FORMULATION AND EVALUATION OF ONDANSETRON MOUTH DISSOLVING TABLETS FOR NAUSEA AND VOMITING

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Abstract:
Ondansetron fast dissolving tablets were prepared by direct compression method using superdisintegrants is Pharmaburst ODT, in varying concentrations. Angle of repose: is 28° shows good flow. Bulk density and tapped density: is 0.410(g/ml) and 0.500 (g/ml), respectively. The values for compressibility index and Hausner ratio is 19.05 and 1.24, respectively. The results for pre-compressed parameters are shown in Table 15. Weight variation test is found 121.4 mg to 126.1 mg as per IP specification. Friability: Less than 0.31%, the results indicate that the percentage losses were not more than 1.0% (complies IP specifications). Thickness: Range from 2.90 mm to 2.99 mm; the results indicate that the tablets are suitable for packing. Content uniformity was found in between 98.62% and 100.3%. Hardness of the tablet was found to be between 4 to 4.6 kg/cm^2. The results indicate that the tablets are mechanically strong and are in limit. Disintegration time which was in-between 0'11 sec to 0'16 sec, the results indicate that disintegration time of tablets is within 30 seconds. Dissolution study was carried out in 6.8 pH phosphate buffer for formulations FZ1, FZ2, FZ3, ZF4, FZ5, ZF6, FZ7, FZ8, and FZ9 from time 0 to 15 min And % assay for optimized batch was found to be 99.2 %. Comparative dissolution study was carried out in 6.8 pH phosphate buffer for formulations FZ9 and marketed product.

Key words: Formulation, Evaluation, Ondansetron, Mouth Dissolving Tablets.

INTRODUCTION:

Convenience of administration and patient compliance are gaining significant importance in the design of dosage forms. Recently, more stress is laid down on the development of an organoleptically elegant and patient-friendly drug delivery system for pediatric and geriatric patients.[1,2] More than 50% of the pharmaceutical products are orally administered for several reasons, and undesirable taste is one of the important formulation problems encountered with such oral products.Taste of a pharmaceutical product is an important parameter for governing compliance. Thus, taste masking of oral pharmaceuticals has become an important tool to improve patient compliance and the quality of treatment, especially in pediatrics. Therefore, formulation of taste-masked products is a challenge to the pharmacists.[3,4]

Ondansetron HCl is a potent antiemetic drug indicated for the treatment and/or prophylaxis of postoperative or chemotherapy- or radiotherapy-induced emesis, and is also used in the early onset of alcoholism.[5] In general, emesis is preceded with nausea and, in such a condition, it is difficult to the administer drug with a glass of water. Hence, it is beneficial to administer such drugs as orodispersible tablets (ODTs). Ondansetron HCl is an intensely bitter drug; hence, if it is incorporated directly into an ODT, the main objective behind formulation of such a dosage form will definitely be futile.[6] Thus, in the present study, an attempt has been made to mask the taste of ondansetron HCl and to formulate ODTs with a good mouth feel so as to prepare a "patient-friendly dosage form."

Mouth-dissolving tablets are dosage forms that disintegrate in patient's mouth within a few seconds without the need of water, or chewing, providing best remedy for patients suffering from dysphagia. Their growing importance was underlined recently when the European pharmacopoeia adopted the term "orodispersible tablet" as a tablet that is to be placed in the mouth where it disperses rapidly before swallowing.[7]

Ion-exchange resins have been increasingly used as taste-masking agents. They are also known to be useful

as disintegrating agents.[8,9]

Difficulty in swallowing (dysphagia) is a common problem of all age groups, especially the elderly and pediatrics, because of physiological changes associated with those groups. Other categories that experience problems in using conventional oral dosage forms include the mentally ill, uncooperative and patients suffering from nausea, motion sickness, sudden episodes of allergic attack or coughing. Sometimes it may be difficult to swallow conventional products due to non-availability of water. These problems led to the development of a novel type of solid oral dosage form called orodispersible tablet, which disintegrates/dissolves rapidly in saliva without the need of drinking water.

