Research Article

DESIGN AND DEVELOPMENT OF TASTE MASKED ORAL DISINTEGRATING TABLET OF ONDANSETRON HYDROCHLORIDE

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ABSTRACT

Ondansetron HCl is effective in the treatment of nausea and vomiting caused in such condition it is difficult to administer drug with a glass of water; hence it is beneficial to administer such drugs as orodispersible. Thus in the present study an attempt has been made to mask the taste of Ondansetron HCl and to formulate orodispersible with good mouth feel so as to prepare a “patients friendly dosage form.” The tablets prepared by sublimation method. The prepared tablets were evaluated for various pharmaceutical characteristics such as hardness, % friability, weight variation, drug content all the results were within the IP. Limit. The tablets prepared possess a weight variation in the range 99 to 101 mg which is below $\pm 7.5\%$, hardness of 2.7 to 3.0 kg/cm², percentage friability of 0.42 to 0.73%. The wetting time of Ondansetron HCl fast dissolving tablets was found to be in the range of 44 to 81 sec. The prepared formulations shows water absorption ratio in the range of 72 to 85%. The percentage drug content of the tablets were found to be between 98.24 to 101.20% of Ondansetron HCl. *In-vitro* disintegration time the formulations OHS4 and OHS8 were found to be promising and showed a 28 sec and 32 sec respectively. Based on the *in-vitro* disintegration time and dissolution studies formulations OHS4 and OHS8 were found to be promising and showed a disintegration time of 28 sec and 32 sec respectively. Formulation OHS4 containing camphor showed highest drug release 99% within 8 min. Formulation OHS8 showed highest drug release 90% within 8 min. From FTIR and DSC study results reveals that there is no interaction between drug and any other formulation excipients. In case of stability study there is decrease in disintegration time, wetting time was observed. The results concluded that fast dissolving tablets of Ondansetron HCl showing enhanced dissolution will lead to improved bioavailability and effective therapy. This drug resin complex was compressed in tablets by adding diluents to see its mouth feel properties and bitter taste is masked.

Key words: Fast dissolving tablets, Ondansetron Hydrochloride, superdisintegrants, sublimation Method.

INTRODUCTION

Fast dissolving dosage form can be disintegrated, dissolved or suspended by saliva in mouth. The fast dissolving tablets disintegrates instantaneously when placed on tongue and releases the drug dissolve or disperses in saliva¹. The fast dissolving tablets are useful in patients²⁻³, like pediatric, geriatric, bedridden or mentally disabled, who may face difficulty in swallowing conventional tablet or capsule⁴ leading to ineffective therapy⁵. Most pharmaceutical forms for oral administration are formulated for direct ingestion or for chewing or for prior dispersion/dissolution in water. Some of them are absorbed in mouth to obviate the problem associated with conventional dosage forms orally fast dissolving tablet have been developed which combine hardness, dosage uniformity, stability and other parameters, since no water is required for swallowing the tablets and they are thus suitable for geriatric, pediatric and traveling patients⁶. The fast dissolving tablet formulation is defined by the food and drug administration (FDA) as, A solid dosage form containing medicinal substances which disintegrates rapidly, usually within matter of seconds, when placed upon the tongue⁷. These FDT are designed to dissolve or disintegrates rapidly in saliva generally within <60 sec⁸.

antagonist which has a role in prophylaxis of postoperative chemotherapy/radiotherapy induced emesis. The adult dose is 8 mg⁹. This makes Ondansetron HCl a suitable candidate for fast dissolving dosages form. Half life of Ondansetron Hydrochloride is 4-6 hrs and undergoes extensive first pass metabolism, Oral Ondansetron Hydrochloride appear efficacious and has been shown to have some clinical advantages over aspirin and ibuprofen⁹. Ondansetron HCl oral bioavailability is about 90% in healthy volunteers when taken with food, which increases absorption by more than 50%. Peak plasma concentration occurs in 2.5-5 hrs¹⁰. Hence, in the present research work Ondansetron Hydrochloride fast dissolving tablets were prepared by Sublimation technique by using different subliming agents like camphor, urea and menthol¹¹. Ondansetron HCl orodispersible tablets with good mouth feel so as to prepare patients friendly dosage form.

MATERIALS AND METHODS

Ondansetron Hydrochloride drug is procured as a gift sample from Dr Reddy Lab Hyderabad, India. Crosspovidone was procured as a gift sample from Signet (Mumbai), Mannitol, MCC, aspartame, camphor, urea, menthol, talc and magnesium stearate purchased from SD. Fine chem., Mumbai. All other materials were of analytical reagent grade.

