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Preparation and *in vitro* evaluation of donepezil hydrochloride orodispersible tablets

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Abstract

Objective: The present study was aimed to prepare and evaluate Donepezil HCl Orodispersible tablets (DO-ODTs) using natural and synthetic superdisintegrants to increase patient compliance.

Methods: Direct compression was adapted using crospovidone, croscarmellose sodium as synthetic and mucilage isolated from fruits of Abelmoschus esculentus as natural superdisintegrants at different concentrations along with microcrystalline cellulose and aerosil. The powder mixture were subjected for pre and post compression evaluation including FTIR spectroscopy, micromeritic properties, tablet weight variation, hardness, friability, drug content, wetting time, dispersion time, water absorption ration, disintegration time and *in vitro* drug release.

Results: The low SD indicate the drug content was uniform, FTIR suggest no interaction between the drug and the excipients used. The DO-ODTs prepared with croscarmellose at higher concentration shows better *in vitro* drug release and relative properties than the DO-ODTs prepared with crospovidone and Abelmoschus esculentus.

Conclusion: The results of this work reveals that DO-ODTs shows water absorption, dispersion, rapid disintegration time, fast drug release and good hardness, further conclude that DO-ODTs can be efficiently and successfully formulated by direct compression method.

Keywords: Orodispersible tablets; Donepezil HCl; Superdisintegrant; Direct compression

1. Introduction

Donepezil HCl is a piperidine type reversible based inhibitor of the enzyme acetyl cholinesterase (AChE) and has been approved for the symptomatic treatment of mild to moderate Alzheimer's disease[1,2]. Donepezil HCl is white crystalline powder, soluble in water, glacial acetic acid, slightly soluble in ethanol and in acetonitrile and practically insoluble in ethyl acetate and n-hexane[3]. The objective of present work is to develop Donepezil HCl loaded orodispersible tablets (ODTs) by direct compression using crospovidone, croscarmellose as synthetic and mucilage isolated from fruits of *Abelmoschus esculentus* as natural superdisintegrants at different concentrations to achieve rapid dissolution of drug and absorption, quick onset of action, to leave minimal or no residue in mouth, to improve better patient compliance.

2. Materials and methods

Donepezil HCl (DO) was a gift sample from Magnus Pharma Ltd, Birgunj, Nepal. Microcrystalline cellulose (MCC), croscarmellose sodium (CCS), crospovidone (CP), Aerosil, Mannitol were procured from SD fine Chemicals, Mumbai.

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Abelmoschus esculentus (AE) fruits were procured from local market. Analytical grade chemicals and solvent were used throughout the research work.

2.1. Isolation of mucilage from *Abelmoschus esculentus* (AE) fruits

Soak 50G of dried, powdered AE fruits in 150ml of distilled water for 24 h in a round bottom flask. Reflux the mixture for 6 h with occasional stirring to extract mucilage, after 6 h, the flask kept aside for 2 h to release completely the mucilage. Further filter the content through a muslin cloth, hot distilled water added through the sides of the marc and squeezed well to remove the mucilage completely. Concentrate the filtrate to 1/3rd of its volume then add equal volume of ethanol to precipitate the mucilage. Keep the obtained precipitate in a refrigerator for overnight for effective settling. After complete settling of the precipitate, filter the contents, collect residue and dried at room temperature. Ground the dried mucilage powder and pass through # 100, stored in air tight wide mouth amber coloured glass container for further study. The mucilage subjected for standard identification test to confirm the presence of carbohydrates. Determine the appearance, colour, taste, solubility, pH and viscosity for mucilage isolated from AE.

2.2. Preparation of DO-ODTs

DO-ODTs were prepared by direct compression method. All the ingredients weighed according to the formula given in table 1. The weighed ingredients were mixed uniformly in polythene bag then, powder mixture is subjected to precompression analysis followed by direct compression using 8mm punch in a 10 station rotary punching machine. In each case batch size of 50 tablets were prepared.

Table 1 Formulae of DO-ODTs and plain tablets

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	Plain
Donepezil HCl	05	05	05	05	05	05	05	05	05	05
CP	04	08	12	-	-	-	-	-	-	-
CCS	-	-	-	04	08	12	-	-	-	-
AE mucilage	-	-	-	-	-	-	04	08	12	-
MCC	100	100	100	100	100	100	100	100	100	100
Mannitol	65	61	57	65	61	57	65	61	57	69
Aerosil	2	2	2	2	2	2	2	2	2	2
Mag. stearate	2	2	2	2	2	2	2	2	2	2
Talc	2	2	2	2	2	2	2	2	2	2
Total weight	180	180	180	180	180	180	180	180	180	180

2.3. Evaluation

2.3.1. Fourier transform infrared spectroscopy (FT-IR)

The interaction between the drug and polymer was studied by FTIR. To produce a stable product, the drug and polymer must be compatible with one another. Drug and polymer interactions were studied by using FT-IR (Shimadzu, Japan model–8400S) as per the method. IR spectral analysis of pure donepezil HCl, croscarmellose sodium, crospovidone, *Abelmoschus Esculentus,* aerosil, mannitol and microcrystalline cellulose and optimized ODTs were carried out. No change in peaks of mixture compared to pure drug indicates the absence of interactions.

