were obtained as a gift sample from Aurabindo Labs, Hyderabad, India. Super disintegrants Crospovidone, Croscarmellose sodium and Sodium starch glycolate were purchased from Yarrow Chem Product, Mumbai, India. Aerosil, Mannitol, Microcrystalline cellulose and all other ingredients used in the study were of analytical reagent grades and obtained from Chemica-biochemica reagents, Mumbai, India. The marketed product of domperidone is known as DOMSTAL manufacture by Torrent Pharmaceutics Ltd., which were purchased from the APPOLLO Pharmacy, MVP Colony, Sector 8, Visakhapatnam for the research purpose.

Method of preparation of SD

SDs were prepared with the different ratios of β-cyclodextrin 1:0.5, 1:0.75 and 1:1 by kneading, physical and neutralization methods and evaluated for their drug content, percentage yield and dissolution properties in comparison with their respective physical mixtures (22).

Preparation of orodispersible tablets:

The ODTs of domperidone SD (DOM) were prepared by direct compression method using three different super disintegrant and formulae given in **Table No. 1**. ODTs were prepared with a total weight of 150 mg of varying polymer

compositions and fixed quantity of domperidone of 10 mg.

Table No. 1: Formulation of domperidone immediate release tablets.

S. No.	Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1.	Domperidone SD	20	20	20	20	20	20	20	20	20
2.	Crospovidone	4.5	6	7.5	-	-	-	-	-	-
3.	Sodium starch glycolate	-	-	-	4.5	6	7.5	-	-	-
4.	Croscarmellose sodium	-	-	-	-	-	-	4.5	6	7.5
5.	Mannitol	10	10	10	10	10	10	10	10	10
6.	Microcrystalline cellulose	109.5	108	106.5	109.5	108	106.5	109.5	108	106.5
7.	Magnesium stearate	3	3	3	3	3	3	3	3	3
8.	Aerosil	3	3	3	3	3	3	3	3	3
	Total weight	**150**	**150**	**150**	**150**	**150**	**150**	**150**	**150**	**150**

The specified quantity of API and superdisintegrants were weighed accurately, mixed and passed through sieve #40. All the materials were transferred to mortar in geometrical order and blended up to 20 mins, except magnesium stearate and aerosil. Prior to the compression the magnesium stearate and aerosil were added and mixed gently for 2-3 min. The tablets were punched using flat faced 8 mm punches. The compression force was adjusted to give tablet hardness in the pharmacopeial range of ODTs (2 – 4 kg/cm^3).

Characterization:

Drug-excipients compatibility studies:

The compatibility studies were performed using Fourier transform infrared spectroscopy (FTIR), Differential scanning calorimetric (DSC), X-Ray diffraction (XRD) and Scanning electron microscopy (SEM).

Precompression evaluation of formulation:

Evaluation parameters for precompression blend: Pre-compression parameters such as angle of repose, bulk density and tap density, Carr ‘s compressibility index and Hausner ‘s ratio was determined [25-30].

Angle of Repose (θ°): It is defined as the maximum angle possible between the surface of a pile of the powder and horizontal plane. It was determined by the funnel method. Accurately weighed powder blend was allowed to flow through the funnel fixed to a stand at definite height. The angle of repose (θ) was

calculated by measuring the height (h) and radius r of the heap of granules,

using **Eq. 1**.

$$\theta = tan^{-1}\left[\frac{h}{r}\right] \text{ ..... Eq. 1}$$

Bulk density and tapped density: These were determined by pouring the powder blend into a graduated cylinder of density apparatus. The bulk density apparatus was allowed to tap for a fixed time to obtain tapped volume (V_f). The bulk volume (V_0) and the weight of powder (M) were determined. The bulk density (ρ_o) and tapped density can be calculated using the formula given in **Eq. 2** and **Eq. 3**.

$$Bulk\ density(\rho_o) = \left[\frac{M}{V_o}\right] \text{.....Eq. 2}$$

$$Tapped\ density = \left[\frac{M}{V_f}\right] \text{.... Eq. 3}$$

Carr's compressibility index and Hausner's Ratio: Flowability of the sample was evaluated by comparing the bulk density and tapped density of powder and the rate at which it packed down was calculated by Carr's compressibility index using the **Eq. 4** and an indirect index of powder flow was calculated by Hausner's ratio using the **Eq. 5**.

$$\%\ Compressibility\ Index = \left[\frac{\rho_t - \rho_o}{\rho_o}\right] X\ 100$$

.. **Eq. 4**

$$Tapped\ density = \left[\frac{\rho_t}{\rho_o}\right] \text{.... Eq. 5}$$

Evaluation of post-compression parameters:

Post-compression parameters such as weight variation, thickness, hardness, friability, water absorption ratio, wetting time, disintegration test, *in vitro* dispersion time, content uniformity and *in vitro* dissolution study were determined.

