International Standard Serial Number (ISSN): 2249-6807

International Journal of Institutional Pharmacy and Life Sciences 2(3): May-June 2012

INTERNATIONAL JOURNAL OF INSTITUTIONAL PHARMACY AND LIFE SCIENCES

Pharmaceutical Sciences **Research Article……!!!**

Received: 25-05-2012; Revised; Accepted: 01-06-2012

FORMULATION AND EVALUATION OF FAST DISINTEGRATING TABLETS OF DOMPERIDONE

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Keywords:

Domperidone, FDT, maltodextrin, evaluation

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ABSTRACT

In the present fast moving world, it is very difficult to cope with the conditions that arise in fraction of seconds. The concept of rationalization is well disguised over the world when it comes to pharmaceuticals. The diseases too have grown at a tremendous rate along with the frequency of their occurrences. To cope with such fast occurring diseases the formulation too must be fast and delayed action must be avoided. In the present research paper, fast disintegrating tablets of domperidone are being formulated and evaluated.

INTRODUCTION

Domperidone is the drug having an Antiemetic activity [1]. The metaclopramide is the active salt present in the marketed preparation commercially available as domperidone. This drug is available in the market by number of trade names wiz Motilium, Motillium, Motinorm Costi and Nomit etc. This drug is effected against all the categories i.e. Padretics, Adults, Geratics. Chemically known as 5-chloro-1-(1-[3-(2-oxo-2,3-dihydro-1*H*-benzo[*d*]imidazol-1-yl)propyl]piperidin-4-yl)-1*H*-benzo[*d*]imidazol2(3*H*)-one.

Domperidone has got some secondary uses too apart from its normal Antiemetic activity. Drug is also utilized in the conditions like Parkinson's disease, gastroparesis (stomach motility condition) and paediatric gastroesophageal reflux (infant vomiting) [2-3].

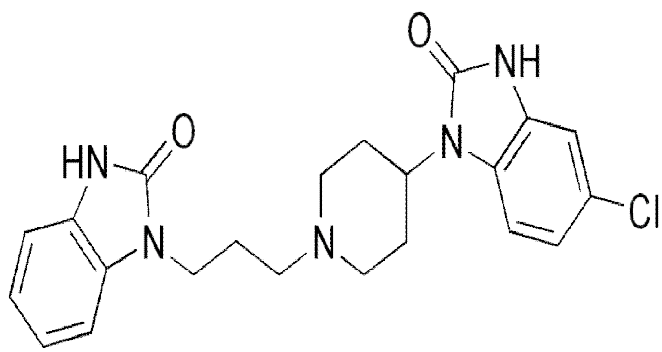

Figure 1: Chemical Structure of Domperidone

This drug Domperidone blocks the action of dopamine. It has strong affinities for the D_2 and D_3 dopamine receptors, which are found in the chemoreceptor trigger zone (CTZ), located just outside the blood brain barrier, which regulates nausea and vomiting. Cardiac arrest and arrhythmia are some of the side effects of the intravenous administration of this drug; orally this drug has no such side effect. Pallikonda et al. [4] prepared different batches of domperidone tablets by slugging method using higher and lower concentrations of superdisintegrants. The outcome of their work showed that crospovidone was best in achievingfast disintegration (below 20 s) and maximum percent of drug release in a shortest time point (4 min). Elnaggar et al. [5] used maltodextrin as a novel excipient to prepare orally disintegrating tablet (ODT) of meclizine. Tablets were prepared by both direct compression and wet granulation techniques El-Arini et al. [6] carried out the evaluation of disintegration testing of different fast dissolving tablets using texture analyzer. Wilson et al. [7] studied the behavior of a fast-dissolving expidet followed by gscintigraphy. Washington et al. [8] utilizes gamma scintigraphic technique to study of gastric coating by expidet tablet andliquid formulations. Brampton et al. [9] carried out double-blind crossover study of the efficacy and acceptability of oxazepam expidet tablets compared to placebo in patients undergoing gynaecological surgery. Morita et al. [10] evaluated the disintegration time of rapidly disintegrating tablets by novel method utilizing a CCD camera. Ali et al. [11] utilized nearinfrared spectroscopy for nondestructive evaluation of tablets. Jedvert et al. [12] evaluated the active ingredient in tablets by NIR and Raman spectroscopy.