2.3.2. Precompression studies[4-6]

Bulk density (ρb)

Weighed quantity of 2 g powder was introduced into a measuring cylinder. After determination of initial volume, the cylinder was allowed to fall under its own weight onto a hard surface from the height of 2.5 cm at 2 sec intervals and the tapping was continued until no further change in volume was noted. LBD and TBD were calculated. The determination was carried out in triplicate.

$$\rho_b = \frac{M}{V_o}$$

ρb- Bulk density (cm^3); M- Weight of powder (gm); Vo- bulk volume (cm^3)

Tapped density (ρt)

A known weight of sample powder that has previously been passed through a U. S. Standard sieve is carefully introduced into a 10 ml graduated cylinder. The cylinder is dropped at 2sec intervals onto a hard wood surface tapped 100 times from a height of 1inch. The tapped density is then obtained by dividing the weight of the sample in grams by the final volume in cm^3 of the sample contained in the cylinder.

$$\rho_t = \frac{M}{V}$$

ρt- Tapped density (cm^3); M- Weight of powder(gm); Vo- Tapped volume (cm^3)

2.3.3. Compressibility index

Compressibility index was determined by placing the powder in a measuring cylinder and the volume (V_0) was noted before tapping, after 100 times tapping again volume (V) was recorded.

$$\textbf{Compressibility index} = \left(1 - \frac{V}{V_o}\right) \textbf{X } 100$$

Where, V_0 - Volume of powder/granules before tapping.

V - Volume of powder/granules after 100 times tapping.

2.3.4. Carr's index

The compressibility index of the powder blend was determined by carr's compressibility index. It is a simple test to evaluate the BD and TD of a powder and the rate at which it packed down. The formula for Carr's index is as below,

$$\textbf{Carr's index } (\%) = \frac{[(\rho_t - \rho_b) \times 100]}{\rho_t}$$

Where, ρ_t- Tapped density; ρ_b- Bulk density

2.3.5. Hausner's ratio

The Hausner's ratio is a number that is correlated to the flow ability of a powder or granular blend.

$$\textbf{Hausner's ratio} = \rho_t / \rho_b$$

Where, ρ_t = Tapped density; ρ_b = Bulk density

2.3.6. Angle of repose (θ)[7,8]

If more powder or granules is added to the pile, it slides down the sides until the mutual friction of the particles, producing a surface at an angle φ, is in equilibrium with the gravitational force. The tangent of the angle of repose is equal to the coefficient of friction, μ, between the particles. The frictional forces in a powder or granules can be measured by the angle of repose, Θ. This is the maximum angle possible between the surface of a pile of powder and the horizontal plane.

Fixed funnel method

A funnel was fixed with its tip at a given height (h), above a flat horizontal surface on which a graph paper was placed. Powder was carefully poured through a funnel till the apex of the conical pile just touches the tip of funnel. The angle of repose (φ) was calculated by following equation,

$$\varphi = \tan^{-1}(h/r)$$

Where, φ = Angle of repose; h = Height of pile; r = Radius of the base of the pile.

2.4. Postcompression evaluation

The DO-ODTs were subjected for post compression evaluation viz., diameter, thickness, uniformity in weight, hardness, friability, dispersion time, disintegration time, wetting time, water absorption ratio and *in vitro* dissolution studies under standard procedures and conditions.

2.4.1. Thickness and diameter[9,10]

The thickness and diameter of DO-ODTs were measured using digital vernier calipers. In each case randomly selected 10 tablets were used for the test. Averages of ten readings were taken and the results were computed.

2.4.2. Hardness[11]

The tablet hardness is the force required to break a tablet in a diametric compression force. Monsanto hardness tester was used in this study, this test applies force to the tablet diametrically, was performed on six tablets and the average was calculated.

2.5. Uniformity of weight

Individually twenty DO-ODTs were selected at random and weighed accurately. The average weight of individual tablets was compared for the determination of weight variation. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in the following and none deviates by more than twice that percentage.

