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HONEY AS A NOVEL EXCIPIENT IN THE FORMULATION DEVELOPMENT OF ONDANSETRON LIQUISOLID TABLETS

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ABSTRACT

Liquisolid approach, a newer formulation strategy is applied for enhancing the dissolution rate of drugs that are sparingly aqueous soluble. New excipient allows the formulation scientists to achieve specific objectives in innovative areas of drug formulation. The current study was aimed at assessing the potential of honey as a non-volatile vehicle in creating liquisolid tablets of ondansetron. Six formulations of ondansetron tablets with uniform weight were prepared in the present work. Two non-volatile solvents, namely propylene glycol, a commonly used solvent and honey, a novel alternative were employed. A constant liquid load factor was maintained for all the formulations and compressed to get 250 mg tablets. The flow property of pre-compression blends was evaluated. All formulations underwent drug release studies. The obtained dissolution profiles were compared with formulation F1 based on similarity factor (f_2), the model-independent approach. Both the bulk drug and the optimized formulation were characterized by FTIR evaluation. Assay, weight variation, friability, disintegration time and hardness results were acceptable for all the tablet batches prepared. The weight variation is less than 5% and the drug content values were within the range of 100 ± 10%, prescribed for ondansetron drug in IP. Ondansetron tablets containing honey showed similar dissolution rates with that of propylene

glycol containing tablets. Formulation F6 containing honey and croscarmellose sodium at 8% level was found to show highest drug release rate and can be considered as the optimum formulation. Based on the FTIR studies ondansetron was found to be compatible with all the excipients employed in this study. Finally, honey is found to be an alternative novel non-volatile vehicle for the formulation of ondansetron liquisolid tablets.

Keywords: Liquisolid tablets, Ondansetron, Honey, FTIR studies, Dissolution studies

INTRODUCTION

Oral administration, the popular route of administration of drugs owing to its feasibility and improved patient adherence. The pharmaceutical industry favors the conversion of medicinal drugs into tablet form because of their enhanced stability and cost efficiency. For effective absorption through the gastrointestinal tract (GIT), orally administered drugs must be solubilized. The drug absorption with low water solubility is hindered by the dissolution step. Development of fast dissolving tablets is a major approach **[1-4]** in this direction. However, liquisolid technology offers a new formulation strategy to boost the dissolution rate and thereby, the bioavailability of low aqueous soluble drugs with better results. The liquisolid system is a "dry, non-adherent, free-flowing, and compressible powder mixture derived from drug suspensions, liquid drugs, or drug solutions in the non-volatile vehicles, utilizing coating materials and selected carriers." Non-volatile vehicles are crucial in liquisolid technology as they either disperse or dissolve the drug within them **[5]**.

In the recent advances of pharmaceutical dosage form design, liquisolid technique **[6]** emerged as a new formulation technique providing multiple applications. Dissolution rate of Lovastatin **[7]**, Rofecoxib **[8]**, Ketoconazole **[9]** and bioavailability of Olanzapine **[10]** were improved by liquisolid technique. Mirtazapine **[11]**, Efavirenz **[12]**, Chlorpromazine **[13]** liquisolid tablets were formulated and optimized using DoE approach. Apart from the poorly soluble drug, the other important formulation components used in this technique are the carrier, coating agent, the non-volatile vehicle, and super disintegrant. The selection of each ingredient and its proportion are critical factors affecting the quality of final tablets prepared by this technique. The nature of non-volatile vehicle the critical formulation variable investigated in this study. In general, organic solvents like liquid polyethylene glycols, propylene glycol, polysorbates and glycerin which are miscible

with water, having high boiling point, less viscosity and inert, are the most successful non-volatile solvents **[14, 15]** already used in earlier studies. In the present work, honey was tried as a new non-volatile vehicle in the formulation of ondansetron liquisolid tablets. Honey is a viscous, translucent yellowish-brown fluid produced by the hive-bee *Apis mellifera* Linn., from the nectar of flowers. It is largely used as a demulcent and sweetening agent as well as for its nutritive properties **[16]**.