The benefits in terms of patient compliance, rapid onset of action, increased bioavailability and good stability make these tablets popular as a dosage form of choice in the current market. Some drugs are in such cases bioavailability of drug is significantly greater than those observed from conventional tablet dosage form.

The basic approach used in the development of the ODTs is the use of superdisintegrants. Many approaches have been developed to manufacture ODTs. These include vacuum drying direct compression, lyophilization and molding. The direct compression method is inexpensive and convenient for producing tablets of sufficient mechanical strength.

Ondansetron are the new serotogenic agonist with excellent oral bioavailability exhibiting a potent symptomatic antimigraine effect. Ondansetron is a selectiveagonist of 5-HT1 B/D receptors.

In the present study, orodispersible tablets of Ondansetron are designed by using polymers namely Pharmabusrst, Pearlitol Flash and Panexcea ODT. Effervescent substances like citric acid and sodium stearyl fumarate.

Accelerated the superdisintegrant action and mask the bitter taste of Ondansetron. The designed tablets were evaluated for thickness, hardness, friability, weight variation, *in vitro* dispersion time, wetting time, water absorption ratio, disintegration time, drug content uniformity, *in vitro* dissolution rate (in pH 6.8 phosphate buffer), short term stability and drug excipient interactions (IR spectroscopy).

MATERIALS AND MEHODS

Materials used

S.NO	Ingredients	Manufacturer
1.	Ondansetron USP	Aurobindo Pharma
2.	Pharmaburst	SPI Pharma
3.	Pearlitol Flash	RoquettePharma
4.	PanExcea ODT	Avantor Performance Materials
5.	Peppermint Flavour 501500 TP0504	FirmenichPharma

PREPARATION OF STANDARD CURVE FOR ONDANSETRON

PREPARATION OF PH 6.8 BUFFER (phosphate buffer)

27.218 gm of potassium dihydrogen orthophosphate was dissolved in 1000 ml of distilled water. And to prepare 0.1 N sodium hydroxide solution. Then from this Potassium dihydrogen orthophosphate solution 250 ml was taken and mixed with 112 ml of 0.1 N Sodium hydroxide solutions. Finally to make up 1000 ml by using distilled water.

PREPARATION OF STANDARD CURVE FOR ONDANSETRON

100 mg of Ondansetron was accurately weighed and dissolved in small portion of phosphate buffer pH 6.8 in a 100 ml of volumetric flask and the volume was made up to 100 ml with buffer. This is the primary stock

solution. From the primary stock solution 10 ml was accurately pippetted out and transferred into a 100 ml volumetric flask. Then the volume was made up to 100 ml with buffer. From the secondary stock solution aliquots equivalent to 2-10 mcg (2ml, 4ml, 6ml, 8ml, and 10 ml) were pippeted out into a series of 10 with buffer. The absorbance of above set solutions was against the phosphate buffer pH 6.8 as blank at 248nm. Then calibration curve was plotted taking concentration on X-axis and absorbance on Y-axis.

Preformulation

It is the first step in rational development of dosage forms of drug substance. Preformulation testing is defined as investigation of physical and chemical properties of a drug substance alone and when combined with excipients. The overall objective of preformulation testing is to generate information useful to the formulator in developing stable and bio-available dosage forms that can be mass-produced.

Preformulation investigations are designed to identify those physicochemical properties and excipients that may influence the formulation design, method of manufacture and pharmacokinetic biopharmaceutical properties of the resulting product.

PROCEDURE FOR PREPARATION OF ONDANSETRON – ETHYL CELLULOSE MIXTURE FOR TASTE MASKING

- API is weighed accurately and sifted through # 40 mesh.
- Ethyl cellulose is weighed accurately and dissolved in isopropyl alcohol in the required ratio (5:1, 5:2, and 5:3).
- API is granulated with the ethylcellulose solution and initially air dried followed by drying with rapid drier.
- The dried mixture is tested for taste evaluation (organoleptic character) orally and until the taste found satisfactory the concentration of ethyl cellulose against the API is increased.

