Research Article **Namdev & Agrawal, 10(1): Jan., 2019:6020-6024]**
CODEN (USA): IJPLCP ISSN: 0976-7126

INTERNATIONAL JOURNAL OF PHARMACY & LIFE SCIENCES
(Int. J. of Pharm. Life Sci.)

Formulation and Evaluation of Mouth Dissolving Tablets of Ondansetron Hydrochloride

Chetan Namdev*and Shikha Agrawal
Department of Pharmaceutics,
Swami Vivekanand College of Pharmacy, Indore, (M.P.) - India

Abstract

The present work was designed to formulate and evaluate Mouth dissolving tablets of ondansetron hydrochloride by direct compression technique. Mouth dissolving tablets were prepared by direct compression method using superdisintegrants like crospovidone (CP), croscarmellose sodium (CCS), sodium starch glycollate (SSG) and combination of super-disintegrates in different concentrations. The prepared formulations were evaluated for the pre-compression parameters like bulk density, tapped density, Carr's compressibility, Hausner's ratio and angle of repose. The prepared batches of Mouth dissolving tablets of ondansetron hydrochloride were evaluated for hardness, weight variation, thickness, friability, drug content, disintegration time, wetting time, water absorption ratio, and *in vitro* dissolution profile. The ondansetron hydrochloride formulation were within the acceptance limit .and release rate of all prepared ondansetron hydrochloride were distinctly higher as compared to pure drug. All the Preformulation parameter were evaluate such as organoleptic characterization of the drug sample, melting point , pH, identification of drug sample by using UV spectroscopy and FTIR analytical methods. Preparation of Calibration curve , solubility studies of drug sample like quanlitive, quantitative and pH-depended solubility of the drug in a buffer solution. All Pre-compression parameter like Bulk density and Tapped density, Angle of repose were found in the range of 0.412–0.433 g/cc and 0.508–0.534 g/cc ,26.47^0 to 29.45^0 respectively. In all formulations & Evaluation post compression parameter like, Tablet weight variation and thickness were within mean±7.5% and mean±5% respectively. Wetting time values lie between 19.50 to 35.70 sec. Water absorption ratio ranged from 76.66 to 91.66 %. The *in vitro* disintegration time for all the 10 formulations varied from 21.24 to 41.22 seconds. Formulation F10 which contained crosspovidone have recorded drug release 99.98±0.06% at the end of 30 min. The formulation containing Sodium Starch glycollate, Crosscarmellose cellulose & crospovidone (F10) showed better performance in terms of disintegration time and drug release when compared to other formulations.

Keywords: Formulation, Ondansetron Hydrochloride, Anti-emetic, Direct compression

Introduction

Some tablet are designed to dissolve in saliva remarkably fast, within a few second, and are true Mouth dissolving tablet other contain agent to enhance the rate of tablet dissolve in the oral cavity. and are more appropriately termed Mouth dissolving tablet as they may take up to a minute to completely dissolve, when put on tongue, this tablet dissolving instantaneously, releasing the drug, which dissolve in the saliva, some drug are absorbed from the mouth, pharynx, and esophagus as the saliva passes down into the stomach.[1-2]

*** Corresponding Author**
E.mail: chetan.namdev1992@gmail.com

Mouth dissolving tablets are include like sweetener and flavor, however, orally dissolving tablets can also be called as Mouth dissolving tablets. Mouth dissolving tablets are also known as "Fast-dissolving", "Mouth-dissolving", "Rapid dissolve", "Quick-disintegration", "Orally disintegrating", "Ondansetron Hydrochloride", "Fast-melt", "Orodispersible", "Melt-in-mouth", "Quick dissolving", "Porous tablets" "freeze dried wafers", "mouth dissolve" and "Effervescent drug absorption system".[2] The Center for Drug Evaluation and Research (CDER), US FDA defined Mouth dissolving Tablets (MDTs) as "A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue." A Mouth dissolving drug delivery system, in most cases, is a tablet that dissolves or disintegrates in the oral cavity without

the need of water. These are also called melt-in-mouth tablets; repi melts, porous tablets, oro-dispersible, quick dissolving or rapid disintegrating tablets. The present work was aimed to develop mouth dissolving tablets of ondansetron hydrochloride.