- Tablets weighed 80 mg or less- Permissible deviation is 10%
- Tablets weighed <80 mg but >250mg- Permissible deviation is 7.5%
- Tablets weighed 250 mg or more - Permissible deviation is 5%

2.6. Friability

The friability (F) of a sample of 20 DO-ODTs was measured using Roche fribilator ((ERWEKA, Germany). Twenty tablets were weighed, rotated at 25 rpm for 4 min. Tablets were reweighed after removal of fines (dedusted) and calculate the percentage of weight loss by using the formula. Friability below 1% was considered acceptable.

$$F = \frac{(W_{initial}) - (W_{final})}{(W_{initial})} \times 100$$

2.7. Dispersion time

The dispersion time was calculated via placing tablets in a watch glass contain 5 ml of pH 6.8 buffer. Three tablets from each formulation were randomly selected and dispersion time was measured.

2.8. Disintegration test (modified method)

In vitro disintegration times of DO-ODTs were carried out at (37±2) ºC in 10 ml of pH 6.8 buffer solution using a disintegration test apparatus. Disintegration time of 6 individual DO-ODTs were recorded and carried out at (37± 2) ºC in 900 ml of pH 6.8 buffer solution.

2.9. Wetting time

Wattman filter paper was placed in a petri plate having an internal diameter 6.5 cm and containing 5 ml of amaranth solution and the tablet was placed and the complete wetting time of the tablet was measured in seconds. Average of three tablets were recorded and computed.

2.10. Water absorption ratio

A test was done with the same procedure as that of wetting time. In this test, the initial weight of the tablet was noted before placing it on a petri dish. After complete wetting, the wetted tablet was then weighed.

The water absorption ratio 'R' was determined using the equation,

$$R = 100\times (Wa-Wb)/Wa$$

Where,

Wa = Tablet weight after water absorption; Wb= Tablet weight before water absorption.

2.11. Drug content uniformity

From each batch three randomly selected tablets were subjected for drug content uniformity test. All tablets are weighed accurately and powdered in a clean and dry glass mortar with pestle. Then powder equivalent to 5 mg of drug was transferred into 50 ml volumetric flask containing 50 ml of pH 6.8. The solution was shaken intermittently for 24 h and then it was filtered, desired dilutions were made and analyzed for drug content at λ_{max} of 271 nm using pH 6.8 as a blank. Triplicate readings were taken and average was computed. The concentration of the drug was computed from the standard curve.

2.12. *In vitro* dissolution studies

In vitro drug release studies were carried out using USP XXII dissolution apparatus type II at 50 rpm. The dissolution medium consisted of 500 ml of pH 6.8, maintained at 37 ± 0.5^0C. Samples were taken after fixed time intervals viz., 1, 2, 4, 6, 8, 10, 15, 20 and 30 min, withdrawn samples (5 ml) were then filtered through 0.45 µm millipore syringe filters, and the concentration of drug in each sample was measured using a double beam UV spectrophotometer at 271 nm with reference to the previously constructed calibration curves. To maintain the sink conditions, 5 ml of fresh buffer solution was added to the medium immediately after sample collection. The UV spectroscopy measurements for each sample were performed in triplicate. The drug release studies were conducted in triplicate for each batch of DO-ODTs.

3. Results and discussion

3.1. FTIR studies

The characteristic FTIR peaks of donepezil HCl were found at 2928.61 and 2852.99 cm^{-1} corresponding to Ar-CH=CH CH stretching of CH_3, CH_2 and Ar-CH=CH stretching absorption band; 1680.14 cm^{-1} corresponds to C=O Ketone stretching absorption band and 1593.52 cm^{-1} corresponds to C=C double bond stretching absorption band. The FTIR spectra of AM shows broad peak obtained at the 3230.22 cm^{-1} is result from the stretching of the -OH bond of alcohol groups and it indicates bonded hydroxyl (-OH) group, more intense absorption peak at 1600.46 cm^{-1} representing amines and amide functional groups, strong peak between 3000-2800 cm^{-1} represent C-H stretching vibration generated by lipids. The strongest absorption band at 1024.65 cm^{-1} could be due to C=N stretching vibrations of aliphatic amines. The characteristic FTIR peaks of donepezil HCl were found in F3, F6, and F9 ODTs with slight shifting towards lower wavelength indicates no interaction or mild interaction at molecular level. As shown in the figures 1-4 and table 2.