Weight variation: Randomly 20 tablets were taken from each batch and their weight were determined individually on a digital weighing balance. Calculate the average weight and compare the individual tablet weight to average weight by using **Eq. 6** (31).

$$Average\ weight = \left[\frac{Weight\ of\ 20\ tablets}{20}\right]$$

… **Eq. 6**

Thickness: Randomly 10 tablets from each formulation were taken, and their thickness was measured using a Vernier caliper and the reading was recorded in millimeters (32).

Hardness: The hardness of a tablet is indicative of its tensile strength and is measured in terms of load/pressure required to crush it when placed on its

edge. The hardness of the tablet was determined using the Monsanto hardness tester and expressed in kg/cm^2. Three tablets were randomly picked from each formulation batch and the mean and standard values were calculated (32). The hardness has influence on disintegration and dissolution times and is such a factor that may affect bioavailabilities.

Friability: Generally, it refers to loss in weight of tablets in the containers due to removal of fine particles from their surfaces. A sample of whole tablets corresponding to about 6.5 g was weighed, and the initial weight was recorded (W_o) and placed in Roche friabilator and rotated at the speed of 25 rpm for 100 revolutions (31). Tablets were reweighed after removal of fines (dedusted) and weighed (W_f). Percentage of weight loss were calculated by using the formula given in **Eq. 7**. Friability below 1 % was considered acceptable.

$$\% \, Friability = \left[\frac{W_o - W_f}{W_o}\right] X \, 100 \quad \ldots$$

Eq. 7

***In vitro* disintegration test:** The *in vitro* disintegration test was performed using USP disintegration test apparatus using 0.1 N HCl medium at 37 ±0.5 ˚C. Time for complete disintegration of the tablet was measured in triplicate (31).

Wetting Time: The wetting time of the tablets can be measured using a simple procedure. A filter paper of 10 cm diameter was placed in a petri dish with a 10 cm diameter. Two mL of water containing amaranth as colouring agent, was added to petri dish. A tablet was carefully placed on the surface of the filter paper. The time required for water to reach the upper surface of the tablet was noted as wetting time. Three determinations were performed (33).

Content uniformity: The drug content was determined by taking 10 dosage units at random and powdered. The blend equivalent to 10 mg of DOM ODTs was weighed and dissolved in 100 mL of 0.1 N HCl buffer, stirred for 15 min, allow insoluble material to settle and filtered. Absorbance was measured at 285 nm using a UV-Visible double beam spectrophotometer (UV- 1700 Shimadzu) (34).

***In vitro* dissolution studies:** *In vitro* dissolution studies of DOM ODTs were performed in USP XXIII dissolution testing apparatus II (Electro lab, India) employing a paddle stirrer at 50 rpm using 900 mL pH 0.1 N HCl at 37±0.5°C as a dissolution medium. Aliquots of 5 mL each were withdrawn at specific time intervals 5, 10, 15, 30, 45 and 60 min respectively and replaced with equal

volume of fresh medium. The withdrawn aliquots were analyzed for drug content spectrophotometrically at λ_{max} 285 nm. Drug concentration was calculated and expressed as cumulative percent of the drug released using an equation obtained from a standard curve. The dissolution experiments were conducted in triplicate (22, 27).

Comparison of Optimized Formulation with Conventional Marketed Tablets: *In vitro* dissolution studies for pure drug, optimised formulation F2 and conventional tablet were carried out using USP apparatus type II at 50 rpm, which shows that the drug release was more than 80% within 10 min which is better than conventional marketed tablet and shown in cumulative drug release **Figure 6**.