Ondansetron HCl is a potent selective serotonin 5HT₃ receptor

Drug-excipients compatibility studies: Fourier Transform Infrared Spectroscopy (FTIR) and Differential Scanning Colorimetry.

Solubility Study: The solubility of Ondansetron HCl was determined in water and different pH buffers. The solubility study was conducted by taking excess amount of the drug in the 100 ml of the solution and the solutions were kept for 28 hr. Then the solutions were filtered and diluted with sufficient amount of the same solvent. The absorbance of the solutions was determined at 249 nm.

Methods of preparation of Ondansetron hydrochloride fast dissolving tablets¹²⁻¹³

Preparation of drug resin complex: An accurately weighed amount of resin particles (Kyron-T-154) were suspended in deionized Water for 15 min. to allow uniform swelling of polymer, after which Ondansetron HCl was added and slurry was stirred with the help of Magnetic stirrer for 45 min to allow the maximum adsorption of drug on to the resin. Resinate thus

formed was filtered and washed with deionized Water. It was then dried at 50°C and the drug content was determined Spectrometrically at 249 nm.

Sublimation method: The basic principle involved in preparing fast dissolving tablets by sublimation technique is inert solid subliming ingredients (Camphor, urea, menthol) were added to other tablet excipients and the blend was compressed into tablet. Removal of volatile material by sublimation generates a porous structure. Compressed tablets have been prepared by sublimation technique. The tablets dissolve within 20-30 secs and exhibit sufficient mechanical strength for practical use. Twelve formulations were developed by varying concentration of different subliming agent. Accurately weighed ingredients were sifted through sieve no.44 and thoroughly mixed for 10 min and magnesium stearate and other ingredients were added to the blend and thoroughly mixed. The tablets were compressed using Rimek tablet punching machine. The compressed tablets were then subjected to sublimation by keeping the tablets in vacuum dryer at 60°C for 3 hrs. The compositions of the tablets were given in **Table 2**.

Figure 1: Schematics figure of Sublimation method for design of Mouth dissolving tablets

Micromeritic properties of powder blend of tablets before compression: The resultant blends were evaluated for pre-compressional parameters to find out the flow properties of powder blend. The pre-compressional parameters such as Bulk density, Tapped density, Angle of repose, Compressibility index and Hausner ratio.

Evaluation of Ondansetron HCl Fast Disintegrating Tablets
The prepared tablets were subjected to post-compression analysis done according to specification given in IP 1996 for the parameters such as hardness, friability, weight variation, drug content, The *in-vitro* disintegration time, wetting time and *in-vitro* dissolution studies.

Hardness: Hardness of the tablet of each formulation was determined using Pfizer hardness tester.

Friability: Tablet Friability was measured using Roche Friabilator according to specification given in IP 1996. This device subjects the tablets to the combined effect of abrasions and shock in a plastic chamber revolving at 25 rpm for 4 min. The tablets were dedusted, and the loss in weight caused by the fracture and abrasion was recorded as the % weight loss. Friability below 1% was considered acceptable.

Weight variation: The tablets were selected randomly from each formulation and weighed individually to check for weight variation. In all the formulations the tablet weight was more than 130mg and less than 324 mg, hence 7.5% maximum difference allowed.

Uniformity of drug content: A tablet was crushed and dissolved in 1 ml of dilute hydrochloric acid and 30 ml of distilled water. This solution was shaken for 15 min. the volume of this solution was made up to 50 ml with distilled water and

centrifuged. Five ml of the clear supernatant was mixed with 10 ml of 0.1 M HCl, and made up to 100 ml with distilled water. The absorption of the solution was determined spectrophotometrically at 249 nm. The same procedure was followed for another nine tablets.

Disintegration time: Disintegration of fast dissolving tablets is achieved by saliva in the mouth, however amount of saliva in the mouth is limited and no tablet disintegration test was found in USP and IP to simulate *in vivo* condition. The disintegration time was measured using a modified disintegration method. According to this method, a Petri dish of 10 cm diameter was

filled with 10 ml of distilled water, the tablet was carefully placed at the centre of the Petri dish, and the time necessary for the complete disintegration of the tablet into fine particles was noted as disintegration time¹⁴.

Wetting time¹⁵: The method was applied to measure tablet wetting time. A piece of tissue paper folded twice was placed in a small petri dish (i.d = 6.5 cm) containing 10 ml of water, a tablet was placed on the paper, and the time for complete wetting was measured. Three trials for each batch were performed and standard deviation was also determined.

