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Formulation and Evaluation of Oro-dispersible Tablets of Ondansetron Hydrochloride by Direct Compression Method

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Abstract

The main aim of this research paper is to formulate and evaluate Oro-dispersible tablets of OndasetronHCl by direct compression method. The oral route of drug administration is that the most vital method for administering drugs for systemic effects. For rapid dissolution of dosage, water must rapidly penetrate into the tablet matrix to cause quick disintegration and instantaneous dissolution may be a fundamental to formulate ODT. Oro-dispersible tablets of ondansetron hydrochloride are prepared by direct compression method. The formulation 75% of super disintegrate (i.e) Starch Glycolate and Cross Povidone, Ac Di Sol & Microcrystalline Cellulose pH102 has shown best release with 99.46% at the top of 30 minutes the bubbling mixture further assists in taste masking of Ondansetron hydrochloride. Consistent with IR studies there's no incompatibility shown. The formulation found stable at 40°C±2ºC and 75%RH±5%RH.

Key words: Oro dispersible tablets, Super disintegrates, Ondansetron hydrochloride, Direct compression

Introduction

Difficulty in swallowing (Dysphagia) is a common problem in all age groups, especially the elderly and pediatrics, because of physiological changes associated with these age groups. It is common to see those afflicted carrying a small device with them, which is used for crushing tablets, enabling easy ingestion. Other categories that experience problems using conventional oral dosage forms include are the mentally ill, uncooperative and nauseated patients, those with conditions of motion sickness, sudden episodes of allergic attack and coughing. Sometimes, it may be difficult to swallow conventional products due to unavailability of water. These problems led to the development of a novel type of solid oral dosage form called mouth-dissolving tablets, which disintegrate and dissolve rapidly in saliva without the need of the water. They are also known as fast dissolving tablets, melt-in-mouth tablets, rapimelts, porous tablets, orodispersible, quick dissolving or rapidly disintegrating tablets.

The freeze-drying approach produces the fastest dissolving tablets, but the process is expensive, and the resulting tablets are mechanically weak. The other most widely used method to manufacture these tablets is via regular compression that can produce tablets with higher mechanical strengths. The disintegration or melting time of the compressed tablets is not as fast as the freeze-dried dosage forms, but the compressed tablets provide many advantages, such as high mechanical strength facilitating their handling and processing.

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The technology of the compressed tablets is also making major improvements, producing tablets that can melt within several seconds in the mouth.
Recent advances in novel drug delivery system aims to provide rational drug therapy by enhanced safety and efficacy of drug molecule by formulating a convenient dosage form for administration and also by ensuring better patient compliance (2). One such approach is Oro Dispersible Tablets (ODTs). An ODT is a solid dosage form that disintegrates and dissolves in the mouth (either on or beneath the tongue or in the buccal cavity) without water within 60 seconds or less. The demand for ODTs has increased enormously during the last decade, particularly for geriatric and pediatric patients who have difficulty in swallowing conventional tablets and capsules (3) Research scientists have formulated ODTs of various categories of drugs like Antipyretic, analgesic, anti-inflammatory agents such as indomethacin, aspirin, diclofenac sodium, ketoprofen, ibuprofen, Antiulcer agents such as ranitidine, sulpiride, cetraxate hydrochloride, gefarnate, irsogladine maleate, Coronary vasodilators such as Nifedipine, isosorbidedinitrate, diltiazem hydrochloride, Peripheral vasodilators such as ifenprodil tartrate, cinepazide, Oral antibacterial and antifungal agents such as penicillin, ampicillin, amoxicillin, cefalexin, erythromycin, Synthetic antibacterial agents such as nlidixic acid, piromidicacid, pipemidic acid trihydrate, enoxacin, cinoxacin, Ofloxacin, norfloxacin, ciprofloxacin hydrochloride, Antitussive, anti-asthmatic agents such as theophylline, aminophylline, methylephedrine hydrochloride are used for therapy in which rapid peak plasma concentration is required to achieve desired pharmacological response.
Direct compression represents a simple and cost effective tablet manufacturing technique. Use of conventional equipment, commonly available excipients and limited number of processing steps are the advantages of this technique. Directly compressed tablet's disintegration and solubilization depends on single or combined action of disintegrants, water soluble excipients and effervescent agents. The commonly used superdisintegrants are croscarmellosesodiumcross linked carboxy
formulation ingredients such as water-soluble excipients and effervescent agents further hastens the process ofdisintegration.
Ondansetron hydrochloride is a selective 5-HT3 receptor antagonist. It is used in the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. It is also used for prevention of post-operative nausea and vomiting in adults. Ondansetron hydrochloride is well absorbed from the gastrointestinal tract and undergoes some first-pass metabolism. Mean bioavailability in healthy subjects, following administration of a single tablet, is approximately86%.
The objective of the present project was to prepare ODTs of ondansetron hydrochloride, because in the emesis condition as well as in above mentioned specific conditions, fast onset of action and avoidance of water is highly desirable. The tablets were prepared by direct compression method using sodium starch glycolate and cross povidone, Ac Di Sol & Microcrystalline cellulose pH102 as superdisintegrants. Pearlitol SD 200 was used as diluents, Starch 1500 used as a dry binder. The combination of these agents gives better disintegration of the dosage form and also does not adversely affect compressibility and flow-ability. Flavor peppermint premium selected due to its pleasant mouth feel property.