Ondansetron is a white or nearly white powder that is sparingly soluble in water. As a 5-HT3 antagonist, it is employed in managing vomiting and nausea due to chemotherapy and radiotherapy. Additionally, it is utilized for the prevention and treatment of postoperative nausea and vomiting. The absolute bioavailability of ondansetron is about 60% in fasting subjects **[17]**. It comprises BCS class-II and its biological half-life is around 3h **[18]**. Ondansetron is available for use by oral administration in the form of tablets of 8 mg strength. Hence improvement of the bioavailability and dissolution rate are rather significant factors relevant to this drug. Within this framework the present work was carried out by selecting ondansetron as the poorly soluble drug and liquisolid technique as the formulation strategy. The study was aimed at improving the rate of dissolution of ondansetron tablets and to study the effect of honey as a new non-volatile solvent at the same time.

MATERIALS AND METHODS

MATERIALS

Ondansetron, Avicel PH102, and Croscarmellose Sodium were acquired from Yarrow Chem Products, Mumbai. Honey was obtained from Dabur Ayurveda, New Delhi. Propylene glycol was procured from Nice Chemicals Private Limited., Cochin. Polyvinyl pyrrolidone and Aerosil were obtained from Oxford Laboratory Limited., Mumbai.

METHODS

A) Preparation of Ondansetron liquisolid tablets

The materials used in the formulation of the tablets were propylene glycol and honey - non- volatile vehicles, Avicel (PH 102) - carrier, Aerosil - coating agent and croscarmellose sodium - super disintegrant. Optimization of liquid load factor (L_f) and carrier: coating ratio (R) **[19]** was performed in preliminary trials using different proportions of the above materials. From these trials the optimum L_f value that showed better flow and compressibility properties was found to be 0.55. The same L_f value was employed for all the formulations. R value in the range

of 2.36-2.90 produced acceptable quality tablets. Based on this data six formulations were designed as shown in **Table 1**. The procedure for the formulation of ondansetron10 mg tablets was given below.

Accurately weighed ondansetron drug was taken into a porcelain mortar and triturated with propylene glycol/honey until a uniform dispersion was formed. Avicel PH 102 was mixed to the contents present in the mortar and continuously mixed till homogeneous wet mass was obtained. Polyvinyl pyrrolidone and croscarmellose sodium were also added and mixed well. Aerosil was the final addition to get a dry powder blend and was compressed to get tablets of 250 mg weight. In case of honey, it was slightly warmed and used to increase its pourability. All the other formulations were prepared similarly.

B) Studies of pre-compression powder blend

The parameter of primary importance when handling drug excipient powder blend is its flow characteristics. When limited amounts of drug blend is available, the flow property is identified by measurements of bulk density and angle of repose. The test procedure for these derived parameters **[20]** is detailed below.

1) **Bulk density and tapped density**

A 10-gram sample of the pre-compression blend was accurately weighed and taken in a cylinder to record the initial volume as Vo. The cylinder was then placed on the platform of the bulk density apparatus (ElectroLab), which was set to perform 200 tapping strokes. Upon completion of the tapping process, the final volume (Vf) of the precompression blend was recorded. The bulk density and tapped density were subsequently determined by the appropriate standard formulas.

Bulk density (D_b) = Powder blend weight/ Initial volume (V_o)

Tapped density (D_t) = Powder blend weight/ Final volume (V_f)

2) **Compressibility index and Hausner ratio**

Bulk density (D_b) and tapped density (D_t) were used to calculate them.

$$\text{Compressibility index (\%)} = \frac{D_t - D_b}{D_b} \times 100$$

$$\text{Hausner ratio} = \frac{D_t}{D_b}$$

3) **Angle of repose**

It is another commonly employed parameter to assess the powder's flow nature. The angle between the horizontal surface and the pile surface of precompression powder is the angle of repose. The below given equation determined angle of repose.

$$\tan\theta = h/r$$

Where h = Pile height r = Radius of pile base.