Figure 2: Simple method for the measurement of wetting time of a tablet

Dissolution studies¹⁵: Tablet test condition for the dissolution rate studies were used according to USP specification using USP 24, type II apparatus. The dissolution medium was 900 ml of 0.1 N HCl (pH 1.2). The temperature of the dissolution medium and the rate of agitation were maintained at $37 \pm 0.5^\circ\text{C}$ and 50 rpm respectively. Aliquots of 10 ml of dissolution medium were withdrawn at specific time interval and the volume replaced by fresh dissolution medium, pre-warmed to $37 \pm 0.5^\circ\text{C}$. The drug concentration was determined spectrophotometrically at 249 nm using UV spectrophotometer (Shimadzu S 1700, Japan).

Stability studies: The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity, light and enables recommended storage conditions. In the present study, stability studies were carried out as per ICH guidelines at $45^\circ\text{C}/75 \pm 5\% \text{ RH}$ and $25^\circ\text{C}/75 \pm 5\% \text{ RH}$ for a specific time period up to 3 months.

RESULTS AND DISCUSSIONS

Fast dissolving tablets of Ondansetron HCl were prepared by sublimation technique using subliming ingredients (Camphor, urea, menthol). Removal of volatile material by sublimation generates a porous structure. Compressed tablets have been prepared by using superdisintegrant like Crospovidone along with Mannitol and aspartame which serve as a sweetening agent. Drug resin complex help in masking bitter taste of the drug.

Solubility study: The solubility studies of Ondansetron Hydrochloride in water/buffer solutions were carried out to know the solubility and decide the appropriate dissolution medium. Table 1 shows the solubility data of Ondansetron HCl in water/ buffer solutions. In this study acidic buffer pH 1.2(1.2 pH 0.1 N HCl) was used as dissolution media as it can maintain perfect sink conditions. The solubility data for the drug in

various buffers and water are shown in Table 1.

Taste evaluation: Taste evaluation was performed on six healthy human volunteers and the results were reported in the Table 3. The pure drug was felt bitter immediately after it was kept on the tongue and the sense was even carried up to 5 min. However the bitterness of the drug was reduced or even masked after complexation with Kyrion T134 in different ratios (1:0.5, 1:1, 1:2, 1:3). In case of 1:0.5 ratio it was felt slightly bitter after 1 min and it is apparent from the results that the increasing concentrations of the polymer have completely have completely masked the bitter taste of the drug. Since the drug is not in the native form and entrapped within the polymeric matrix, and there by reduction in the solubility of the drug in the saliva could have led to the masking of the bitter taste. Even though the Ondansetron HCl taste was masked with drug polymer complex (1:0.5, 1:1, 1:2, 1:3) ratios, we have selected 1:1 for further studies, since higher amounts of polymer may retard the dissolution performance of the final fast disintegrating tablets of Ondansetron HCl.

Pre-compression parameters: Powder containing drug and various excipients were subjected for pre-compression parameters (Micromeritic properties) to study the flow properties of powder, to achieve uniformity of tablet weight. The values of pre-compression parameters evaluated were within prescribed limits and indicated good free flowing property. The results of all the preformulations parameters are shown in Table 4.

Drug - Excipient compatibility studies

FTIR Studies: The FTIR spectra of pure drug peaks are observed in the Ondansetron HCl sample and formulations were showed same characteristic absorption bands at or near that of Ondansetron HCl absorption bands values indicating that there was no chemical and physical change in the functional groups present in Ondansetron HCl. [Shown in Figure 3].

Table 1: Solubility study data of ondansetron hydrochloride

Sr. No	Solvent or Buffer	I time (mcg/ml)	II time (mcg/ml)	Average (mcg/ml)
1	Water	66.25	3.428	4.839
2	0.1 N HCL	17.61	19.24	18.450
3	Phosphate buffer 6.8	8.58	9.75	11.600
4	Phosphate buffer 7.4	7.445	9.740	8.592

Table 2: Formula of ondansetron HCl FDT prepared by sublimation method (1-tablet)