PROCEDURE FOR FORMULATION AND COMPRESSION OF TABLETS (FOR FORMULATION FZ1, FZ5, FZ6, FZ7, FZ8 AND FZ9)

- All the ingredients were weighed accurately as per the formula made
- Initially all the listed ingredients were sifted through #40 mesh
- API mixture was added to the blend geometrically by mixing with the other excipients while sifting
- Load the sifted ingredients in a 5L Double Cone Blender and blend for 5 minutes at 15 RPM
- Unload the blended materials and again sift through #40 mesh.
- Load the sifted materials again in the 5L Double Cone Blender and blend for 20 minutes at 15 RPM
- Sift Colloidal Silicon Dioxide and Sodium Stearyl Fumarate through #60 mesh
- Blend the sifted materials along with blended materials in a 5L Double Cone Blender and blend for 5 minutes at 15 RPM
- Compress the blended materials using 7.15 mm Round Flat Faced Bevel Edged Plain Tooling

PROCEDURE FOR FORMULATION AND COMPRESSION OF TABLETS (FOR FORMULATIONFZ2, FZ3 AND FZ4)

- All the ingredients were weighed accurately as per the formula made
- Initially all the listed ingredients were sifted through #40 mesh
- API mixture was added to the blend geometrically by mixing with the other excipients while sifting
- Load the sifted ingredients in a 5L High shear mixture granulator and granulate with purified water with impeller and chopper at high speed for three minutes.
- Dry it in the rapid dryer until it reaches the LOD of 2.5%.
- Unload the dried materials and again sift through #40 mesh.
- Load the sifted materials along with the extra granular material in the 5L Double Cone Blender and blend for 20 minutes at 15 RPM
- Sift Colloidal Silicon (if applicable) Dioxide and Sodium Stearyl Fumarate through #60 mesh
- Blend the sifted materials along with blended materials in a 5L Double Cone Blender and blend for 5 minutes at 15 RPM

- Compress the blended materials using 7.15 mm Round Flat Faced Bevel Edged Plain Tooling

BLENDING Blending (Pre Lubrication)
The blending step involves mixing of additives using double cone blender (DCB). In this step all the ingredients are transferred into the DCB except the lubricating agents and the machine is allowed to rotate at the speed of 15±1RPMfor 5minutes. Then the blend is unloaded and sieved by using the sieve of #40 mesh. The sieved blend was again loaded into the blender and allowed to rotate for 25 minutes. The blend uniformity sample was taken at 20, 25 and 30 minutes from ten different positions using the sampling rod for optimizing the blending time for pre lubrication.

BLENDING (LUBRICATION)
Lubricating agents are added to the blend after sieving with #60 mesh. And the blend is allowed to rotate for 5 min for lubrication. The blend uniformity sample was taken at 4, 5 and 6 minutes from ten different positions using the sampling rod for optimizing the blending time for lubrication.

COMPRESSION
Compression is done by using machine Cadmach compression machine which is double rotary having 16stations. Compression was carried as per BMR using standard concave shaped punches with hard chrome platedtips. Number of stations : 16

Type of tooling : "D" type

Procedure is done for description, average weight, disintegration time, friability, thickness and hardness.

Formulation and their composition:

S. No	Composition	Ratio (API: Ethyl cellulose: IPA)	Inference form organoleptic evaluation by selected volunteers
1	Ondansetron Ethyl cellulose Iso propyl alcohol	5 : 1 : 1	Bitterness was not efficiently .asked
2	Ondansetron Ethyl cellulose Iso propyl alcohol	5 : 2 : 1	Comparatively low, but bitterness still found.
3	Ondansetron Ethyl cellulose Iso propyl alcohol	5 : 3 : 1	Comparatively better taste.

Table: 1 Composition of unit dose of Ondansetron – ethylcellulose mixture for taste masking formulations

Various batches were planned and executed with the unit concentration of the ingredients used in the batch as shown in the table below.