Table 2 Comparative FTIR data

Batches	Ar-CH=CH CH stretching of CH_3,CH_2 absorption band (cm^{-1})	C=O Ketone stretching absorption band cm^{-1}	C=C Stretching absorption band cm^{-1}
Donepezil HCl	2928.61, 2852.99	1680.14	1593.52
F3	2913.45, 2852.78	1671.26	1592.97
F6	2918. 36, 2855.11	1676.43	1590.42
F9	2918.58, 2853.35	1678.96	1590.56

3.2. Precompression and post compression evaluation

The powder blend was prepared as per the formulae table, further the powder blend was evaluated for precompression properties viz., bulk density, tapped density, Carr's index, Hausner's ratio and angle of repose. The results were given in table. After precompression evaluation the donepezil HCl ODTs were prepared by direct compression method, the digital photographs of various formulations were depicted in figure 5. The prepared ODTs were evaluated for post compression parameters viz., thickness, diameter, weight variation, hardness, friability, dispersion time, disintegration

time, wetting time, water absorption ratio drug content uniformity, *in vitro* dissolution and the results were given in figures 6 to 8 and table 3 to 6.

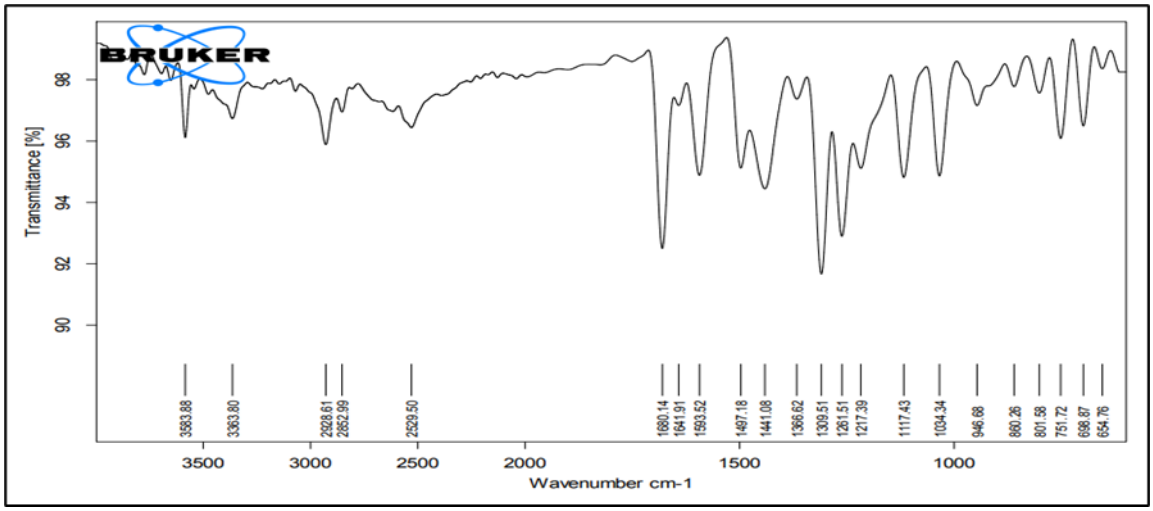

Figure 1 FTIR spectrum of donepezil HCl

Figure 2 FTIR spectrum of F3 DO-ODTs

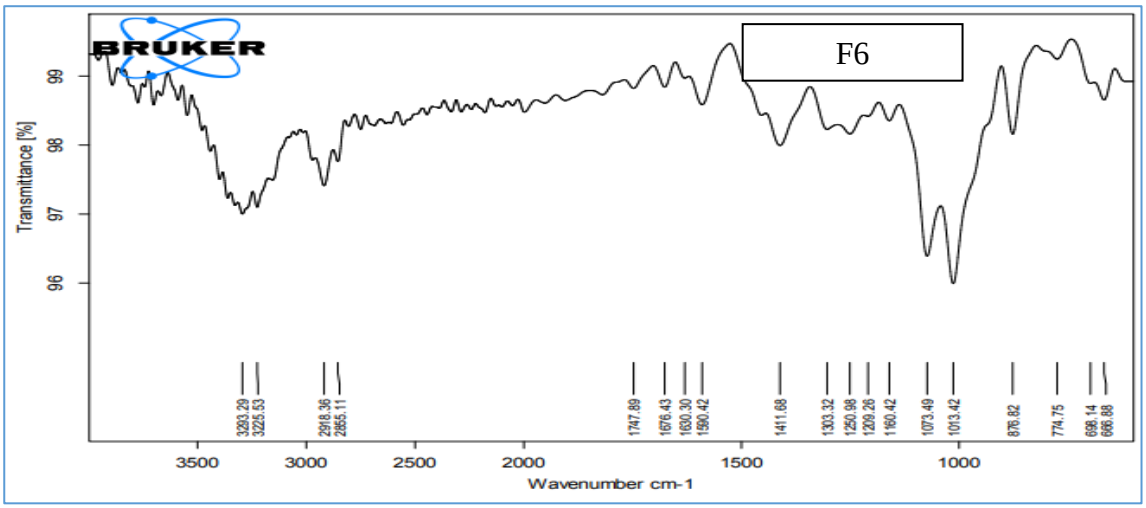

Figure 3 FTIR spectrum of F6 DO-ODTs

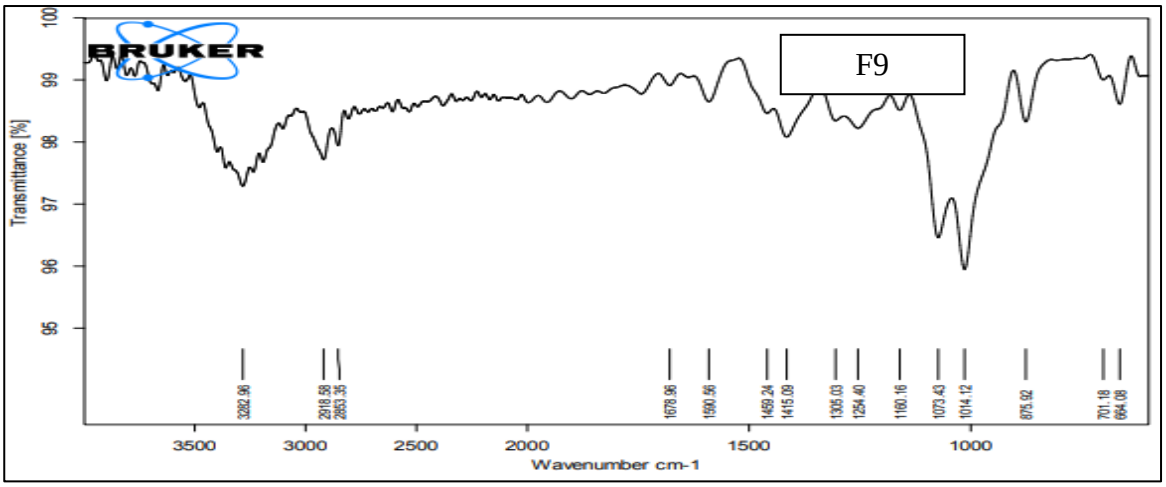

Figure 4 FTIR spectrum of F9 DO-ODTs

Figure 5 Digital photographs of different DO-ODTs and plain tablets

Figure 6 Wetting time of F3, F6, and F9 DO-ODTs at different time intervals