RESULTS AND DISCUSSION

Compatibility Studies: The pure drug DOM, DOM SD, crospovidone and optimized formulation F2 were characterized by IR spectroscopy, DSC, XRD and SEM to test the compatibility and were shown in **Figure 2-4**.

FTIR studies: The FTIR analysis of the pure drug DOM, DOM SD, crospovidone and optimized formulation F2 were taken in the range of 4000 - 400 cm^{-1} using ATR. The IR spectrum of the pure drug showed a characteristic stretching peak at 3350.9 cm^{-1}, aromatic C-H stretch at 3024.2 cm^{-1}, symmetric -C-H stretching at 2955.2 cm^{-1}, indicates N-H and stretching at 1700.9 cm^{-1} indicates C=O, -C=C- stretch denoting the presence of alkyl halide at 731.5 cm^{-1} indicating the purity of drug. IR spectra of physical mixture 1:1 of DOM and various excipients were performed to find out any possible drug – excipients interaction by KBr pellet method using Bruker FTIR series (model – 1615) spectrophotometer. From the, IR spectra of pure form it was observed that there is no appearance of new peaks and shifting of already existed peaks when comparing the IR formulation with API indicates absence of drug excipients incompatibility. IR spectrum of formulation showed absorption bands in the same wave number region as that of API absorption bands [23, 24]. So, no disappearance of existed bands and sifting of bands was occurred indicates the compatibility, are shown in **Figure 1**.

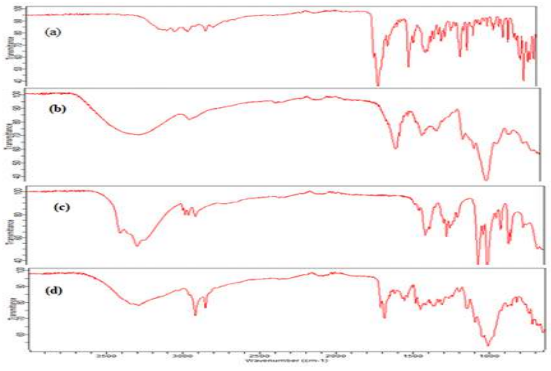

Figure 1: FTIR spectra of a) Domperidone, b) DOM SD c)

Crospovidone and d) Optimised formulation F2 with 4 % w/w CP.

DSC studies: The DSC thermograph of pure drug DOM, CP, mannitol, optimized formulations F2 with 4 % w/w CP were shown in **Figure 2**. The DSC thermograph of DOM was characterised by melting sharp endotherm at 252.8 °C due to the melting point of the drug in **Figure 2a**. The DSC thermograph of CP, mannitol showed an endothermic peak at 131.8 °C, 169.24 °C in **Figure 2b** and **Figure 2c**. The optimized formulation F2 with 4 % CP showed a characteristic endothermic peak at 257.6 °C in **Figure 2d,** that the DOM was rendered entirely amorphous in the solid dispersion as indicated by the absence of the melting sharp endothermic peak at 252.8 °C. This indicates the crystallinity nature of the drug converted to an amorphous state.

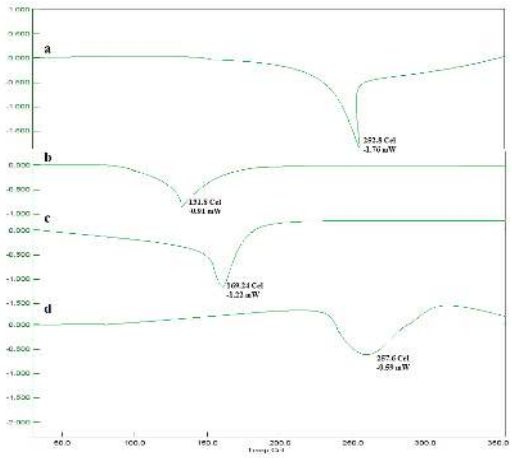

Figure 2: DSC thermogram of a) Domperidone, b) Crosspovidone, c) Mannitol and d) Optimised formulation F2 with 4 % w/w CP.

XRD studies: The XRD pattern of pure DOM and optimized formulations F2 with 4% CP were shown in **Figure 3**. The diffraction spectrum of pure DOM showed that the drug was of crystalline in nature as demonstrated by numerous, distinct peaks at 2θ. The spectrum of solid dispersion showed a reduction in total number of peaks, base broadening of appeared peak along with a reduction in peak intensity providing convincing evidence for the formation of amorphous form in solid dispersion. The result indicates that the drug in solid dispersion was in amorphous form. Hence, increased dissolution of the drug was observed.