Ingredients (mg)	Formulations code											
	OHS1	OHS2	OHS3	OHS4	OHS5	OHS6	OHS7	OHS8	OHS9	OHS10	OHS11	OHS12
Drug resin mixture Equivalent to 4mg of Ondansetron HCl	10	10	10	10	10	10	10	10	10	10	10	10
MCC	20	20	20	20	20	20	20	20	20	20	20	20
Mannitol	60	58	54	46	60	58	54	46	60	58	54	46
Camphor	2	4	8	16	-	-	-	-	-	-	-	-
Urea	-	-	-	-	2	4	8	16	-	-	-	-
Menthol	-	-	-	-	-	-	-	-	2	4	8	16
Crosspovidone	6	6	6	6	6	6	6	6	6	6	6	6
Mg stearate	1	1	1	1	1	1	1	1	1	1	1	1
Talc	1	1	1	1	1	1	1	1	1	1	1	1
Total Weight	100	100	100	100	100	100	100	100	100	100	100	100

Table 3: Comparative taste evaluation

Form of Ondansetron HCl	10 sec	30 sec	1 min	2 min	5 min
Pure drug	3	3	3	3	2
DPC (1:0.5)	0.5	1	1	1	0
DPC (1:1)	0	0	0.5	0.5	0
DPC (1:2)	0	0	0.5	0	0
DPC (1:3)	0	0	0.5	0	0

Table 4: Pre-Compression parameters of blend used for sublimation method

Formulation code	Bulk density* (g/cc) $\pm$ SD	Tapped Density* (g/cc) $\pm$ SD	Angle of repose* (degree) $\pm$ SD	Carr's Index* (%) $\pm$ SD	Hausner's Ratio* $\pm$ SD
OHS1	0.322 $\pm$ 0.06	0.420 $\pm$ 0.01	29.51 $\pm$ 1.71	16.44 $\pm$ 1.23	1.19 $\pm$ 0.03
OHS2	0.320 $\pm$ 0.06	0.425 $\pm$ 0.01	28.34 $\pm$ 1.58	16.31 $\pm$ 1.02	1.17 $\pm$ 0.02
OHS3	0.325 $\pm$ 0.06	0.428 $\pm$ 0.01	28.11 $\pm$ 1.30	15.96 $\pm$ 1.03	1.18 $\pm$ 0.03
OHS4	0.356 $\pm$ 0.06	0.561 $\pm$ 0.02	27.78 $\pm$ 1.29	14.68 $\pm$ 1.25	1.16 $\pm$ 0.03
OHS5	0.372 $\pm$ 0.01	0.425 $\pm$ 0.01	24.14 $\pm$ 0.13	21.66 $\pm$ 1.51	1.27 $\pm$ 0.01
OHS6	0.389 $\pm$ 0.02	0.527 $\pm$ 0.02	24.98 $\pm$ 1.21	23.25 $\pm$ 1.59	1.31 $\pm$ 0.02
OHS7	0.461 $\pm$ 0.03	0.551 $\pm$ 0.02	23.11 $\pm$ 1.07	17.97 $\pm$ 1.19	1.20 $\pm$ 0.03
OHS8	0.376 $\pm$ 0.04	0.558 $\pm$ 0.02	20.29 $\pm$ 1.26	19.20 $\pm$ 1.08	1.24 $\pm$ 0.01
OHS9	0.401 $\pm$ 0.09	0.425 $\pm$ 0.02	24.14 $\pm$ 1.20	21.66 $\pm$ 0.60	1.27 $\pm$ 0.02
OHS10	0.401 $\pm$ 0.15	0.327 $\pm$ 0.03	24.98 $\pm$ 1.55	23.24 $\pm$ 0.75	1.31 $\pm$ 0.04
OHS11	0.396 $\pm$ 0.02	0.556 $\pm$ 0.02	23.12 $\pm$ 1.42	16.98 $\pm$ 1.23	1.20 $\pm$ 0.01
OHS12	0.350 $\pm$ 0.13	0.659 $\pm$ 0.01	21.56 $\pm$ 1.35	19.73 $\pm$ 0.67	1.24 $\pm$ 0.07