MATERIALS AND METHOD

Materials

Domperidone was obtained as gift sample from Meridian labs Pvt. Ltd Solan, India. Maltodextrin was purchased from Vivek scientific Laboratories Pvt. Ltd, Ambala. Ac-Di-Sol, sodium starch glycolate, crospovidone and avicel PH102 were purchased from Meridian Pvt. Ltd, Solan. Talc and magnesium stearate were procured from Nector Life Sciences Ltd, Derabassi. Sodium hydroxide, potassium dihydrogen phosphate, concentrated hydrochloric acid and methanol were purchased from Vivek scientific Pvt – Ltd, Ambala, India. UV/VIS spectrophotometer (Shimadzu 1700) having double beam detector configuration was used for *in-vitro* dissolution studies. All other chemicals used were of analytical grade and were used as received.

METHOD

Table 1: Formulation Of Fast Dissolving Tablets of Domperidone

Ingredients	FDT1	FDT2	FDT3	FDT4	FDT5	FDT 6	FDT7	FDT8	FDT9
Domperidone	10	10	10	10	10	10	10	10	10
Maltodextrin	35	35	35	52.5	52.5	52.5	70	70	70
Ac-Di-Sol	3.5	14	28	3.5	14	28	3.5	14	28
Avicel PH102	287.5	277	263	270	259.5	245.5	252.5	242	228
Talc	10	10	10	10	10	10	10	10	10
Mg.Stearate	4	4	4	4	4	4	4	4	4

Preparation of fast dissolving tablets of Domperidone was done by direct compression method using different drug: polymer ratio. The formulation was carried out in triplet.

EVALUATION OF FAST DISSOLVING TABLETS

Hardness: Hardness of FDT of each batch was determined using Monsento hardness tester.

Disintegration Test: Assessment of *in-vitro* disintegration time was carried out using USP- disintegration test apparatus. Disintegration time of both fresh and conditioned batches was measured. It uses 6 glass tubes that are open at the top, and held against a 10 mesh screen at the bottom end of the basket rack assembly which operates at a frequency of 28 to 32 cycles per minute. One tablet was placed in each tube and the basket assembly was positioned in 900 ml of water maintained at 37 ± 2ºC, in such a fashion that the tablets remain 2.5 cm below the surface of the liquid on their upward movement and descend not closer than 2.5 cm from the bottom of beaker. The end point of disintegration was manifested as the disappearance of the last tablet fragment from the tube.

Content uniformity: Twenty randomly selected tablets from each trial batch were weighed and powdered in a glass mortar pestle. The weight equivalent to 10 mg of DOM was taken and dissolved in 10 ml of methanol in volumetric flask. The volume was adjusted to 100 ml with 0.1 N HCl and the sample was centrifuged for 5 minutes. An aliquot of 2.5 ml of solution was taken and diluted to 10 ml with 0.1N HCl in separate volumetric flask. The absorbance of above sample was determined spectrophotometrically at 284 nm and content was determined using calibration curve.

RESULTS AND DISCUSSION

The results of hardness and disintegration observed with the formulated batches were satisfactory. Moreover, results obtained were as per prescribed in official monographs.

Table 2: Representation of Hardness and Disintegration Time

Formulation Code	Ac-Di-sol Concentration	Maltodextrin Concentration (% w/w)	Hardness (Kg/cm^2)		Disintegration Time (s)	
			0 Day	4th Day	0 Day	4th Day
FDT1	1	10	1	2±0.2	20.13±2.10	26.21±1.69
FDT2	4	10	1	2.2±0.1	19.73±2.18	24.78±1.37
FDT3	8	10	1	2.5±0.1	15.78±2.06	20.84±1.63
FDT4	1	15	1	2.8±0.2	30.43±1.07	33.04±1.83
FDT5	4	15	1	3±0.2	29.21±1.06	32.18±1.09
FDT6	8	15	1	3±0.2	26.66±1.49	30.41±1.48
FDT7	1	20	1	4.5±0.3	90±1.19	124.32±1.69
FDT8	4	20	1	5±0.1	52±1.42	108.02±1.30
FDT9	8	20	1	5±0.1	36±1.47	82.28±1.41

The cumulative drug release pattern was in accordance with the criteria as per specified for fast disintegrating tablets. Some batches too shows fluctuation from the normal trend which might be because of the inappropriate compression or manufacturing defect.