θ = Angle of repose

C) Evaluation of prepared tablets

Evaluation tests were conducted to monitor thickness, hardness, friability, weight variation, and disintegration time for the tablets. The weight variation was decided by randomly collecting 20 tablets from every formulation. Each tablet was independently weighed with an analytical balance. The thickness of individual tablets was assessed with a sliding caliper scale. The hardness was measured with a hardness tester (Pfizer). The friability was assessed with a Roche friabilator. The time of disintegration of prepared tablets was established by employing a tablet disintegration tester (Electrolab).

1) Content of the drug

Ten tablets were randomly chosen, crushed, and blended to achieve a uniform powder. Accurately weighed quantity of this powder mixture containing 8 mg of ondansetron was taken and placed in a 10 mL flask. The content of the drug was decided by taking 0.1N HCl as the solubilizing solvent, measured at a wavelength of maximum absorbance (λ max) of 310 nm with a UV-visible double beam spectrophotometer (SL 159).

2) Protocol for dissolution

Dissolution testing in in-vitro was performed with a USP Type II (rotating paddle apparatus) equipment (Electrolab, TDT-08L) with 500 mL of 0.1N HCl for a duration of one hour. The temperature was constantly sustained at 37 ± 0.5ºC, and the paddle speed was maintained at 50 rotations per minute. 5 mL volume were taken at 5, 10, 20, 30, 45, and 60 minutes. These samples were examined at a wavelength of 310 nm with a UV-visible spectrophotometer **[21]**. The cumulative percent of the drug dissolved (CPD) was calculated, and dissolution profiles were plotted with time on X-axis and CPD on Y-axis.

3) Statistical analysis

Similarity factor (f_2), a model-independent method was used for contrasting dissolutions. It was determined using the given below algorithm:

$$f_2 = 50 \times \log\{[1+(1/n)\Sigma^{n}_{t=1}(R_t - T_t)^2]^{-0.5} \times 100\}$$

Where n, number of considered time intervals; T_t and R_t, cumulative percentage of dissolved drug of the test and reference respectively

f_2 more than 50 reflect the similarity between the two dissolutions. In the present work F1 is considered as the reference and the remaining other formulations are considered as test products.

D) Fourier Transform Infrared spectroscopic (FTIR) studies

The incompatibility among bulk drug and the excipients was assessed by infrared spectroscopy. The optimized formulation's FTIR was carefully compared to the bulk drug. KBr pellet method was followed in the present work. Ondansetron and the optimized formulation were compressed under the hydraulic press to get a compact mass. Then the prepared KBr pellet was sweeped in the spectrophotometer and the obtained spectrum was studied.

RESULTS AND DISCUSSION

Optimization of Lf, the liquid load factor and R, the carrier/coating ratio was conducted during preliminary trials using various proportions of the selected excipients. Among the tested formulations, an Lf value of 0.55 was identified as optimal, providing superior flowability and compressibility characteristics. Consequently, this Lf value was maintained across all subsequent formulations. Additionally, R values within the range of 2.36 to 2.90 were found to yield tablets with acceptable physical and mechanical properties. Tablets with uniform size and appearance were obtained in the present study. No capping, sticking and picking were observed during the compression of Ondansetron liquisolid tablets. The results of precompression analysis of liquisolid powders are reflected in **Table 2**. The angle of repose values collected were from 22.47 to 29.74, which are present in the range of 20-30 as per standard table and hence indicates good flow characteristics. The Carr's index numericals denote fair and passable flow property of the powders. All the values of Hausner ratio obtained are below 1.25 indicating good flow property. Hence the flow characteristics were good, and the powder blend is suitable for further compression into tablets.

The various tablet parameters evaluated are shown in **Table 3**. The hardness values were present around 4 kg/cm^2 and friability results were less than one, which indicates sufficient physical strength of the obtained tablets. The weight variation is less than 5% and the assay values were within the range of 100 ± 10 %, prescribed for ondansetron drug in IP **[22]**. The difference in the thickness was very less and the thickness was present within 1±0.1 mm. As the percentage of superdisintegrant was increased, the disintegration time decreased. Formulations F4, F5 and F6 containing honey as the non-volatile solvent showed similar disintegration times compared to F1, F2 and F3.

