Journal Homepage: www.ijarpr.com ISSN: 3049-0103 (Online)

International Journal of Advance Research Publication and Reviews

Vol 03, Issue 9, pp 631-637, September, 2026

Formulation & Evaluation of Mouth Dissolving Tablets of Domperidone Using Copressed Superdisintegrants

Mr. Naveen Kumar*, Dr. Rajesh Sharma[$], Dr. Gurpreet Singh, Dr. G. Jeyabalan, Dr. Praveen Goyal

* Research Scholar, Dept. of Pharmaceutics, Alwar Pharmacy College, M.I.A. Alwar, Rajasthan, India

[$]Professor & Supervisor, Dept. of Pharmaceutics, Alwar Pharmacy College, M.I.A. Alwar, Rajasthan, India

Email: naveenjangra723203@gmail.com

ABSTRACT:

This research involves preparation of mouth dissolving tablets of Domperidone by direct compression method using various concentrations of co-processed superdisintegrants i.e. Sodium starch glycolate and crospovidone prepared by Microwave technology. SSG and crospovidone used in different ratio (1:1, 1:2, 1:3, 2:1, 2:2, 2:3, 3:1, 3:2 and 3:3). 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 (CP:SSG = 3:3) (DM-9) was identified as ideal and better formulation among all formulations developed for Domperidone tablets. *In vitro* release of optimized formulation of Domperidone Mouth dissolving tablets (DM-9) prepared by microwave technology was found to be 99.06% drug release within 15minutes and *in-vitro* disintegration time being ranges between 20-23sec. Optimized formulation DM-9 showed very good stability profile. From this observation it was concluded that the formulated tablets of Domperidone (DM-9) were superior, economic and effective in achieving patient compliance.

Keywords: Domperidone, fast dissolving, antiemetic, co-processed superdisintegrants

1. 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].

MDT is not only indicated for people who have swallowing difficulties, but also are ideal for active people [4]. Mouth dissolving tablets are also called as fast-dissolving tablets, melt-in mouth tablets, orodispersible tablets, rapimelts, porous tablets, quick dissolving etc. Fast dissolving tablets are those when put on tongue disintegrate instantaneously releasing the drug which dissolve or disperses in the saliva [5].

Nausea and vomiting are the most commonly occurring symptoms in majority of pathophysiological conditions such as motion, cancer, pregnancy, and postoperative conditions. Nausea refers to feeling of impending vomiting. Vomiting refers to forceful expulsion of contents of the stomach and the proximal small intestine [6,9].

Antiemetic drugs are used to prevent or suppress vomiting. They act by blocking several receptors located in vomiting centres such as H1 histaminic, dopamine D2, 5-HT3 receptor, muscarinic, and neurokinin1(NK1) receptor. Drugs such as Anticholinergics, H1-antihistamines, Neuroleptics, 5-HT3 antagonists act by penetrating blood brain barrier which leads to sedation [7,10].

In the present investigation, the preparation and evaluation of Domperidone fast dissolving tablets by using coprocessed superdisintegrants containing crospovidone and sodium starch glycolate by microwave method was studied. The reasons for selection of crospovidone are high capillary activity, pronounced hydration capacity and little tendency to form gels [8,6]. Sodium starch glycolate was chosen because of its high swelling capacity [9,7]. The concept of formulating fast dissolving tablets (FDT) of metoclopramide hydrochloride (anti-emetic) [10,8] using co-processed superdisintegrants helps to increase the water uptake with shortest wetting time and thereby decrease the disintegration time of the tablets by simple and cost effective direct

compression technique.

2. Materials & Methods:

2.1. Materials.

Domperidone (API) was obtained as a gift sample from Wockhardt Research Centre, Aurangabad, Maharashtra, India and other excipients Sodium Starch Glycolate, Crospovidone, Mannitol, Microcrystalline Cellulose, Talc, Magnesium Stearate, and 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:

2.2.1 Preparation of physical mixture and co-processed superdisintegrants:

The physical mixture of sodium starch glycolate and crospovidone was prepared by mixing them together in glass pestle motor. The coprocessed superdisintegrant was prepared by Microwave Technology. Blends of SSG and crospovidone in different ratio (1:1, 1:2, 1:3, 2:1, 2:2, 2:3, 3:1, 3:2 and 3:3) were prepared.