The bulk density was found to be in the range of 0.465 ± 0.0040 to 0.504 ± 0.0030 g/cm^3; tapped density 0.535 ± 0.0041 to 0.613 ± 0.0032 g/cm^3; compressibility index value 11.5 ± 0.300 to 17.43 ± 0.060 and Hauser's value 1.16 ± 0.100 to 1.213 ± 0.020 for F1 to F9 and plain ODTs formulations indicates good compressibility and flowability and can be used for direct compression. The angle of repose was found to be in the range of 21.67 ± 0.152 to 29.47 ± 0.305 for F1 to F9 and plain ODTs showing that the blends of powder were free flowing. The post compression data suggest that the DO-ODTs have desired mechanical strength, tablet integrity and uniform weight throughout the batches prepared. The integral ODTs parameter data were found to be 17 ± 2.1 to 48.33 ± 2.082 sec of dispersion time; 8.34 ± 0.619 to 55.24 ± 0.340 sec of disintegration time; 18.67 ± 3.512 to 60 ± 2.13 sec of wetting time; 10.78 ± 0.491 to 23.37 ± 0.127% of water absorption ratios for donepezil HCl ODTs viz., F1 to F9 and plain tablets. *In vitro* wetting time and dispersion times of donepezil HCl ODTs decreased by increasing synthetic super disintegrant concentration viz., crospovidone and croscarmellose sodium from 4% to 12%, similar results were observed with natural super disintegrant viz., AE. It was also observed that all formulations showed deceased values of wetting and dispersion times compared to the plain

donepezil tablets. The decrease in wetting time and dispersion times in all formulations may be attributed to the presence of super disintegrant which absorbs water and swells causing rupture of the tablets.