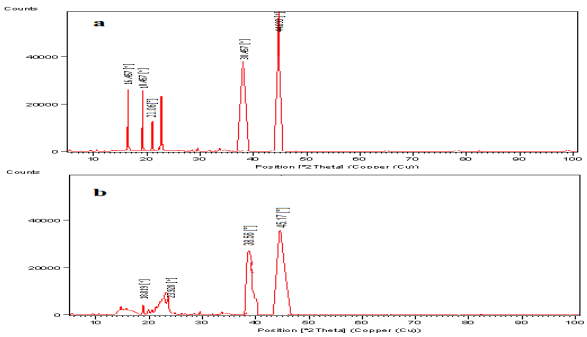

Figure 3: XRD of a) Domperidone and b) Optimised formulation F2 with 4 % w/w CP.

SEM studies: SEM analysis was performed to visualize the morphology of pure DOM, CP, mannitol and solid dispersions. The DOM samples exhibited hexagonal shape crystal structures shown in **Figure 4a**, which were relatively

smaller than particles of CP (**Figure 4b)** and mannitol (**Figure 4c)**; the optimised formulation F2 shown in **Figure 4d** revealed absence of crystalline structure of the drug; it shows the changes produced are more porous in nature. Thereby supporting the transformation of drug from the crystalline to the amorphous state. Solid state characterization studies revealed partial loss of drug crystallinity which can bring about significant change(s) in the drug dissolution rate. However, other factors like reduced particle size, increased surface area, and closer contact between the hydrophilic carrier and the drug may also be influential in enhancing drug solubility rate observed with the solid dispersion particles.

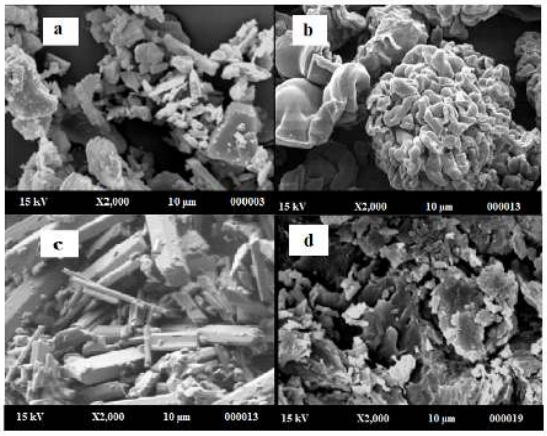

Figure 4: DSC thermogram of a) Domperidone, b) Crosspovidone, c) Mannitol and d) Optimised formulation F2 with 4 % w/w CP.

Pre-compression evaluation:

The angle of repose was in the range of 25.01° to 30.16° shows that values were within IP range indicating powder blend having good flow property. The bulk density and tapped density for the formulations were calculated. The value ranges from 0.251 to 0.257 g/cm^3 and 0.258 to 0.283 g/cm^3. The Carr's index of various formulations was calculated. The compressibility index and Hausner's ratio of pre compressed blends was in the range of 11.80 % to 16.30 % and 1.09 to 1.20 respectively. From the above results it was found that the powder blend has good to excellent flow properties.

Post compression parameters

The post compression results of all the prepared formulations F1 to F9 were given in **Table 2**. Weight variation results were found to be within specification ±7.5 % as per I.P. The thickness of all the formulations was in the range of 2.58 to 2.72 mm. The hardness test results were in the range of 2.5 to 3.5 kg/cm². Friability of all the formulation was found to be <1.0% and was within the specification. The results were in the range of 0.52 to 0.83 % and for optimized formulation the friability was found to be 0.59 %. Disintegration results were found to be within the specification i.e., within 1 minute as per USP in the range of 22 to 56 sec. The wetting time results were in the range of 30 – 47 sec and optimized formulation was found to be 37 sec. Drug

content of the optimized formulation was found to be 100.5 %.

Table 2: Physicochemical properties of the domperidone.