Material and Methods

Materials

Four super-disintegrating agents were used at lower concentration and medium and higher concentration. Eight formulations were designed. Sodium Starch Glycolate used in concentration of 5%, 7.5%, Cross Povidone 2.5%, 5%, Ac Di Sol 5%, 7.5%. Avicel pH102 (Microcrystalline cellulose pH102) 7.5%, 10%., which is also a super-disintegrant. Each formulation was composed of drug, Pearlitol SD 200 was used asdiluents, Starch 1500 used as a dry binder. This design technique was used to optimize and obtain a better formulation with respect to in vitro dispersion time. Refer Table1 for formulation details.

Methods

Ondansetron Hydrochloride, Superdisintegrants, Pearlitol SD 200, Starch1500, Sucralose, Magnesium Stearate, and Aerosil 200,

FlavorPeppermint Supreme mixed (Geometrically mixing) uniformly with all excipient. The resulting powder mixture was compressed into tablets compression machine.

Table: 1 Formulation composition

Tablet ingredients(mg)	F1	F2	F3	F4	F5	F6	F7	F8
Drug	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12
Sodium starch glycolate	7.5	11.25	-	-	-	-	-	-
Crospovidone	-	-	3.75	7.5	-	-	-	-
AC-DI-SOL	-	-	-	-	7.5	11.25	-	-
Avicel pH102	-	-	-	-	-	-	11.25	15
Pearlitol SD 200	111.88	108.13	115.63	111.88	111.88	108.13	108.13	104.38
Starch 1500	20	20	20	20	20	20	20	20
Flavor peppermint premium	3	3	3	3	3	3	3	3
Sucralose	3	3	3	3	3	3	3	3
Magnesium stearate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Aerosil 200	2	2	2	2	2	2	2	2
Total wt of tablet	150	150	150	150	150	150	150	150

Evaluation of powder granules

Organoleptic properties

Color taste & odor was checked on illuminated place with the help of tongue as well as smelled to get the order.

Loss on drying

Determine on 1.000 g by drying in an oven at 100°C to 105°C for 3 hours

Bulk density

Apparent bulk density (g/ml) was determined by placing pre-sieved bulk powder blend into a graduated cylinder via a large cylinder and measuring the volume and weight "as it is".

Tapped density

It was determined by placing a graduated cylinder, containing a known mass of powder on mechanical tapping apparatus, which was operated for fixed number of taps (around 1250) until the powder bed volume reached a minimum. Using the weight of powder in a cylinder and this minimum volume, the tapped density was computed (15). From the results of bulk density and tapped density, Carr's index was calculated.

Flow properties (Angle of repose)

For the measurement of angle of repose, a glass funnel was secured with its tip at a given height (H) above a piece of graph paper placed on a horizontal surface. Powder was poured through the funnel until the apex of the conical pile touched the tip of the funnel. The angle of repose was calculated with the formula tan a = H/R, where a is the angle of repose and R is the radius of the conical pile (15).

Compression of tablets

The powder blends prepared for different batches were compressed into flat tablets, 80 mg in weight, and 8.0 mm in diameter, by using rotary tableting machine.

Evaluation of tablets

Uniformity of weight (Weight Variation)

Twenty tablets were selected at a random and average weight was determined. Then individual tablets were weighed and the individual weight was compared with an average weight.