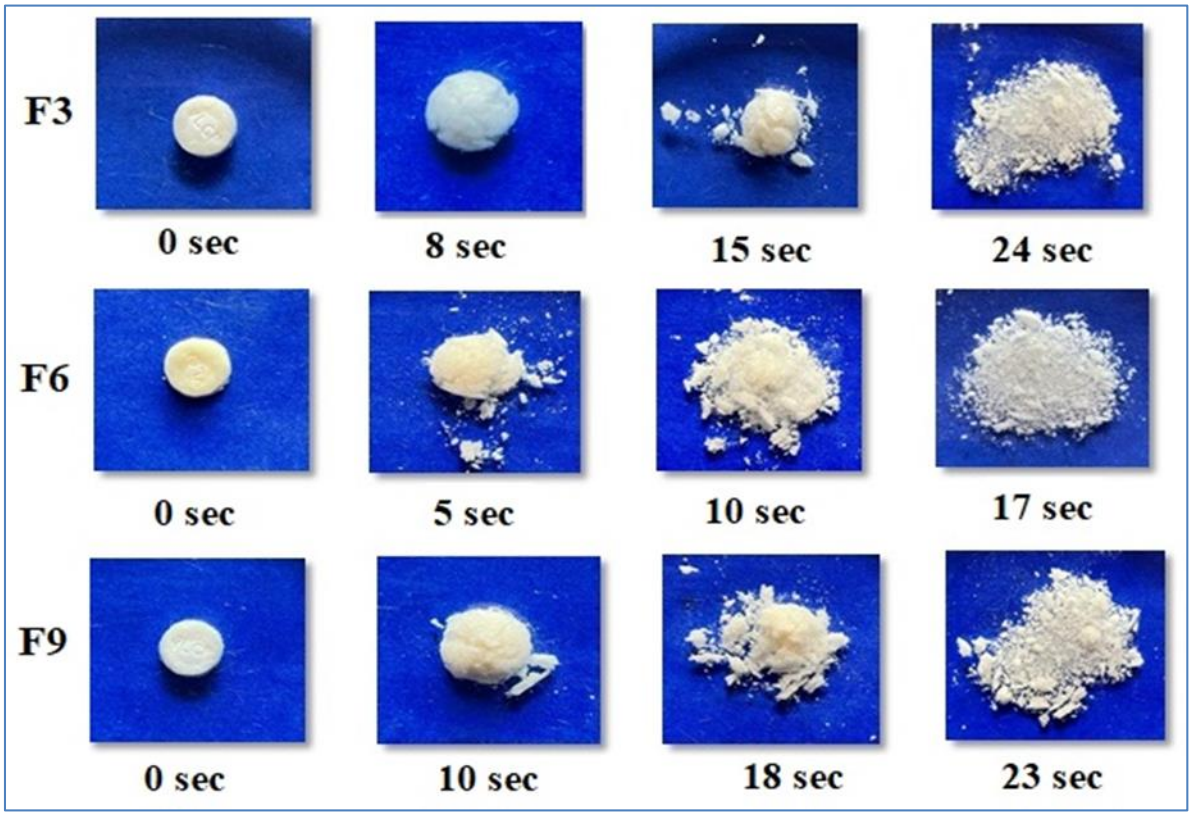

Figure 7 Dispersion time of F3, F6 and F9 DO-ODTs at different time intervals

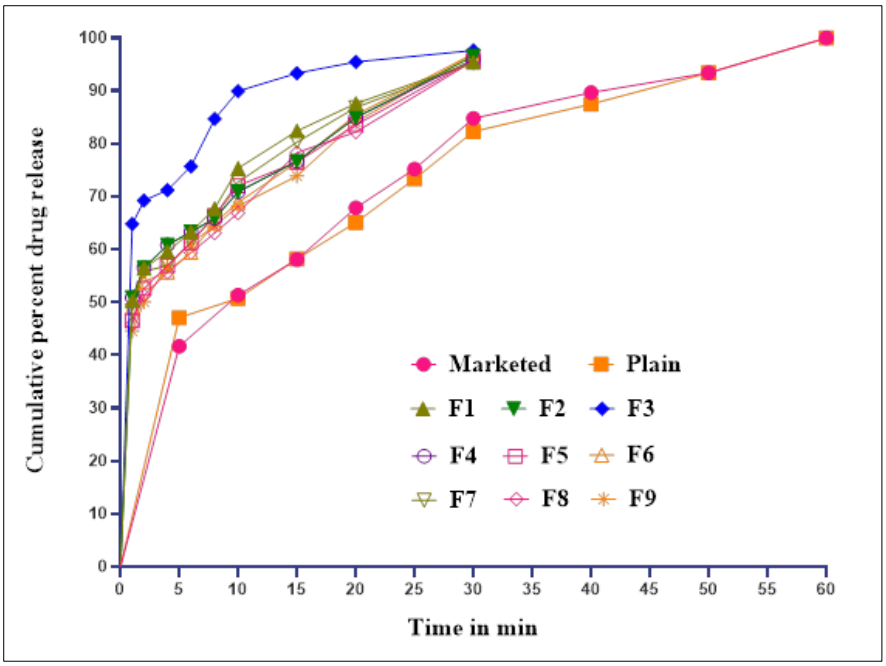

Figure 8 Comparative in vitro dissolution profile of DO-ODTs, plain and Mktd tablets