Material and Methods

Materials

Ondansetron hydrochloride was as gift sample from Alkem Laboratories Ltd, (Mumbai India) Microcrystalline cellulose, Signet Chemical Ltd.) Crospovidone, Magnesium stearate, Pregalitinised starch were purchased from Sneha chemical Pvt Ltd. Gujarat) Sodium sachaarine, Mannitol, Lactose, Kerin life science Pvt. Ltd. (Alwar). Crosscarmellose cellulose, Sodium Starch glycollate, was obtained from SDFCL Pvt Ltd. Mumbai.

Preparation method[3]

Direct compression method

All the required ingredients were passed through 60 mesh to get uniform size particles and weighed accurately. Drug, mannitol, super disintegrates except lubricant were mixed in the increasing order of their weights in a mortar. To this mixture talc and magnesium stearate were added. The final mixture was shaken manually for 5-10 min in a plastic bag. This powder was passed through the hopper of 10 station rotary tablet machine and punched into tablets using 10 mm s/c.

Evaluation

Different quality control tests were performed for all the Mouth dissolving tablet formulations to check whether these have met the specifications along with other *In vitro* tests like wetting time and water absorption ratio as per standard protocols[4-5].

Results and Discussion

The results of the preformulation studies indicate that the drug is white crystalline powder, sparingly soluble in water, ethanol, Dichlomethane and soluble in methanol. 0.1 gm of ondansetron hydrochloride dissolved in 10 ml water, pH of the solution was found to be 3.45. The partition coefficient of Ondanstron Hydrochloride was determined in n-octanol: water system.The drugs accurately weight (10mg) and added to 10ml each of n-octanol and aqueous phase. Mixture was shaken and then separated by separating funnel. Aqueous phase was analyzed for amount of drug after appropriate dilution by using UV spectrophotometer. The detailed results are mentioned in table 1.The present analytical method obeyed Beer's law in the concentration range of 2–10 µg/ml and is suitable for the estimation of ondansetron hydrochloride from different solutions. The correlation coefficient (r) value for the linear regression equation was found to be 0.998, indicating a positive correlation between the concentration of ondansetron hydrochloride and its corresponding absorbance values (Fig 1 & 2).

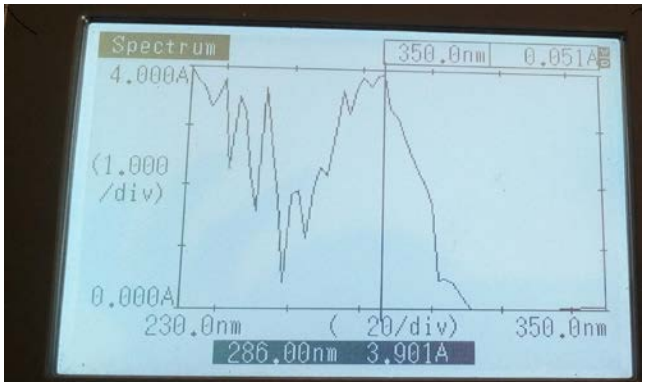
The FTIR spectrum of pure odansetron hydrochloride (Fig. 3) show a peak at 3346.79 cm -1 which is attribute to the N-H and NH_2 stretching and peak at 1469.79 cm-1 – 1490.97 cm-1. Are due to C=C aromatic and aliphatic stretching. Peak at 1381.03 is due to C=N vibration, peak at 1049.28 cm-1 is due to –OH bending confirmation presence of alcoholic group, peak at 702.09, 763.81 and 798.53 cm-1 confirm the C-H bending (aromatic). The results of Pre-formulation were presented in table 2, whereas the evaluation parameters results along with the % drug release were mentioned in table 3,4 & 5.