Friability

Friability of tablets was measured by using Roche Friabilator (16) (Electrolab, Mumbai, India). Friability was evaluated from the percentage weight loss of 20 tablets tumbled in a friabilator at 25 rpm for 4 minutes. The tablets were dedusted, and the loss in weight caused by fracture or abrasion was recorded as the percentage weight loss. Friability below 1% was considered acceptable.

In-vitro dissolution

The disintegration time was measured using the assembly utilizes dissolution apparatus USP 2 paddle apparatus (Make Electrolab). The vessel

was filled with 500 ml of water maintained at 37 °C. The paddle was rotated at 50 revolutions per minute. The tablet was placed inside the sinker and the time at which it passes completely through the mesh of sinker was taken as the disintegration of the tablet.

Wetting time

The wetting time of the tablets was measured using a simple procedure. Five circular tissue papers of 6.5-cm diameter were placed in a petri dish with a 6.5cm diameter. containing 6ml of water. A tablet was carefully placed on the surface of tissue paper. The time required for water to reach the upper surface of the tablets was noted as the wetting time.

Results and Discussion

The present experiment was undertaken to formulate and evaluate oro dispersible tablets of ondansetron hydrochloride by direct compression method using direct compression method using sodium starch glycolate and cross povidone, Ac Di Sol & Microcrystalline cellulose pH102 as superdisintegrants. Pearlitol SD 200 was used as diluents, Starch 1500 used as a dry binder. The primary requirement for both dosage forms is quicker disintegration. The results obtained by evaluating the powder blends of drug and excipients is shown in Table 2. The two most important attributes for the direct compression formula are good flow and good compressibility (21). The values obtained for bulk density and tapped density does not affect the compression of tablets. The angle of repose gives important information about the flow characteristics of the powder mixture. The powder flow depends on three general areas: the physical properties of the particle (e.g., shape, size, compressibility), the bulk powder properties (e.g., size distribution, compaction); and the processing environment (e.g., storage, humidity). The Hausner ratio (1.55) indicates free flowing material and can be used for direct compression. The value for compressibility index found 35.55%, indicating that all the batches of powder blends were having good compressibility.

Table 2: Evaluation of Powder Blends of Ondansetron HCl and Excipients

Batch code	Bulk density	Tapped density	Angle of repose	Carr's Index	Hausner's Ratio.
F1	0.46	0.54	25.28	14.81	1.17
F2	0.44	0.53	24.35	16.91	1.20
F3	0.47	0.56	26.18	16.07	1.19
F4	0.45	0.53	24.53	15.09	1.17
F5	0.43	0.50	23.73	14.00	1.16
F6	0.46	0.52	25.80	15.38	1.13
F7	0.43	0.51	26.32	15.68	1.18
F8	0.42	0.50	25.21	16.00	1.19

Table 3: Evaluation of ODTs of Ondansetron HCl

Batch code	Weight variation	Thickness (mm)	Hardness	Friability (%)	In vitro Disint. Time	Wetting Time (secs)	Assay (%)	In vivo Dispersion Time
F1	Pass	2.93	2.2	0.21	35	34	98.62	31
F2	Pass	2.96	2.4	0.22	27	31	99.06	29
F3	Pass	2.91	2.3	0.24	25	32	98.78	28
F4	Pass	2.30	2.1	0.28	24	31	100.21	27

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F5	Pass	2.98	2.2	0.30	21	30	99.39	25
F6	Pass	3.0	2.6	0.31	22	33	99.88	30
F7	Pass	3.1	2.3	0.33	20	29	100.03	27
F8	Pass	2.95	2.4	0.39	19	26	99.98	23

The data are expressed as mean±S.D.(*n*=3)

Table 4: Percentage cumulative drug release profile of batch F1-F8

Table 4: Percentage cumulative drug release profile of batch F1-F8

Time	% Drug Release							
	F1	F2	F3	F4	F5	F6	F7	F8
2	77.22±2.46	79.23±1.32	88.25±0.94	89.25±2.8	81.22±0.32	89.41±1.21	82.41±0.30	84.41±0.98
4	93.72±0.91	94.79±1.56	92.01±1,36	95.01±2.18	91.72±1.13	94.88±0.53	93.69±1.63	94.25±0.88
6	96.33±1.94	96.29±1.65	95.13±2.06	97.13±1.69	93.33±0.73	97.30±0.33	94.30±1.02	96.32±0.47
8	97.73±2.53	96.88±2.14	97.35±0.53	98.35±1.87	96.73±0.86	98.73±0.73	97.73±0.81	96.99±0.60
10	98.03±2.52	97.71±1.97	98.11±1.78	99.45±2.68	98.70±1.03	99.05±1.13	98.91±0.61	99.02±0.54