The profiles of drug dissolution testing are given in **Figure 1**. Formulations F1, F2 and F3

contains propylene glycol and formulations F4, F5 and F6 contain honey as the non-volatile solvent. F1, F2, F3 and F4 showed similar dissolution profiles as indicated from f_2 values of 69.50, 52.48 and 63.99 respectively between F1 versus F2, F1versus F3, F1versus F4 dissolution data calculations. F1 versus F5 and F1 versus F6 dissolution data calculations showed f_2 values of 46.06 and 38.16 respectively, which indicated that, F5 and F6 showed higher dissolution rate when compared to F1. Formulation F4, employing honey and 4% of croscarmellose sodium showed similar dissolution rate when compared to that of F1. Formulations F5 and F6 containing croscarmellose sodium at 6% and 8% concentration showed similar drug dissolution with respective to F2 and F3 containing propylene glycol as indicated from f_2 values of 54.50 and 51.92. When the superdisintegrant concentration was increased from 4% to 8%, honey showed more enhancement in dissolution rate compared to propylene glycol. Formulation F6 containing honey and croscarmellose sodium at 8% level was found to release the total drug before one hour and hence can be considered as the best formulation. **Table 4** represents the regression parameters derived from plotting the dissolution data to appropriate kinetic models. Formulation F6 ranked first order followed by Hixon-Crowell model **[23]**.

Propylene glycol is a non-volatile solvent used in liquisolid compacts of many drugs where it produced tablets with acceptable properties and dissolution rate **[24]**. Honey used in herbal products was proved to augment their efficacy and safety profile. Yuntao Dai *et.al* **[25]** provided the theoretical basis for improvement of stability and absorption aspects related to herbal products when honey was employed in the formulations. Honey enhanced the dissolution of active ingredients and thereby, their oral absorption. Honey has broad medical applications and is a potential excipient **[26]**. Previous study conducted also demonstrated the non-volatile vehicle property of honey in the domperidone liquisolid tablets **[27]**.

The FTIR spectrum of Ondansetron shown in **Figure 2** presents a characteristic peak of N-H bonding at 1622 cm^{-1} and two strong peaks of C-N stretching and ortho-substitution phenyl C-H bending - 1244 cm^{-1} and 756 cm^{-1}, respectively **[28]**. FTIR of formulation F6 represented in **Figure 3** shows that the available peaks were similar to characteristic peaks of drug without much deviation. FTIR of optimized formulation F6 was identical to that of the bulk drug. This suggests the absence of interaction between drug and

excipient in ondansetron liquisolid tablets. Infrared spectroscopic studies used in the formulation indicated compatibility among the drug and the other selected excipients.

Table 1: Formulation of Ondansetron liquisolid tablets

Components (mg)	F1	F2	F3	F4	F5	F6
Ondansetron	8	8	8	8	8	8
Propylene glycol	50	50	50	-	-	-
Honey	-	-	-	50	50	50
Avicel PH102	90	90	90	90	90	90
PVP	10	10	10	10	10	10
Croscarmellose Sodium	14	21	28	14	21	28
Aerosil	78	71	64	78	71	64
Total	250	250	250	250	250	250

Table 2: Pre-compression parameters of the powder blend

Formulation	Angle of Repose (θ)	Bulk Density (g/ml)	Tapped Density (g/ml)	Carr's Index	Hausner Ratio
F1	22.47	1.2	1.0	20.02	1.133
F2	27.74	1.3	1.1	18.18	1.146
F3	29.74	1.4	1.2	16.66	0.953
F4	19.47	1.3	1.6	18.75	1.078
F5	23.55	1.3	1.1	18.18	0.946
F6	26.50	1.4	1.2	16.66	0.968

Table 3: Evaluation of the formulated tablets

Formulation	Hardness (kg/cm^2)	Friability (%)	Weight Variation (mg)	Drug Content (%)	Disintegration Time (s)
F1	4.2±0.2	0.42	250±3.17	98.34±1.22	94±11
F2	4.1±0.2	0.51	251±2.23	99.12±0.44	76±06
F3	3.9±0.1	0.62	250±4.53	97.68±1.76	67±03
F4	4.0±0.2	0.52	249±5.48	97.86±1.82	122±23
F5	4.1±0.3	0.57	250±2.39	98.44±1.08	65±15
F6	4.0±0.2	0.65	251±3.31	98.08±1.62	58±05