* Average of three determinations

Table 5: Post compression parameters of tablets prepared by sublimation method

FC	Parameters						
	Hardness (kg/cm ²) $\pm$ SD	Friability (%)	Weight variation (mg) $\pm$ SD	In-vitro disintegration time* (sec) $\pm$ SD	Wetting time* (sec) $\pm$ SD	Water absorption ratio* (%) $\pm$ SD	Drug Content* (%) $\pm$ SD
OHS1	3.0 $\pm$ 0.20	0.72	101 $\pm$ 0.20	51 $\pm$ 1.0	61 $\pm$ 2.10	72 $\pm$ 1.34	100.48 $\pm$ 1.21
OHS2	2.9 $\pm$ 0.10	0.61	100 $\pm$ 0.40	46 $\pm$ 1.4	57 $\pm$ 2.10	74 $\pm$ 1.31	99.98 $\pm$ 1.41
OHS3	2.8 $\pm$ 0.21	0.52	100 $\pm$ 0.45	42 $\pm$ 1.2	49 $\pm$ 1.35	81 $\pm$ 1.73	99.99 $\pm$ 0.55
OHS4	2.7 $\pm$ 0.05	0.42	99 $\pm$ 0.55	28 $\pm$ 2.1	40 $\pm$ 1.79	85 $\pm$ 1.54	99.99 $\pm$ 1.53
OHS5	3.0 $\pm$ 0.11	0.65	101 $\pm$ 0.34	66 $\pm$ 1.50	77 $\pm$ 1.00	73 $\pm$ 1.24	98.24 $\pm$ 0.22
OHS6	3.0 $\pm$ 0.10	0.55	100 $\pm$ 0.20	58 $\pm$ 1.0	69 $\pm$ 1.42	72 $\pm$ 1.09	100.19 $\pm$ 0.34
OHS7	2.9 $\pm$ 0.15	0.61	101 $\pm$ 0.40	52 $\pm$ 1.7	63 $\pm$ 1.89	72 $\pm$ 1.12	100.80 $\pm$ 1.63
OHS8	2.8 $\pm$ 0.10	0.59	99 $\pm$ 0.45	32 $\pm$ 1.0	44 $\pm$ 1.15	82 $\pm$ 1.14	98.91 $\pm$ 1.16
OHS9	3.0 $\pm$ 0.10	0.73	100 $\pm$ 0.55	70 $\pm$ 1.1	81 $\pm$ 1.48	74 $\pm$ 1.12	99.93 $\pm$ 1.42
OHS10	3.0 $\pm$ 0.15	0.61	101 $\pm$ 0.34	68 $\pm$ 1.7	78 $\pm$ 1.89	73 $\pm$ 1.12	100.80 $\pm$ 1.3
OHS11	2.9 $\pm$ 0.11	0.55	101 $\pm$ 0.34	61 $\pm$ 1.50	71 $\pm$ 1.00	74 $\pm$ 1.24	98.23 $\pm$ 0.22
OHS12	2.7 $\pm$ 0.20	0.42	99 $\pm$ 0.20	50 $\pm$ 1.00	62 $\pm$ 2.10	73 $\pm$ 1.34	101.20 $\pm$ 3.4

*Formulation Code

Table 7: Result of stability study				
Sr. No.	Formulation code	In-vitro disintegration time (sec) $\pm$ SD	Wetting time (sec) $\pm$ SD	Drug content (%) $\pm$ SD
25 $\pm$ 2° C, 60 % $\pm$ 5° C % RH				
1	OHS4	28 $\pm$ 1.00	40 $\pm$ 1.00	99.87 $\pm$ 1.32
2	OHS8	32 $\pm$ 1.94	44 $\pm$ 1.24	98.61 $\pm$ 0.37
3	OHS12	50 $\pm$ 1.34	62 $\pm$ 2.56	101.37 $\pm$ 0.56
40 $\pm$ 2° C, 75 % $\pm$ 5° C % RH				
4	OHS4	27 $\pm$ 1.12	38 $\pm$ 1.22	99.67 $\pm$ 1.36
5	OHS8	30 $\pm$ 1.00	41 $\pm$ 1.21	98.60 $\pm$ 0.37
6	OHS12	49 $\pm$ 1.27	59 $\pm$ 1.17	101.30 $\pm$ 0.55

Figure 3: IR spectra of pure drug Ondansetron HCl and Drug with additives

Figure 4: DSC spectra of pure drug Ondansetron HCl and Drug with additives

Figure 5: Comparison of Disintegration time of different formulation prepared by Camphor

Figure 6: Comparison of Disintegration time of different formulation prepared by Urea

Figure 7: Comparison of Disintegration time of different formulation prepared by Menthol

Figure 6: Release profile of Ondansetron HCl FDT Prepared by Sublimation method by using Camphor

Figure 7: Release profile of the Ondansetron HCl FDT Prepared by Sublimation method by using Urea

Figure 8: Release profile of the Ondansetron HCl FDT Prepared by Sublimation method by using Menthol

DSC Studies: The study also reveals that the thermogram of pure drug and other formulations [Shown in Figure 4] shows negligible changes in the melting point range. Thus the DSC Thermograms study reveals that there is no any kind of interaction of the drug with different types of polymer and their excipients used during the study.