Formulation Code	Weight variation (kg/cm^2)[a]	Thickness (mm)[b]	Hardness (kg/cm^2)[b]	Friability (%)[c]	Disintegration Time (sec)[d]	Dispersion time (sec)[d]	Wetting time (sec)[d]	Drug content (%)[e]
F1	148.7±0.11	2.63±0.14	2.5±0.21	0.61	40.22±1.61	33.21±0.83	30.05±0.25	99.3±0.56
F2	**151.5±0.12**	**2.71±0.16**	**2.7±0.11**	**0.59**	**26.53±1.24**	**26.83±0.92**	**37.14±0.14**	**100.5±0.51**
F3	148.1±0.13	2.62±0.18	2.6±0.30	0.52	31.34±1.22	42.5±0.51	39.13±0.06	100.3±0.68
F4	147.5±0.11	2.71±0.24	3.0±0.50	0.45	29.22±1.44	38.1±0.72	42.41±0.72	99.4±0.21
F5	153.4±0.14	2.58±0.23	3.1±0.10	0.66	56.43±1.35	44.42±0.14	31.22±0.15	99.6±0.26
F6	148.3±0.12	2.72±0.15	3.1±0.30	0.71	51.36±1.32	65.41±0.77	32.35±0.72	100.2±0.67
F7	149.5±0.13	2.70±0.18	3.3±0.30	0.68	23.04±1.06	32.21±0.16	36.57±0.71	99.8±0.45
F8	153.2±0.11	2.68±0.22	3.1±0.24	0.70	22.41±1.03	37.32±0.38	47.40±0.67	101.1±0.35
F9	151.8±0.14	2.67±0.15	3.4±0.11	0.72	30.25±1.32	35.43±0.17	35.22±0.98	99.6±0.64

Where a: mean±% deviation. (n=20); b: n=5; c: n≈6.5gm of total weight, d: n=3, e: n=10

Drug Release Studies

The *in vitro* drug release profiles of the prepared formulations F1 to F9 and comparison of pure drug with marketed product with optimized formulation were shown in **Figure 5**. From the *in vitro* data, it was observed that all the formulations were able to release more than 70 % of drug within 30 min. But the pure drug and formulation F9 with 3 % of CCS are not able to release 70 % of drug in 30 min. Among nine formulations, F2 formulation is selected as optimized formulation because of its lowest disintegration time, dispersion time, wetting time and highest drug release, drug content. In comparisons, formulation F9 was compared with conventional marketed formulation and pure drug. The drug release of marketed product and F9 formulation was found to be 63.06±0.03 and 98.54±0.04 at the end 30 min and shown in **Figure 6**.