S. No	Ingredients	Fz1 (mg)	Fz2 (mg)	Fz3 (mg)	Fz4 (mg)	Fz5 (mg)	Fz6 (mg)	Fz7 (mg)	Fz8 (mg)	Fz9 (mg)
Intragranular Portion										
1	Ondansetron	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00
2	Ethyl cellulose	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00
3	Iso propyl alcohol	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
4	Mannitol	109.00	109.0	104.0	99.00	-	-	-	-	-
5	Purified Water	-	10.00	10.00	10.00	-	-	-	-	-
6	Pearlitol Flash	-	-	-	-	109.0	-	-	-	-
7	Pharma Burst	-	-	-	-	-	109.0	-	-	-
8	Pan Excea ODT	-	-	-	-	-	-	109.0	107.7	106.5
9	Orange flavour	1.25	1.25	1.25	1.25	-	-	-	-	-
10	Peppermint Flavour	-	-	-	-	1.25	1.25	1.25	1.25	1.25
11	Citric Acid Anhydrous, USP	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00
12	Sucralose	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00
Extragranular portion										
13	Polyplasdone XL 10	-	-	5.00	10.00	-	-	-	-	-
14	Colloidal Silicon Dioxide (Aerosil 200)	-	-	-	-	1.25	1.25	1.25	2.50	2.50
15	Sodium Stearyl Fumarate (Pruv)	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	2.50
16	Total	125.00	125.00	125.00	125.00	125.00	125.00	125.00	125.00	125.00

Table 2. Composition of unit dose of various Formulations Characteristics of final blend

RESULTS AND DISCUSSION

Ondansetron Characteristics

Bulk density : 0.34 g / mL
Tapped density : 0.42 g / mL
Compressibility index : 19.05
Hausner ratio : 1.24
Loss on Drying (105°C / Automode) : 3.18%

PSD by Malvern master Sizer
d10 : 6 microns
d50 : 11 microns
d90 : 16 microns

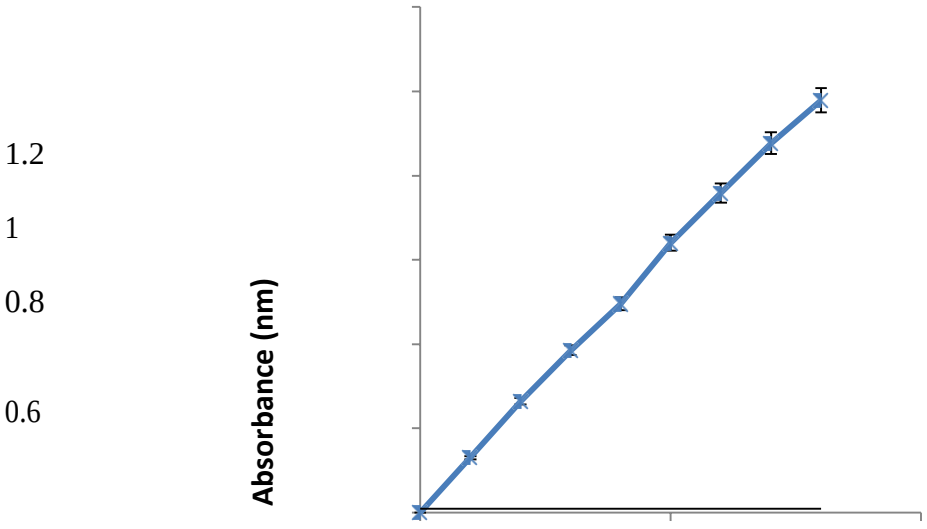
Drug Manufacturer : Aurobindo Pharma, Hyderabad.
Batch No : ZIP1004110

Calibration curve data for Ondansetron

Concentration(µg/ml)	Absorbance
1	0.130±0.003
2	0.264±0.001
3	0.385±0.002
4	0.495±0.001
5	0.640±0.002
6	0.758±0.004
7	0.877±0.001
8	0.979±0.003

Table 3. Calibration curve data for Ondansetron in 0.1N HCL

Standard curve of Ondansetron In 0.1N HCL



$y = 0.1233x + 0.0098$ $R^2 = 0.9991$

Figure 1: calibration curve of Ondansetron in .01N HCL

Drug and excipient compatibility studies of optimized formulation

The individual IR spectra of Ondansetron optimized formulation were shown in the figure. The following principle peaks were observed from the IR Spectral analysis.