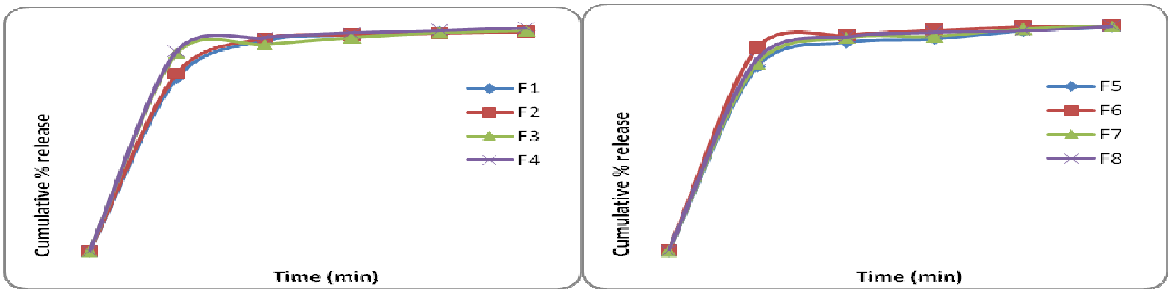

Fig. 1: *In vitro* drug release

Table 5: Percentage cumulative drug release profile of marketed Tablet

Time (min)	% Drug Release		
	F4	Time (min)	Granicip
2	89.25±2.8	5	46.71±1.94
4	95.01±2.18	10	55.23±2.4
6	97.13±1.69	15	67.27±2.11
8	98.35±1.87	20	78.09±1.88
10	99.45±2.68	30	90.18±0.99
		45	99.16±1.92

Table 6: Similarity factor in dissolution between best formulation F4 and other formulations

S.no.	Formulations	Similarity factor (%)
1	F1	91.44
2	F2	90.11
3	F3	82.63
4	F5	77.28
5	F6	99.08
6	F7	86.07
7	F8	93.51

The results for evaluation of different batches of ondansetron hydrochloride ODTs prepared by direct compression method are shown in Table 3. Percent weight variation was well within the acceptable limit for uncoated tablets as per Indian Pharmacopoeia. One of the primary requirements

of immediate release preparation is faster disintegration. It is well known to formulation scientists that the tablets with higher crushing strength show longer disintegration time. Since mechanical integrity is of paramount importance in successful formulation of ODTs, hence the hardness of tablets was determined and wasfound to be in the range of 2.1 to 2.6 Kg/cm . Friability was observed between 0.21 to 0.39%, which were below 1%.indicating sufficient mechanical integrity and strength of the prepared tablets. Thus, hardness and friability data indicates good mechanical resistance of tablets. In vitro and in vivo disintegration time for different batches of ODTs was 20 to 31 seconds and 27 to 31 seconds respectively. The tablet formulations containing Pearlitol SD 200 and Crosspovidone at ≈ 80% concentration showed higher values of 52 to 70 seconds for in vitro and in vivo disintegration time. The in vitro and in vivo disintegration time for formulations containing super disintegrates in combination was observed to be 23 to 27 seconds. This result of in vitro and in vivo disintegration time indicates that the batch F4 found best formulation. Hence the batch F4 was used for further studies like wetting time, wetting volume, dissolution profile studyDissolution profile with 6.8 phosphate buffer & market preparation shows 99.45 % drug release at 10 minutes' compare to 99.16% at 55 minutes against the marketed product.

Stability studies results (ACC conditions) for 3 months was performed and found no impact on physical and drug release. The dissolution data shows result 98.22 at 10 minutes.

Conclusion

Oro dispersible tablets of ondansetron hydrochloride were prepared by direct compression method using Pearlitol SD 200 and Cross povidone as superdisintegrants. The tablets disintegrated rapidly in oral cavity and had acceptable hardness and friability. In vitro drug release from the tablets shows significantly improved drug dissolution. Hence it could be concluded that the superdisintegrant based oro dispersible tablets of ondansetron hydrochloride would be quite effective in emesis, providing quick onset of action without need for water for swallowing or administration.

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