Table 3: Representation of Cumulative % drug Release Domperidone

Time (min)	Cumulative % Drug Release								
	FDT1	FDT2	FDT3	FDT4	FDT5	FDT6	FDT7	FDT8	FDT9
0	0	0	0	0	0	0	0	0	0
1	74.23± 0.17	76.43 ±1.21	77.34± 0.47	73.25± 0.24	76.77± 0.25	76.57± 0.13	30.29 ±0.33	35.35± 0.19	61.48± 0.33
2	79.70± 0.33	81.68 ±0.84	82.65± 0.23	80.79± 0.14	82.26± 0.93	85.36± 0.13	44.67 ±0.28	77.06± 0.44	78.57± 0.45
4	81.72± 0.25	87.20 ±0.64	91.49± 0.77	87.28± 0.17	92.87± 0.12	92.58± 0.21	85.62 ±0.28	87.21± 0.49	86.11± 0.13
6	90.87± 0.46	98.93 ±0.21	99.06± 0.19	92.85± 0.24	97.14± 0.17	98.45± 0.14	94.55 ±0.74	96.72± 0.38	93.61± 0.41
8	90.55± 0.13	98.71 ±0.38	98.11± 0.82	91.07± 0.31	96.08± 0.42	96.33± 0.70	92.59 ±0.43	94.48± 0.59	92.22± 0.29
10	90.70± 0.20	97.93 ±0.11	98.59± 0.93	91.16± 0.09	96.88± 0.28	96.92± 0.33	92.19 ±0.19	94.27± 0.20	92.24± 0.76
15	91.42± 0.64	98.56 ±0.39	98.49± 0.66	91.18± 0.24	95.98± 0.33	96.99± 0.80	92.22 ±0.33	92.29± 0.25	92.74± 0.55
20	91.94± 0.66	98.48 ±0.53	98.39± 0.73	90.85± 0.26	96.51± 0.65	97.17± 0.30	90.16 ±0.23	93.48± 0.33	92.87± 0.49
25	92.24± 0.71	98.40 ±0.72	98.44± 0.49	91.09± 0.23	95.08± 0.54	95.75± 0.90	92.02 ±0.32	94.67± 0.18	93.06± 0.28
30	93.79± 0.33	97.73 ±0.68	98.06± 0.50	91.32± 0.37	96.60± 0.54	97.41± 0.50	93.55 ±0.12	94.49± 0.66	92.67± 0.39

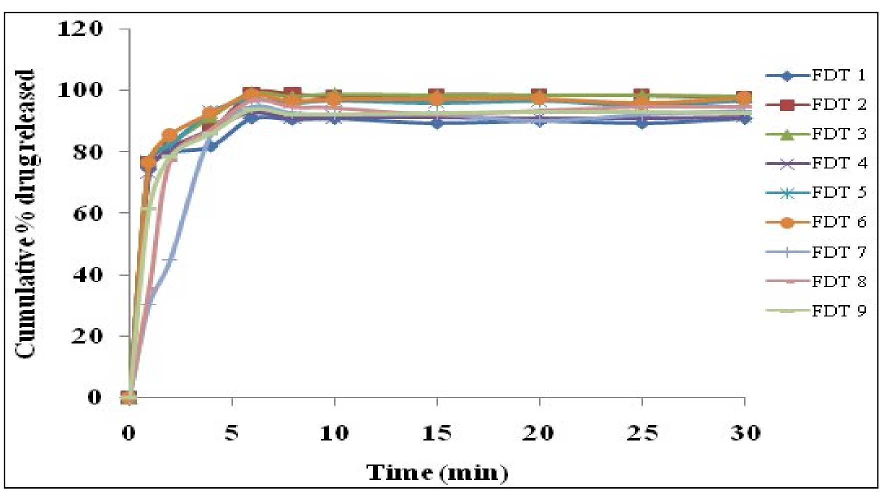

Figure 2: Graphical representation of Cumulative % drug Release Domperidone

CONCLUSION

The tablets of domperidone prepared using Maltodextrin showed excellent results. The triplet study too has strengthened the prospect. Further, some chances of modification are also possible which could be devised. The analytical evaluation of the prepared formulation could be applied for further investigation. The prepared formulation might be useful from technological point of view.

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