Table 1: Formulation consideration of mouth dissolving tablets of Ondansetron Hydrochloride

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Ondansetron HCL	4	4	4	4	4	4	4	4	4	4
Lactose	36	36	36	36	36	36	36	36	36	36
Mannitol	20	20	20	20	20	20	20	20	20	20
Microcrystalline cellulose	90	75	60	90	75	60	90	60	75	60
Crosspovidone	16	16	16	16	16	16	16	16	16	16
Cross Carmellose sodium	15	30	45	-	-	-	15	30	-	45
Sodium Starch Glycollate	-	-	-	15	30	45	-	15	30	-
Magnessium Stearate	7	7	7	7	7	7	7	7	7	7
Talc	1	1	1	1	1	1	1	1	1	1
Starch	4	4	4	4	4	4	4	4	4	4
Sodium Saccharin	7	7	7	7	7	7	7	7	7	7

Table 2: Pre-formulation Observations for Ondansetron Hydrochloride

Test	Observation	Specification
Description	White powder	A white off white crystalline Powder
Identification	Complies	BY UV & IR
Solubility	Complies	Sparingly soluble in water
pH determination	3.45	3.0 to 4.0
Melting Point	179°C	178°C to 179°C
Partition Coefficient	0.88	0.85 to 0.89



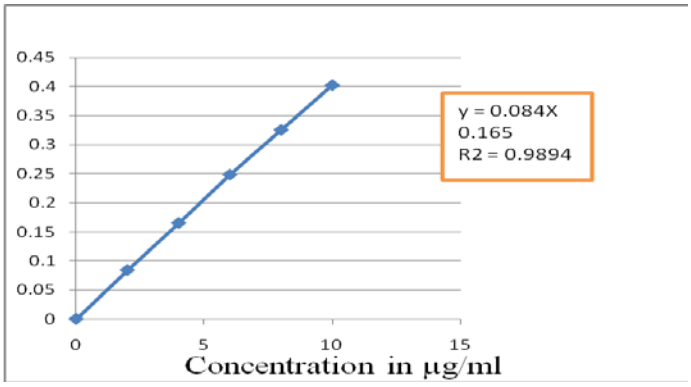


Fig. 1: UV Spectrophotometer of Ondansetron Hydrochloride Fig. 2: Standard curve calibration of Ondansetron Hydrochloride