The observed principle peaks were identical in the IR spectra of rug and the IR spectra of optimized formulation (FZ9). Hence there was no chemical or physical interaction between the drug and the excipient used in this investigation.

IR spectra of bands

S.No	Wave Number in cm^{-1}	Characteristic bands
1.	3551.32	O – H stretching
2.	3402.32	N – H stretching
3.	2931.47	C – H stretching
4.	1622.30	C = C stretching
5.	1455.80	C – H Bending
6.	1142.94	C – O stretching Ether
7.	1018.19	C – O stretching
8.	873.33, 766.75, 669.19,	C – H (OOP) For Aromatic rings
9.	465.97, 450.74, 444.88,	C – X stretching

Table 4. The principle peaks were observed from IR spectra of Ondansetron

Final blend was characterized with various parameters like bulk density, tapped density, angle of repose and loss on drying for each batch and their results were tabulated below.

S.	Parameters	FZ1	FZ2	ZF3	FZ4	FZ5	FZ6	FZ7	FZ8	FZ9
1	Bulk Density(gm/mL)	0.33	0.35	0.36	0.34	0.38	0.38	0.41	0.39	0.41
2	Tapped Density (gm/mL)	0.38	0.39	0.4	0.38	0.48	0.48	0.51	0.49	0.50
3	Angle of Repose (°C)	33	31	31	32	31	31	29	29	28
4	Loss on Drying (%)	2.93	3.19	3.18	3.14	2.04	2.04	3.12	2.98	2.86

Table 5; Result for bulk density, tapped density, angle of repose and loss on drying.

Particle Size Distribution

Particle Size Distribution for final blend of the trial batches were performed and the results are tabulated below

S. No	Sieve size#	FZ 1	FZ2	ZF3	FZ4	FZ5	FZ6	FZ7	FZ8	FZ9
1	20	0	0	0	0	0	0	0	0	0
2	40	0	2	1	1	1	0	0	0	0
3	60	5	10	11	12.1	12	7.5	15	15	11.1
4	80	30	5	6	7.2	5.5	5	5	20	13.9
5	100	10	5	7.5	9.4	9	17.5	5	17.5	19.4
6	140	10	43	46	43.8	42	5	20	20	27.8
7	200	7.5	20	17.5	15.4	17.6	17.5	20	17.5	16.7
8	Pan	27.5	15	11	11.1	12.9	37.5	35	10	11.1

Table 5; Particle size distribution results for the final blend

Blend Uniformity

Percentage content of samples from final blend of trial batches were analyzed and the results are tabulated below

S. No	Fz1	Fz2	Fz3	Fz4	Fz5	Fz6	Fz7	Fz8	Fz9
1	95.7	96.7	94.6	96.6	96.8	98.7	96.7	97.6	98.9
2	96.9	96.8	95.7	96.8	99.7	98.3	100.6	98.7	99.5
3	96.9	97.1	95.9	97.2	99.5	98.8	96.7	97.4	99.9
4	97.1	97.8	96.8	97.5	94.7	99.1	99.8	99.6	99.6
5	97.3	97.9	97.2	97.9	98.1	99.8	99.6	98.9	99.8
6	97.5	98.3	97.6	98.1	97.4	98.9	99.3	99.6	99.1
7	97.9	98.5	97.9	98.5	98.9	99.1	98.1	100.2	98.1
8	98.3	98.7	98.5	98.7	99.7	99.3	100.9	100.1	99.6
9	98.5	99.1	98.9	99.2	100.2	99.5	97.9	100	100.8
10	98.6	99.2	98.9	99.8	97.1	99.6	98.7	99.1	101.2
AVG	97.47	98.01	97.2	98.03	98.21	99.11	98.83	99.12	99.65
Min	95.7	96.7	94.6	96.6	94.7	98.3	96.7	97.4	98.1
Max	98.6	99.2	98.9	99.8	100.2	99.8	100.9	100.2	101.2
%RSD	0.92	0.93	1.49	1.06	1.76	0.46	1.50	1.00	0.89