Dispersion time for ODTs which are desired to be less than one minute for orally disintegrating tablets, this rapid disintegration assists swallowing and also plays a role in drug absorption in buccal cavity, *In vitro* water absorption ratio of ODTs plays an important parameter which directly relates to the disintegration of the tablets, as water

absorption ratio increases the swelling and wicking properties of super disintegrant increase, these properties were justified by water absorption ration data, which increases with increase in concentration of synthetic super disintegrant viz., cross povidone and cross caramellose from 4% to 12%, similar results were observed with natural super disintegrant viz., AE. These results further justified with in vitro disintegration time data. The term direct compression is used to define the process by which tablets are compressed directly from powder ends of active ingredient and excipients, which flow uniformly in the dies and forms a compact tablet. MCC is considered as diluent having self binding properties and it is predictable as one of the preferred direct compressible binder because of its dry binding properties in comparison to other excipients. When MCC and super disintegrants both are mixed together it may be complementary to promote fast dispersible. Mannitol was used as taste masking agent because drug has slightly bitter in taste and also used as directly compressible vehicle since the dose is too low (5 mg).

Table 3 Various dissolution parameters and model fitting values

Batches	**DP_{10}**	**t50**	**DE_{10}**
Mktd. tablets	52.5	8.6	54.00
Plain tablets	57.9	6.1	59.89
F1	72.6	1.1	58.66
F2	74.6	1.0	59.16
F3	85.5	0.2	72.20
F4	71.4	1.6	55.93
F5	71.7	1.3	56.68
F6	73.0	1.2	58.66
F7	70.5	2.1	55.31
F8	70.1	2.0	54.62
F9	73.1	1.5	57.44

Table 4 Post compression evaluation data for DO-ODTs

Parameters	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**
Weight variation**	177.7 ± 0.577	177.3 ± 0.577	178.3 ± 1.155	177.7 ± 1.52	178 ± 0.98	177.7 ± 0.577
Thickness (mm)*	3.567 ± 0.0030	3.567 ± 0.0032	3.595 ± 0.0037	3.585 ± 0.0025	3.586 ± 0.0026	3.585 ± 0.0026
Diameter (mm)*	8.064 ± 0.003	8.082 ± 0.002	8.074 ± 0.004	8.084 ± 0.002	8.082 ± 0.003	8.085 ± 0.004
Hardness (kg/cm^2)***	2.53 ± 0.01	2.59 ± 0.01	2.61 ± 0.01	2.66 ± 0.01	2.59 ± 0.01	2.5 ± 0.01
Friability (Percentage)**	0.766 ± 0.015	0.763 ± 0.023	0.750 ± 0.020	0.766 ± 0.023	0.756 ± 0.020	0.773 ± 0.015
Dispersion time (sec)***	24.67 ± 0.577	26 ± 1.11	24 ± 1.02	24.67 ± 1.52	18 ± 2.1	17 ± 2.1
Disintegration time (sec)***	12.43 ± 2.536	9.54 ± 0.190	8.34 ± 0.619	10.57 ± 0.440	10.53 ± 0.365	8.48 ± 0.386
Wetting time (sec)***	39 ± 3.21	33 ± 3.557	18.67 ± 3.512	28.33 ± 3.024	27 ± 3.606	22.67 ± 5.686
Water absorption ratio (%)***	13.21 ± 0.092	13.72 ± 0.075	18.14 ± 0.086	12.75±0.060	18.06 ± 0.107	23.36 ± 0.127
n = 10*/20**/6*** (Average of 10 tablets)						

Table 5 Postcompression evaluation data for DO- ODTs

Parameters	**F7**	**F8**	**F9**	**Plain**
Weight variation**	178.3 ± 577	177.7 ± 0.577	178.7 ± 0.577	177.7 ± 0.577
Thickness (mm)*	3.584 ± 0.0020	3.585 ± 0.0040	3.594 ± 0.0045	3.593 ± 0.0017
Diameter (mm)*	8.086 ± 0.002	8.073 ± 0.002	8.075 ± 0.002	8.067 ± 0.002
Hardness (kg/cm^2)***	2.61 ± 0.01	2.48 ± 0.01	2.54 ± 0.01	2.51 ± 0.01
Friability (Percentage)**	0.770 ± 0.010	0.776 ± 0.005	0.760 ± 0.010	0.770 ± 0.010
Dispersion time (sec)***	28.33 ± 2.082	24.33 ± 2.082	23 ± 2.001	48.33 ± 2.082
Disintegration time (sec)***	20.1 ± 0.185	19.21 ± 0.14	16.04 ± 0.073	55.24 ± 0.340
Wetting time (sec)***	36.33 ± 1.786	29 ± 1.12	20.33 ± 2.163	60 ± 2.13
Water absorption ratio (%)***	13.72±0.07	16.75±0.573	19.43±0.378	10.78±0.491
n = 10*/20**/6*** (Average of 10 tablets)				