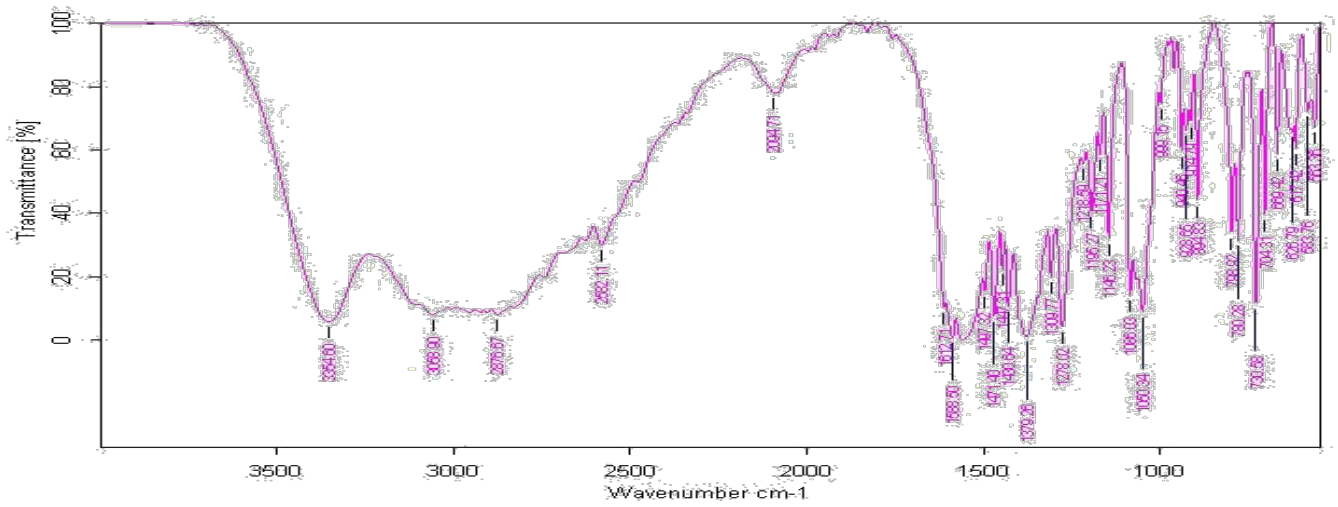


Fig. 3: FTIR spectra of Ondansetron Hydrochloride

Table 3: Pre-Compression Parameter characteristics of Ondansetron Hydrochloride of Mouth dissolving tablets by direct compression technique

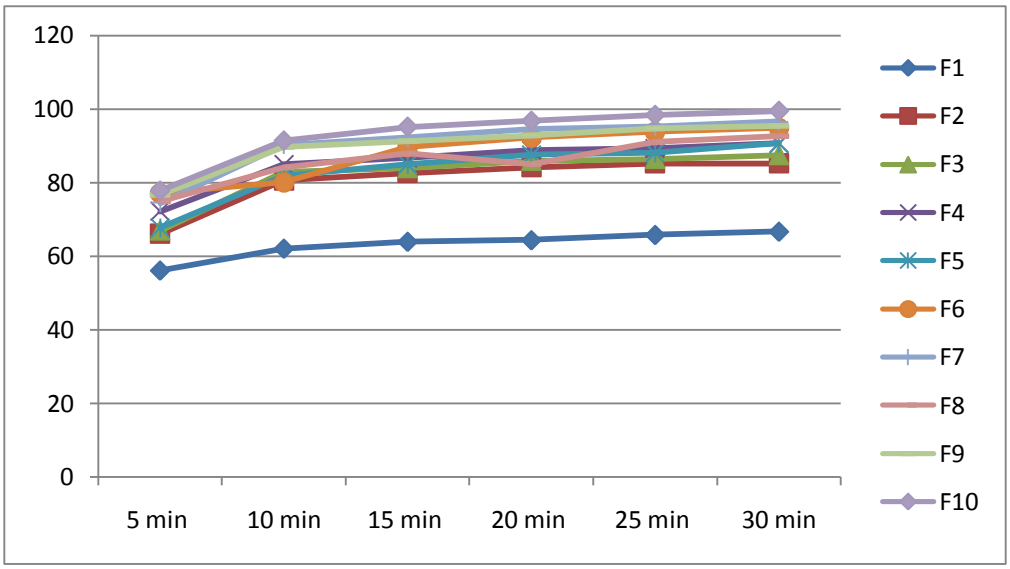
Formulation	Bulk density(g/cc)	Tapped density(g/cc)	Hausner's ratio	Compressibility index (%)	Angle of repose (Θ)
F1	0.412	0.529	1.21	16.30	27.28
F2	0.419	0.523	1.20	17.55	29.29
F3	0.432	0.510	1.23	17.31	28.12
F4	0.429	0.534	1.20	17.65	28.43
F5	0.420	0.522	1.24	17.75	29.45
F6	0.433	0.516	1.22	17.45	28.12
F7	0.431	0.529	1.22	17.46	27.65
F8	0.430	0.522	1.23	16.25	28.48
F9	0.425	0.513	1.20	16.65	29.44
F10	0.428	0.508	1.20	16.75	26.47

Table 4: Post-Compression Parameter characteristics of Ondansetron Hydrochloride of Mouth dissolving tablets by direct compression technique