Table 6. Results of B6lend uniformity samples of final blend

Disintegration Time:

Minimum and maximum time taken by the six tablets from each batch was noted and tabulated in the table below

Parameters	FZ1	FZ2	ZF3	FZ4	FZ5	FZ6	FZ7	FZ8	FZ9
Minimum Time (min)	0’22	6'00	3'28"	1'45"	0’15	0’18	0’12	0’10	0’11
Maximum Time (min)	0’29	7'38"	4'45"	2'25"	0’21	0’24	0’16	0’15	0’16

Table 7. Disintegration time of each formulation

Assay & Water by Kf

Results of assay and moisture content evaluated by karlfischer reagent was tabulated below

Parameters	FZ1	FZ2	ZF3	FZ4	FZ5	FZ6	FZ7	FZ8	FZ9
Assay(%)	104.2	102.3	101.2	99.6	96.7	101.0	98.7	97.9	99.2
Water by Kf (%)	5.25	5.15	5.12	5.16	4.22	4.01	4.97	4.96	4.82

Table 8. Assay and water by kf results of the formulations.

Related substance

The analytical method for related substance was performed and the highest unknown impurity and total impurity values of the respective batches were tabulated below.

Parameters	FZ1	FZ2	ZF3	FZ4	FZ5	FZ6	FZ7	FZ8	FZ9
Highest Unknown Impurity (%)	0.09	0.77	0.33	0.11	0.23	0.39	0.03	0.02	0.03
Total Impurities (%)	2.29	2.95	3.00	3.01	3.20	3.19	0.07	0.08	0.06

Table 8. Highest unknown impurity and total impurities results of the respective formulations.

Dissolution

Percentage release of drug was analyzed during 15 minutes of dissolution and the results for the respective batches were tabulated below.

Formulations	5 min	10 min	15 min
FZ1	94.3±0.16	98.9±0.78	100.2±0.06
FZ2	66.8±0.48	85.9±0.95	94.8±0.07
FZ3	78.8±0.34	88.3±0.66	96.8±0.09
FZ4	88.0±0.38	94.2±0.57	98.8±0.04
FZ5	93.2±0.62	99.5±0.12	100.2±0.08
FZ6	86.5±0.41	96.4±0.18	99.7±0.02
FZ7	92.7±0.06	99.8±0.06	100.1±0.01
FZ8	94.8±0.09	100.1±0.12	99.8±0.04
FZ9	95.8±0.09	99.9±0.02	100.3±0.02

Table 9. Results of dissolution data of the formulations.

And the graphical representation of the batches is shown below.