2.2.2 Preparation of fast dissolving tablets:

The tablets were prepared by using single punch tablet machine to produce flat faced tablets weighing 200 mg each with a diameter of 5 mm. A minimum of 50 tablets were prepared for each batch. Before compression tablet blends were evaluated for mass-volume relationship (Bulk density, Tapped density, Hausner's ratio, Compressibility index) and flow properties (Angle of repose).

The superdisintegrants (Sodium Starch Glycolate and Crospovidone) coprocessed by various techniques were used to develop the tablets. All the ingredients were shown in Table 1 were passed through sieve no. 60 and were co-grounded in a glass pestle motor [11-13].

Table 1: Composition of MDT with Coprocessed* Superdisintegrants

Ingredients	DM1	DM2	DM3	DM4	DM5	DM6	DM7	DM8	DM9
Drug	10	10	10	10	10	10	10	10	10
SSG	2	2	2	4	4	4	6	6	6
Crospovidone	2	4	6	2	4	6	2	4	6
Avicel PH 102	40	40	40	40	40	40	40	40	40
Mannitol	50	50	50	50	50	50	50	50	50
Talc	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Mg. stearate	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Lactose (qs)	200	200	200	200	200	200	200	200	200
Ratio(SSG:CP)	1:1	1:2	1:3	2:1	2:2	2:3	3:1	3:2	3:3
% superdisintegrant	2	3	4	3	4	5	4	5	6

*M indicates microwave technique

Nine MDT formulations each weighing 200mg, were prepared by using constant amount(10mg) of Domperidone, along with a mixture of Crospovidone, Sodium starch Glycolate at different concentrations viz. 2,3,4,5 & 6% as these superdisintegrants work best in between range of 2% to 8%. Powdered blends, each weighing 200mg, 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.

3. Evaluation Parameters

3.1 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.

Flow property of all formulation batches for preparing tablets by direct compression technique was accessed through the parameters like Tapped density, Bulk density, Angle of repose, Carr's index, Hausner's ratio. Results were shown in table 2.

Table 2: Pre-compression characterization of different batches blend of Domperidone MDT

Batch No.	Bulk Density	Tapped Density	Angle of Repose	Hausner's ratio	Carr's index
DM1	0.447	0.493	25.54	1.102908	9.330629
DM2	0.458	0.510	23.26	1.113537	10.19608
DM3	0.460	0.522	24.22	1.134783	11.87739
DM4	0.463	0.511	25.62	1.103672	9.393346
DM5	0.481	0.536	23.46	1.114345	10.26119
DM6	0.465	0.517	26.99	1.111828	10.05803
DM7	0.463	0.516	25.62	1.114471	10.27132
DM8	0.473	0.518	26.14	1.095137	8.687259
DM9	0.469	0.522	24.23	1.113006	10.15326

Table 2 reported results of flow properties of powder blends for preparing tablets by direct compression technique. It was found that all the batches exhibited acceptable flow property with respect to angle of repose, Carr's index, Hausner's ratio.

3.2 Evaluation of Compressed Tablets:

After compression of powder blends, all the prepared batches of MDT's were evaluated for organoleptic characteristics like color, odor, taste and physical characteristics like diameter, thickness, hardness, friability, weight variation, disintegration time, and dissolution studies.

3.2.1 Shape and Colour of Tablets:

Randomly picked tablets from each formulation batch examined under lens for shape and in presence of light for colour. Tablets showed flat, circular shape & in white colour.

3.2.2 Thickness Test:

Average tablet thickness (Table No.3) was found to be consistent throughout the batch. Tablet thickness ranges between 2.51mm to 2.56mm.

3.2.3 Hardness Test:

The results of hardness are given in Table No.3. Hardness test was performed by Monsanto tester. Hardness was maintained to be within 2.00 kg/cm^2 to 4.20 kg/cm^2, as these tablets are rapidly disintegrating. The lower standard deviation values indicated that the hardness of all the formulations were almost uniform in specific method and possess good mechanical strength with sufficient hardness.

3.2.4 Friability Test:

The study results are tabulated in Table No.3, was found well within the approved range (<1%) in all the formulation [14].