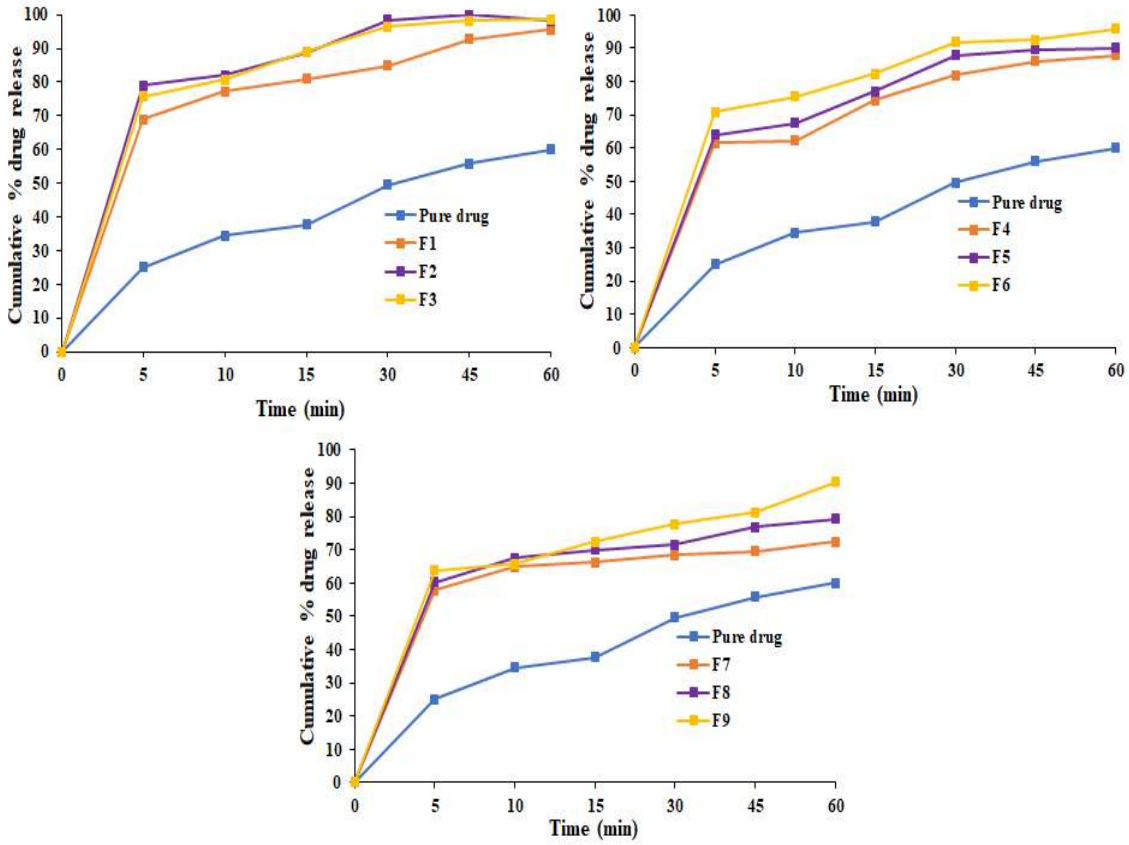

Figure 5: *In vitro* cumulative % drug release profiles of domperidone pure drug with a) FI to F3 (CP), b) F4 to F6 (SSG) and c) F7 to F9 (CCS).

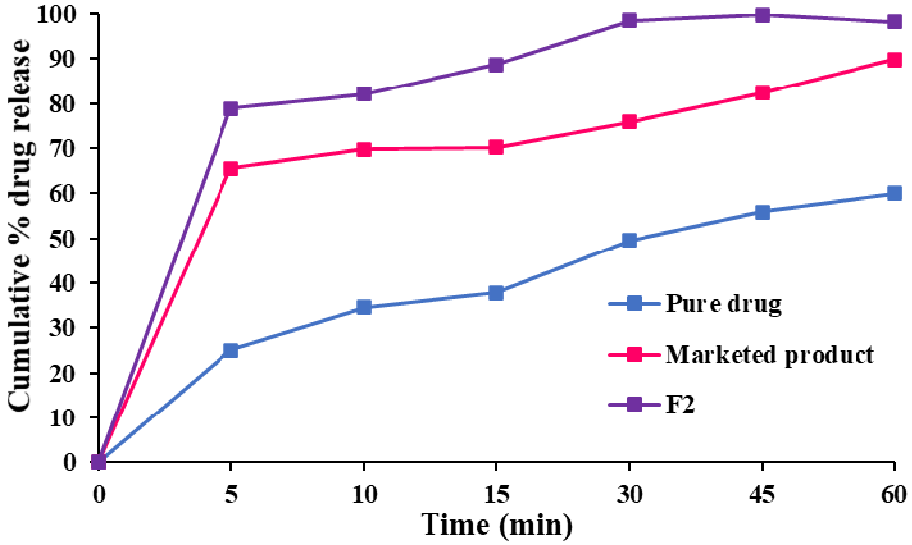

Figure 6: *In vitro* cumulative % drug release profiles of domperidone pure drug and optimised formulation F2 in comparison with marketed product.

CONCLUSIONS

Solid dispersion od DS prepared with β-cyclodextrin by kneading method in greater increasing in drug dissolution. Using optimised DS SD in 1:1 in further preparation of ODT formulations by using different super disintegrant along with excipients. Preformulation studies were performed on the drug. Different formulations of tablets were performed by using direct compression method. All the formulation were evaluated for preformulation and post compression studies and compared to marketed drugs. Among all the formulations F2 (6 % of crospovidone) formulation showed better results that is percentage of drug release was found to be 99.45 % in 30 min and disintegration time was found to be 26.54 sec. Dissolution of all the formulations was found to be increased by using super disintegrant. *In vitro* release profile of the dispersible tablets was satisfactory and complete drug release was satisfied. All the formulation was found under the limits.

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