The results of post-compressional parameters were within I.P prescribed limits. The results of post-compression parameters were given in **Table 5**. The hardness of the tablets prepared by sublimation method was maintained in the range of 2.70 kg/cm² to 3.00 kg/cm². From the hardness analysis data it was observed that, there was decrease in hardness of the tablet when we increased the concentration of subliming agent in tablets prepared by sublimation method. The friability result were found in all designed formulations in the range of 0.42 to 0.73% to be well within the approved range (<1%). The friability results were found in the range of 0.42 to 0.73%. The weight variation was found in 99 to 101mg in sublimation method. The mean weight variation test results are tabulated in table no.5. All the tablets passed weight variation test as the average percentage weight variation was within 7.5% i.e. in the pharmacopoeia limits.

Wetting time is closely related to the inner structure of the tablet. The wetting time of Ondansetron HCl fast dissolving tablets prepared was found to be in the range of 44 to 81 sec. The prepared formulations shows water absorption ratio in the range of 72 to 85 %. The percentage drug content of the tablets were found to be between 98.24 to 101.20 % of Ondansetron HCl. The results were within the range and indicate uniformity of mixing. The values of water absorption

ratio and drug content were showed in Table 5.

In-vitro disintegration (Figure 5-7) time and dissolution studies formulations OHS4 and OHS8 were found to be promising and showed a disintegration time of 28 sec and 32 sec respectively. This may be due to their lowest hardness and the porous structure is responsible for faster water uptake¹⁶. Crospovidone containing tablets rapidly exhibits high capillary activity and pronounced hydration with a little tendency to gel formation and disintegrate the tablets rapidly¹⁷.

The Ondansetron HCl promised formulations OHS4, OHS8, OHS12 shows nearly faster drug release. The formulation OHS4, OHS8, and OHS12 90% of drug released in 6min, 8min and 10min respectively when compare to other formulation. All these promised formulations contacting maximum concentration of volatile component i.e. OHS4 contain 16% camphor, OHS8 contain 16%, urea and OHS12 contains 16% menthol. This leads to formation of more pores within the tablets¹⁸. The result also revealed that, all the formulations were having enough mechanical strength, low wetting and disintegration time and good mouth feel¹⁹. All the formulations were having good mouth feel because all the tablets were fabricated using mannitol as filler will produce sweetness and negative heat of solution, which leaves a pleasant, cooling sensation in mouth²⁰. The dissolution release profiles of Ondansetron HCl from the tablets are shown in (Figure 8-10). The tablets prepared by sublimation technique, the dissolution rate of tablet were increase with increase in concentration of camphor. Formulation OHS4 containing camphor showed highest drug release 99% in 8 min. This may be due to their lowest hardness and the porous structure was responsible for

faster water uptake, hence it facilitates wicking action of Crospovidone in bringing about faster disintegration.

Based on the *in-vitro* disintegration time and dissolution studies formulations OHS4 and OHS8 were found to be promising and showed a disintegration time of 28 sec and 32 sec respectively. Formulation OHS4 containing camphor showed highest drug release 99% within 8 min. Formulation OHS8 showed highest drug release 90% within 8 min. This may be due to their lowest hardness and the porous structure was responsible for faster water uptake, hence it facilitates wicking action of Crospovidone in bringing about faster disintegration.

The promising formulations (OHS4, OHS8 and OHS12) were subjected to stability study by storing the formulations at $25 \pm 2^\circ\text{C}$ 60% $\pm$ 5 % RH and $40 \pm 2^\circ\text{C}$, 75 $\pm$ 5 % RH up to one month in the stability chamber. After one month the formulations were taken from the chamber and investigated the parameters (Table 6). In case of stability study at 40°C , 75

RH there is decrease in disintegration time, wetting time were observed in formulations prepared by this method. It may be due to formation of extra pore in the tablet texture due to removal of trace amount of volatile substance.

CONCLUSION

The above results concluded that, the fast dissolving tablets of Ondansetron HCl showing enhanced dissolution may lead to improved bioavailability and effective therapy by using sublimation method. Based on the *in-vitro* disintegration time and dissolution studies formulations OHS4 and OHS8 were found to be promising and showed a disintegration time of 28 sec and 32 sec respectively. Formulation OHS4 containing camphor showed highest drug release 99% within 8 min. Formulation OHS8 showed highest drug release 90% within 8 min. This may be due to their lowest hardness and the porous structure was responsible for faster water uptake, hence it facilitates wicking action of crospovidone in bringing about faster disintegration

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