3.2.5 Weight Variation Test: 83

20 tablets from each formulation were randomly selected to calculate average weight and standard deviation. All the formulations exhibited uniform weight (as per IP-2010) with low standard deviation values (Table No.3). It was found between 200mg to 204mg, indicating the uniformity of the tablets prepared by direct compression method [15].

3.2.6 Drug Content Uniformity: 88

The drug content of randomly selected tablets was determined. Three trials from each formulation were analyzed spectrophotometrically. The mean value and standard deviation of all the formulations were calculated. The percent drug content of the tablets was found between 96.69% - 99.87% of Domperidone. Drug content of all the formulations was found to be within the limits (Table 3) specified in IP 2010, indicating the uniformity of the tablets prepared by direct compression method & melt granulation method [16].

Table 3: Weight, Thickness, Hardness, Friability & Drug Content of tablets

Form. Code	Uniformity of Thickness (n = 3) (mm)	Diameter (n = 3) (mm)	Hardness (n = 3) (kg/cm2)	Friability %	Weight Variation (n = 20) (mg)	Drug Content Uniformity (n = 10) (%)
DM1	2.51	7.03	2.55	0.54	201	99.64
DM2	2.53	7.03	2.53	0.51	200	96.69
DM3	2.54	7.04	2.62	0.52	202	97.58
DM4	2.56	7.02	2.51	0.51	201	99.73
DM5	2.55	7.05	2.69	0.51	202	99.79
DM6	2.53	7.00	2.55	0.55	201	98.35
DM7	2.54	7.04	2.57	0.57	203	99.26
DM8	2.52	7.02	2.53	0.59	202	97.06
DM9	2.52	7.01	2.59	0.52	204	99.87

3.2.8 Mouth Feel and In vivo Disintegration Time:

The internal structure of tablets, which is pore size distribution, water penetration into tablets and swelling of disintegration substance are suggested to be the mechanism of disintegration.

The results are shown in Table No.4. This was determined as per U.S.P 30 NF 25 & Japanese Pharmacopoeia [17] for all the formulations. All formulations showed disintegration time less than 30 seconds. Formulation **DM9** showed fast disintegration compared to other formulation due to high concentration of disintegrants.

The results of both parameters are shown in Table No. 4. The prepared formulations were subjected for mouth feel. The volunteers felt good taste in all the formulations. As the drug is not bitter presence of Mannitol showed good, palatable taste.

Table 4: Results of *in vitro*, *in vivo* disintegration test with Mouth Feel **(Microwave Technology)**

Formulation Code	In vitro Disintegration Time (Sec)	In-vivo Disintegration Time (Sec)	Mouth Feel
DM1	26-29	30-33	Good
DM2	24-28	27-30	Good
DM3	22-24	25-27	Good

Formulation Code	In vitro Disintegration Time (Sec)	In-vivo Disintegration Time (Sec)	Mouth Feel
DM4	25-27	27-29	Good
DM5	23-25	26-29	Good
DM6	21-24	24-28	Good
DM7	23-25	26-28	Good
DM8	28-30	24-27	Good
DM9	20-23	20-23	Good

3.2.9 In-vitro Dissolution or Drug release studies: [18,19]

Studies were carried out using USP-II dissolution apparatus. Drug release studies were performed in 0.1 N HCl (1, 2, 4, 6, 8, 10 & 15min). Samples of 1 ml were taken from the medium at the definite time intervals and diluted to ten times by same dissolution media. The samples were assayed by using double beam UV spectrophotometer. Table 5 & fig. 1 showed percentage release of Domperidone in 0.1 N HCl buffer from tablets prepared by direct compression technique (Microwave Technology**)**. It was observed that formulation **DM9** show **99.06%** drug release in 15 minutes.

Table 5: Percentage release of Domperidone in 0.1 N HCl buffer from tablets prepared by direct compression technique (**Microwave Technology)**

Time(min)	DM1	DM2	DM3	DM4	DM5	DM6	DM7	DM8	DM9
1	23.55	26.46	30.2	27.57	31.4	34.32	32.65	35.66	38.9
2	43.45	46.18	49.72	47.38	50.46	53.68	51.89	54.64	57.11
4	57.32	60.24	64.86	61.34	65.81	68.89	66.66	69.74	72.27
6	68.34	71.85	74.02	72.47	75.53	78.43	76.71	79.43	82.62
8	77.43	79.27	82.25	80.63	83.72	86.69	84.77	87.41	90.72
10	82.5	85.41	88.98	86.67	89.44	92.96	90.2	93.41	96.51
15	84.85	87.42	90.31	88.46	92.03	94.9	92.36	95.76	99.06