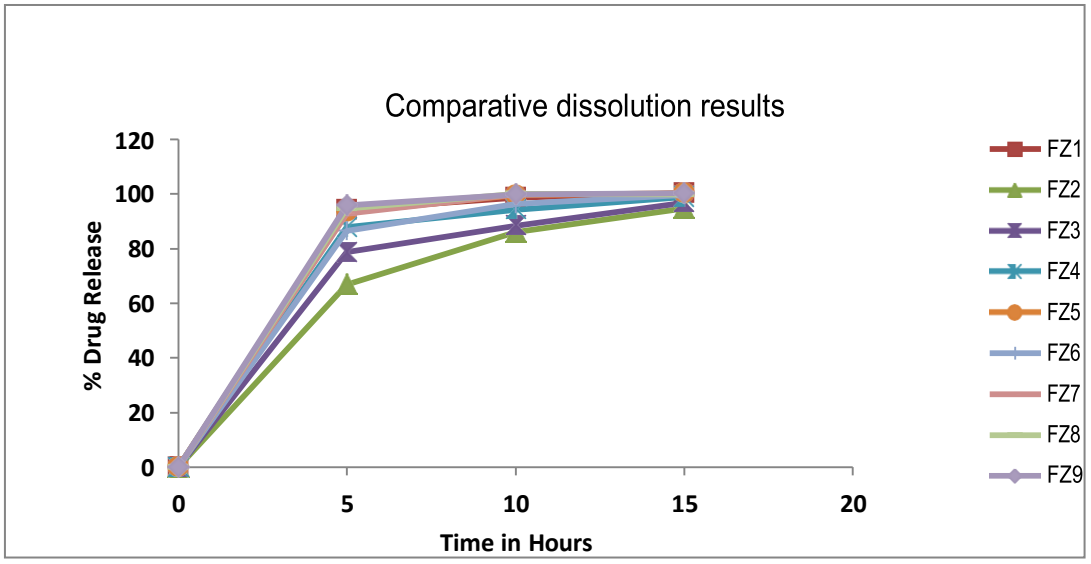


Figure 2: Graphical representation of Percentage dissolution of the formulations

DISCUSSION

Ondansetron fast dissolving tablets were prepared by direct compression method using superdisintegrants is Pharmaburst ODT, in varying concentrations.

Angle of repose: is 28° shows good flow**.**
Bulk density and tapped density: is 0.410(g/ml) and 0.500 (g/ml), respectively. The values for compressibility index and Hausner ratio is 19.05 and 1.24, respectively. The results for pre-compressed parameters are shown in Table 15.

Weight variation test is found 121.4 mg to 126.1 mg as per IP specification. Friability: Less than 0.31%, the results indicate that the percentage losses were not more than 1.0% (complies IP specifications). Thickness: Range from 2.90 mm to 2.99 mm; the results indicate that the tablets are suitable for packing.

Content uniformity was found in between 98.62% and 100.3%. Hardness of the tablet was found to be between 4 to 4.6 kg/cm^2. The results indicate that the tablets are mechanically strong and are in limit.

Disintegration time which was in-between 0’11 sec to 0’16 sec, the results indicate that disintegration time of tablets is within 30 seconds.

Dissolution study was carried out in 6.8 pH phosphate buffer for formulations FZ1, FZ2, FZ3, ZF4, FZ5, ZF6, FZ7, FZ8, and FZ9 from time 0 to 15 min, the results are shown in Table 26. And % assay for optimized batch was found to be 99.2 % as shown in Table 24

Comparative dissolution study was carried out in 6.8 pH phosphate buffer for formulations FZ9 and marketed product. The results are shown in table 31 and figure 19.

Storage condition: Tablets were stored at 45°C ± 2°C/75% for a storage period of 0, 30, 60, and 90 days, Hardness was increased with time but in all cases, hardness was within the limit. Disintegration time: At various storage conditions increases but maximum 20 sec which is < 30 seconds (specification of IP). Dissolution studies shows there was no significant change in dissolution data of formulations at initial and after specified storage period.

CONCLUSION

Orodispersible tablets of Ondansetron are prepared by direct compression method. The formulation FZ9

containing 10% of superdisintegrant (i.e) Pharmaburst ODT has shown best release with 100.3% at the end of 15minuts. The effervescent mixture further assists in taste masking of Ondansetron.
According to FTIR studies there is no incompatibility shown in FZ9. The formulation FZ9 was stable at 40°C±2ºC and 75%RH±5%RH.
In conclusion formulation FZ9 achieved the targets of the present study such as,

- Not require water to swallow, but it should dissolve or disintegrate in the mouth in matter of seconds.
- To mask the bitter taste.
- Have a pleasant mouth feel.
- Rapid dissolution of drug and absorption which may produce rapid, onset of action.
- Improved bioavailability.

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