Table 4: Drug release kinetics

Formulations	Zero-order		First-order		Hixcon-Crowell		Higuchi	
	r^2	K_o	r^2	K_1	r^2	K_2	r^2	K_3
F1	0.846	0.912	0.921	0.042	0.952	0.045	0.904	4.218
F2	0.746	0.684	0.981	0.054	0.964	0.031	0.864	3.374
F3	0.855	0.621	0.945	0.068	0.942	0.042	0.829	3.465
F4	0.637	0.548	0.928	0.071	0.934	0.038	0.754	3.347
F5	0.698	0.487	0.974	0.073	0.913	0.026	0.785	2.665
F6	0.728	0.346	0.986	0.076	0.918	0.021	0.846	2.245

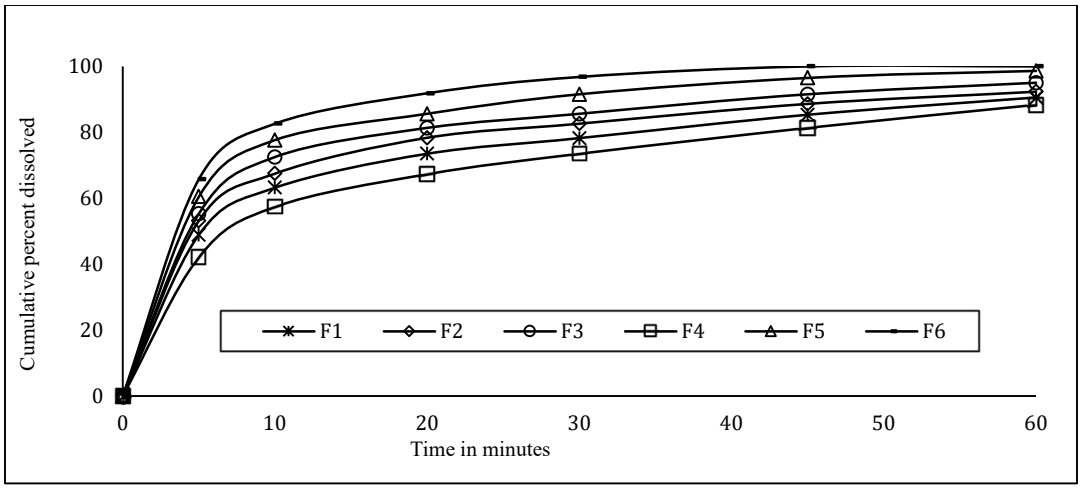

Figure 1: Drug dissolution profiles

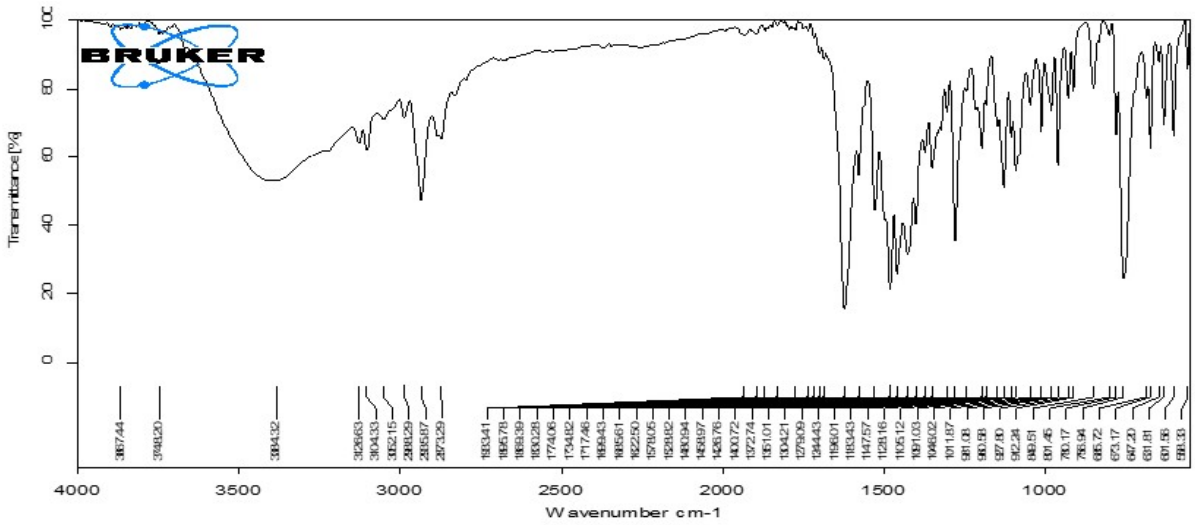

Figure 2: FTIR of Ondansetron pure drug

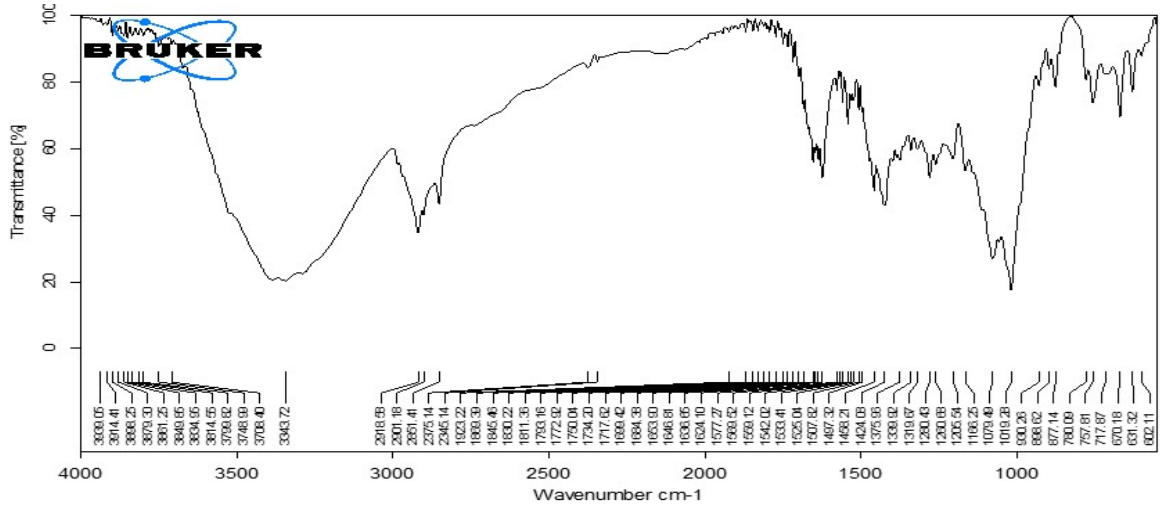

Figure 3: FTIR of Ondansetron optimized formulation (F6)

CONCLUSIONS

The majority of drugs that are being developed recently suffer from low aqueous solubility. The pharmaceutical scientists face a serious challenge in the task of improvising the dissolution rate of these sparingly aqueous soluble drugs. The liquisolid approach, which involves converting a fine liquid dispersion of the drug to a powder with good flowability and compressibility, represents a novel strategy to address the issue. The potential of honey in the formulation of a low dose and sparingly water-soluble drug, ondansetron by liquisolid technology was investigated. Propylene glycol and honey were used as non-volatile solvents, and a constant liquid load factor was employed for all the formulations. Tablets of uniform weight and acceptable appearance were obtained in this study. Incorporation of the natural liquid, honey showed more improvement in dissolution rate as the super disintegrant concentration was increased. It can be concluded that honey has the potential to serve like a non-volatile vehicle in the development of ondansetron liquisolid tablets. Liquisolid systems are typically based on the use of non-volatile vehicle systems to produce a suspension, solution, or emulsion. The investigation of novel excipients represents a promising and prospective area of research in pharmaceutical sciences, with significant potential to enhance drug formulation and delivery.

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