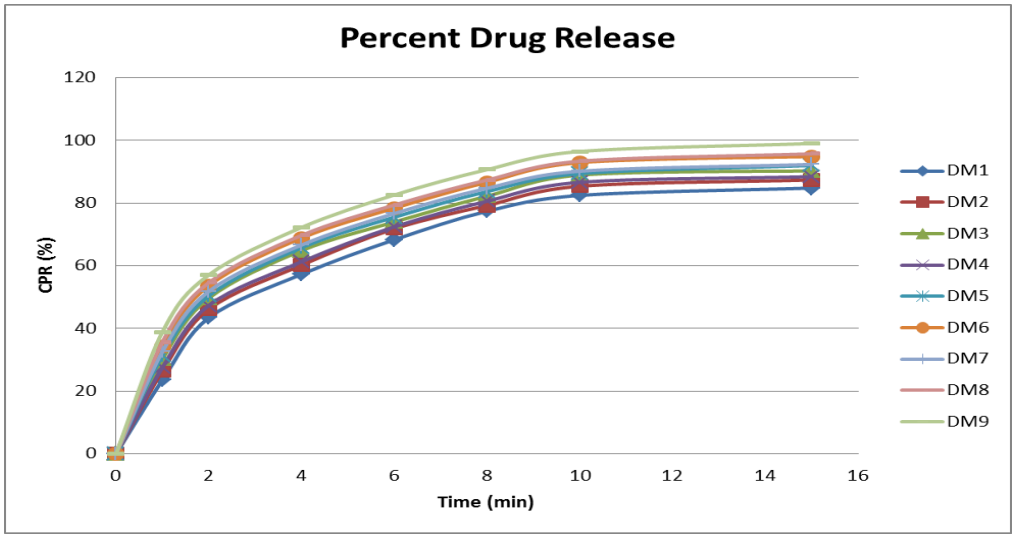

Fig. 1: Percent release of Domperidone MDTs prepared by direct compression technique

4. Study of Release Kinetics of optimized batches [20-22]

The data obtained from *in vitro* dissolution studies were fitted in different models to determine the mechanism of drug release.

Study of Release Kinetics of batch DM9

The correlation coefficient values obtained for all five models, Zero order, first order, Hixon Crowell & Higuchi models were fitted on the optimized formulations. Statistical kinetics values of batch **DM9** is shown in table 10.

Table 10: *In vitro* drug release parameters for Batch DM9

Time (minutes)	Sqaure root of time	Log time	% CDR	Log %CDR	cumulative drug remaining	Log % cumulative drug remaining
0	0	0	0	-	100	2
1	1	0.00	38.9	1.58995	61.10	1.79
2	1.414214	0.30103	57.11	1.756712	42.89	1.63
4	2	0.60206	72.27	1.858958	27.73	1.44
6	2.44949	0.778151	82.62	1.917085	17.38	1.24
8	2.828427	0.90309	90.72	1.957703	9.28	0.97
10	3.162278	1	96.51	1.984572	3.49	0.54
15	3.872983	1.176091	99.06	1.995898	0.94	-0.03

Among the entire kinetic model studied for the batch (DM9), it was found that the batch followed **first Order** kinetics because of having maximum R^2 value of **0.9827** (closest to 1.0).

5. Stability Study:

The stability studies carried out on optimized formulation DM9 at 40±2˚C temperature and 75±5% RH for 90 days. The formulation DM9 was showing good stability with no remarkable changes in Appearance, Drug content, Hardness and *in vitro* drug release profile.

6. Conclusion

Mouth dissolving tablets of Domperidone were formulated using coprocessed super disintegrating Sodium starch glycolate & Crospovidone using microwave technology. Domperidone was selected for the research work, due to less central nervous system (CNS) side-effects and better pharmacokinetic properties that are well suited for its formulation as MDT. Nine batches of Mouth dissolving tablets of Domperidone were successfully prepared using sodium starch glycolate and crospovidone by direct compression method **(DM1 – DM9)**.

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 (CP:SSG = 3:3) (DM-9) was identified as ideal and better formulation among all formulations developed for Domperidone tablets.