Codes	Weight (mg)	Drug Content %)	Hardness (kg/cm2)	Friability (%)	Thickness (mm)	Disintegration time (sec)	Wetting time (sec)	Water absorption ratio (%)
F1	200.4	95.56	3.40	0.55	3.35	34.64	35.70	76.66
F2	200.2	96.01	3.23	0.52	3.34	41.22	32.70	78.22
F3	200.1	98.12	3.26	0.45	3.34	31.34	29.41	81.36
F4	200.3	99.56	3.30	0.42	3.32	30.41	28.73	85.72
F5	200.1	98.24	3.33	0.48	3.31	28.22	25.75	86.30
F6	200.3	97.99	3.52	0.51	3.34	38.54	21.41	88.36
F7	200.2	98.46	3.12	0.48	3.32	35.43	19.50	89.36
F8	199.9	99.70	3.16	0.46	3.33	24.22	22.74	90.71
F9	200.2	98.31	3.20	0.44	3.34	29.41	25.70	89.45
F10	200.1	99.98	3.28	0.40	3.32	21.24	24.45	91.66

Table 5: *In-Vitro* drug release Cumulative percent Ondansetron Hydrochloride from optimized formulation (F10) by direct compression method Cumulative % drug release

Formulation Code	% *In-Vitro* Drug release					
	5 min	10min	15 min	20 min	25 min	30 min
F1	56.15	62.08	62.95	64.37	65.80	66.69
F2	66.14	80.60	82.66	84.19	85.18	85.63
F3	66.98	82.94	83.92	85.46	86.45	87.45
F4	72.19	84.63	86.71	88.80	89.27	90.28
F5	67.80	81.78	84.94	87.57	88.03	90.67
F6	77.15	80.07	89.63	92.28	93.85	94.89
F7	74.47	90.26	92.26	94.50	95.00	96.59
F8	74.98	84.21	87.93	84.48	91.04	92.61
F9	76.65	89.74	91.31	92.88	94.46	95.50
F10	77.78	91.45	95.20	96.79	98.39	99.49



Graph 1: Drug release profile of the formulation

Conclusion

Hence in the present work it confirms the structure of drug ondansetron hydrochloride, from examination of the recorded FTIR spectra data. It can be seen that all the characteristic peak of the drug are also seen in the FTIR spectra of the physical mixture and some peak were observed with physical mixture, which could be attributed to the presence of polymer. These results indicate that there is no interaction between the drug and polymer taken up for the investigation.

The formulation F10 containing Crosscarmellose cellulose sodium and sodium starch glycollate showed the MDT's with fast drug release as compared to the other formulation. Mouth dissolving tablet of ondansetron hydrochloride is prepared by direct compression method. The formulation F10 containing 10% of superdisintegrant (i.e) Cross carmellose sodium has shown best release with 99.49% at the end of 30 min. The effervescent mixture further assists in taste masking of ondansetron hydrochloride.

Acknowledgements

I am grateful to Dr .P.K Dubey (Principal, SVCP Indore) providing all the research facilities.

References

1. Abay F.B. and Ugulu T. Goyal S. Soni A. (2017). Ondansetron Hydrochloride Mouth dissolving tablet, International Journal of Pharmaceutical science & Drug Research:,9(5) 240-246.
2. Kumar Vivek, and patel Anil, Mishra Manoj.(2016). Formulation and evaluation of mouth dissolving tablet of Lecocetrizine Dihydrochloride tablet, A international journal of science and research Volume7. Issue 6.
3. Sharma, Shah, & Mehta A.K., Ghadge, (2015) design and formulation and evaluation of fast dissolving tablet of Lornoxicam as methods." 5 Volume 7, issue 2., 631-642.632-639.
4. Pandey S,(2014) formulation & evaluation of Nimesulide fast dissolving tablet by direct compression methods. Interational journal of pharmaceutical science and research :88-12.
5. Guatam SP. Rai JP, Billashaiya Uma, Jain Nilesh.(2013)..Design formulation and evaluation of mouth dissolving tablet of loperamide. International journal pharma-ceutical science and research volume.4,issue 5.

How to cite this article

Namdev C. and Agrawal S. (2019). Formulation and Evaluation of Mouth Dissolving tablets of Ondansetron Hydrochloride. *Int. J. Pharm. Life Sci.*, 10(1):6020-6024.

Source of Support: Nil; Conflict of Interest: None declared

Received: 06.12.18; Revised: 24.12.18; Accepted: 22.01.19