Table 6 *In vitro* dissolution data of DO-ODTs, plain and Mktd tablets

Time in minutes	Cumulative percentage drug released Mean ± SD n=3										
	Mktd Tablet	**Plain tablet**	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
1	---	---	50.28±1.90	50.91±3.95	64.83±1.10	50.91±3.95	46.48±1.90	49.01±2.90	48.38±3.29	45.85±1.10	44.58±1.90
2	---	---	56.47±1.91	56.48±1.93	69.28±1.09	56.48±1.93	52.64±1.88	53.93±3.94	55.82±2.91	51.37±2.19	50.09±2.19
4	---	---	59.57±1.11	60.84±1.95	71.23±2.91	60.84±1.95	56.96±1.90	55.73±2.92	57.01±3.25	55.67±2.89	56.91±3.27
5	41.69±0.38	47.11±1.10	---	---	---	---	---	---	---	---	---
6	---	---	63.31±1.91	63.33±1.89	75.72±2.86	63.33±1.89	61.31±1.91	59.44±1.84	61.37±1.91	59.38±1.90	61.27±3.80
8	---	---	67.73±1.88	65.85±1.83	84.69±2.88	65.85±1.83	66.34±2.21	65.08±1.12	66.39±1.09	63.13±2.19	64.40±1.05
10	51.37±0.79	50.75±1.90	75.34±2.86	70.91±1.12	89.93±1.91	70.91±1.12	72.05±1.87	68.88±1.15	72.73±2.16	66.90±2.87	68.19±1.93
15	58.11±0.58	58.21±2.88	82.39±1.92	76.66±1.96	93.33±2.87	76.66±1.96	76.54±1.86	76.50±4.97	80.39±1.90	78.30±3.81	73.90±2.86
20	67.90±0.57	65.11±1.89	87.61±1.06	84.98±1.84	95.48±1.90	84.98±1.84	83.59±2.92	85.45±3.97	86.85±1.89	82.21±3.99	84.10±3.95
25	75.20±0.38	73.34±1.89	---	---	---	---	---	---	---	---	---
30	84.77±0.58	82.28±2.91	95.40±1.93	96.54±4.75	97.65±5.82	95.91±5.85	95.78±6.65	97.02±5.05	95.27±1.88	95.65±5.87	96.92±1.92
40	89.66±0.59	87.50±1.05	---	---	---	---	---	---	---	---	---
50	93.39±0.59	93.40±2.89	---	---	---	---	---	---	---	---	---
60	99.99±0.60	99.98±1.13	---	---	---	---	---	---	---	---	---

In case of super disintegrant addition approach, increasing the concentration of super disintegrant from 4 % w/w to 12 % w/w in DO-ODTs resulted in an increase in the dissolution rate. The cumulative percent drug release was found to be 66.90 ± 2.87 to 89.93 ± 1.91 for F1 to F9 ODTs compared to plain tablet 50.75 ± 1.90 and 51.37 ± 0.79 marketed tablets after 10 min, accelerating the swelling, wicking properties of crospovidone, croscarmellose sodium and AE facilitating tablet breakdown. This consequence led to an increase in the tablet dissolution rate and further justified by comparing dissolution parameters viz., DE_{10}, DP_{10} and t_{50} as shown in table 5, *in vitro* dissolution data in table 6 and comparative dissolution profile in figure 10.

4. Conclusion

An attempt was done to develop Donepezil hydrochloride loaded ODTs with an objective to improve bioavailability. FTIR spectra revealed that, superdisintegrants and excipients used were compatible with drug. The formulated tablets showed compliances for various physiochemical parameters viz. hardness, friability, weight variation, content uniformity and disintegration. *In vitro* disintegration and wetting, studies indicated good results. Water absorption studies also indicated good absorptive in all formulation. *In vitro* release studies of drug for all the formulations revealed that maximum drug was released from the formulations within 30 min. F3 prepared with crospovidone at higher concentration showed faster drug release. The direct compression technique may be utilized in preparing ODTs. Hence the overall objective of the investigation was justified and fulfilled.

Compliance with ethical standards

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Disclosure of conflict of interest

No conflict of interest.

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