In vitro release of optimized formulation of Domperidone Mouth dissolving tablets of DM-9 was found to be 99.06% drug release within 15minutes and *in-vitro* disintegration time being ranges between 20 and 23sec. Optimized formulation DM-9 showed very good stability profile. From this observation it was concluded that the formulated tablets of Domperidone (DM-9) were superior, economic and effective in achieving patient compliance.

7. References:

1. Aulton ME. Pharmaceutics - The science of dosage from design. 2001, 2nd edition, pp 7-37. London: Churchill Livingstone

2. Wang B, Siahaan T, Soltero R. Drug delivery: principles and applications. John Wiley and sons Inc. 2005;58:68-69.

3. Biradar SS, Bhagavati ST, Kuppasad IJ. Fast dissolving drug delivery systems: A brief overview. The Internet Journal of Pharmacology. 2006;4(2).

4. Kaushik D, Dureja H, Saini TR. Mouth dissolving tablets: A review. Ind. Drugs 2004:41(4); 187-93

5. Orodispersible Tablets: Dosage Form. European Pharmacopoeia. E.P. 5.0: 628.

6. Pleuvry B.J. Physiology and pharmacology of nausea and vomiting. Anaesthesia Intensive Care Med. 2006;7(12):473–477.

7. Tripathi K.D. fifth ed. Jaypee Brothers Medical Publishers (P) LTD; 2003. Essentials of Medical Pharmacology. p. 604.

8. Handbook of pharmaceutical excipients, 4th Edn. Washington, DC: American Pharmaceutical Association, London, Pharmaceutical Press, 2003,pp.184-5.

9. RW Miller. Sodium starch glycolate. In: RC Rowe, PJ Sheskey, PJ Weller (eds.) Handbook of pharmaceutical excipients, 4th ed. Washington, DC: American Pharmaceutical Association, London, Pharmaceutical Press, 2003,pp.581-4.

10. SC Sweetman, editor. Martindale: The Complete Drug Reference, 33rd Edn,Pharmaceutical Press, London.2002, 1235-1237.

11. Kuchekar BS, Atul, Badhan C, Mahajan HS. Mouth dissolving tablets: A novel drug delivery system. Pharma Times 2003; 35:7-9.

12. Bogner R and Meghan F. Fast dissolving tablets. US Pharmacist 2005; 27:03

13. Gregory GK, Ho DS. Pharmaceutical dosage form packages. US Patent 4,305,502; 1981.

14. Friability of Uncoated Tablets. Indian Pharmacopoeia. Indian Pharmacopoeia Commission: Government of India, Ministry of Health and Family Welfare, Controller of Publications, Delhi. 2010; (1):193.

15. Uniformity of Weight of Single-Dose Preparations. Indian Pharmacopoeia. Indian Pharmacopoeia Commission: Government of India, Ministry of Health and Family Welfare, Controller of Publications, Delhi. 2010; (1):192

16. Uniformity of Content of Single-Dose Preparations. Indian Pharmacopoeia. Indian Pharmacopoeia Commission: Government of India, Ministry of Health and Family Welfare, Controller of Publications, Delhi. 2010; (1):192-193.

17. Battu SK, Repay MA, Maunder S and Rio MY, Formulation and evaluation of rapidly disintegrating tablet Fenoverine tablets: Effect of Superdisintegrants, Drug Dev. Ind. Pharm.(2007); 33: 1225-1232.

18. Dissolution Test. Indian Pharmacopoeia. Indian Pharmacopoeia Commission: Government of India, Ministry of Health and Family Welfare, Controller of Publications, Delhi. 2010; (1):189-192.

19. Dissolution. United States Pharmacopoeia. USP 30 NF 25. 711(1-4).

20. Costa, P.; Manuel, J.; Sousa, L. Modeling and comparison of dissolution profiles: A review. Eur. J. Pharm. Sc. 2001, 13, 123-133.

21. Lachman L, Lieberman HA, Kanig JL. The Theory & Practice of Industrial Pharmacy. Varghese Publishing House. 3rd Edition (Reprint 1991); 760-803.

22. Yuksel N, Kanik AE, Baykara T. Comparison of in vitro dissolution profiles by ANOVA-based, model-dependent and independent methods. Int. J. Pharm. 209 (2000):57-67.