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FORMULATION AND *IN-VITRO* CHARACTERISATION OF VILAZODONE IMMEDIATE RELEASE TABLETS

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Keywords:

Vilazodone, Immediate release tablets, Croscarmellose, Crospovidone, Sodium starch glycolate

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ABSTRACT: The aim of the present study is to develop and evaluate the immediate release tablet of Vilazodone by direct compression method. The superdisintegrant crospovidone (CP), croscarmellose sodium (CCS), sodium starch glycolate (SSG), and Locust beam gum were used for the immediate release of drug from the tablet. Optimization of superdisintegrant concentration that can control the release of the drug as the hypothetical release profile was based on the release profile of the prepared trials. The prepared tablets were evaluated for all pre-compression parameters. Evaluation parameters Like weight variation, the hardness of the tablet, friability, thickness, disintegration test, drug content uniformity, and *in-vitro* release studies were performed. The drug-excipients interaction was investigated by FTIR. All formulation showed compliances with Pharmacopoeial standards. Among all the formulations, a formulation containing croscarmellose sodium as a super disintegrant is fulfilling all the parameters satisfactorily. The study reveals that formulations prepared by direct compression F5 exhibits the highest dissolution using croscarmellose sodium showed faster drug release 96.57% over 30 min.

INTRODUCTION: An immediate release dosage form allows a manufacturer to extend market exclusivity while offering patients a convenient dosage form or dosage regimen. Immediate Release Tablets are those tablets which are designed to disintegrate and release their medication with no special rate controlling features, such as special coatings and other techniques, [1, 2] immediate releases and fast dispersing drug delivery system may offer a solution to these problems. Recently, immediate release tablets have started gaining popularity and acceptance as a drug delivery system, mainly because they are easy to administer, has a quick onset of action is economical and lead to better patient compliance.

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They are also a tool for expanding markets, extending product life cycles and generating opportunities [3, 4]. Immediate release tablets are those which disintegrate rapidly and get dissolved to release the medicaments. The immediate release may be provided for by way of an appropriate pharmaceutically acceptable diluent or carrier, which diluent or carrier does not prolong, to an appreciable extent, the rate of drug release and/or absorption. This term excludes formulations which are adapted to provide for "modified", "controlled", "sustained", "prolonged", "extended" or "delayed" release of the drug. Vilazodone is used to treat depression. It is an SSRI (selective serotonin reuptake inhibitor) and partial serotonin receptor agonist. It works by helping to restore the balance of certain natural substances in the brain (neurotransmitters such as serotonin) [5, 6].

MATERIALS AND METHODS:

Materials: Vilazodone was kindly gifted by Hetero Drugs Ltd., Hyderabad, India. Sodium Starch Glycolate and Povidone K30 were obtained Akin

laboratories, Hyderabad. Microcrystalline cellulose and crospovidone purchased from signet chemicals, Mumbai India. Magnesium stearate was purchased from SD fine chemicals limited, Mumbai, India.

Methods:

Preparation of Immediate Release Vilazodone Tablets: Drug and different concentrations for super Disintegrates and required ingredients were accurately weighed and passed through a 40-mesh screen to get uniform size particles and mixed in a glass mortar for 15 min. The obtained blend was lubricated with magnesium stearate, and glidant (Talc) was added, and mixing was continued for further 5 min. The resultant mixture was directly compressed into tablets by using the punch of rotary tablet compression machine. Compression force was kept constant for all formulations [7, 8].

TABLE 1: FORMULATION OF IMMEDIATE RELEASE TABLETS OF VILAZODONE

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Vilazodone	10	10	10	10	10	10	10	10	10	10	10	10
Cross Povidone	10	20	30	-	-	-	-	-	-	-	-	-
Crosscarmellose sodium	-	-	-	10	20	30	-	-	-	-	-	--
Sodium starch glycolate	-	-	-	-	-	-	10	20	30	-	-	-
Locust beam gum	-	-	-	-	-	-	-	-	-	10	20	30
Aspartame	3	3	3	3	3	3	3	3	3	3	3	3
Mg stearate	6	6	6	6	6	6	6	6	6	6	6	6
Talc	6	6	6	6	6	6	6	6	6	6	6	6
MCC	85	75	65	85	75	65	85	75	65	85	75	65
Total weight	120	120	120	120	120	120	120	120	120	120	120	120

Evaluation of Immediate Release Acyclovir Tablets:

Uniformity of Weight: [9] Individually, 20 tablets were weighted at random using electronic balance and the average weight was determined.

Tablet Hardness: Automatic Tablet Hardness Tester (Pfizer hardness tester) was used to determine the crushing strength. 6 tablets were randomly selected from each formulation, and the pressure at which each tablet crushed was recorded [10].

Thickness: The thickness of tablets was determined by using Digital Micrometer. Ten individual tablets from each batch were used, and the results averaged.

Tablet Friability: 20 tablets of each formulation were weighed and subjected to abrasion by employing at 25 rev/min for 4 min. The tablets were then weighed and compared with their initial weights, and percentage friability was obtained [11].

***In-vitro* Disintegration Test:** 6 tablets from each formulation were employed for the test in distilled water at 37 °C using Tablet Disintegration Tester. The time required for disintegrating the tablet and to break down from a large particle too small particle completely was recorded.

Assay: The content of the drug was carried out by five randomly selected tablets of each formulation. The five tablets were ground in a mortar to get powder; this powder was dissolved in pH 6.8 phosphate buffer by sonication for 30 min and filtered through filter paper. The drug content was analyzed spectrophotometrically at 241 nm using UV spectrophotometer. Each measurement was carried out in triplicate, and the average drug content was calculated.

***In-vitro* Dissolution Study:** Drug release from Vilazodone tablets was determined by using dissolution test United States Pharmacopoeia (USP) 24 type II (paddle). The parameters used for performing the dissolution were pH 6.8 phosphate buffer as the dissolution medium of quantity 500 ml. The whole study is being carried out at a temperature of 37 ºC and a speed of 50 rpm. 5 ml aliquots of dissolution media were withdrawn each time at suitable time intervals (5, 10, 15, 20, 25 and 30 min) and replaced with fresh medium.

After withdrawing, samples were filtered and analyzed after appropriate dilution by UV spectrophotometer. The concentration was calculated using the standard calibration curve.

RESULTS AND DISCUSSION:

Drug-Excipient Compatibility Studies by FTIR Studies:

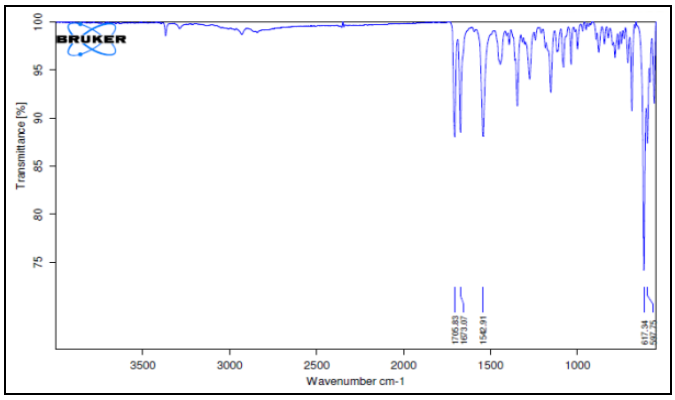

FIG. 1: FTIR SPECTRA OF PURE DRUG

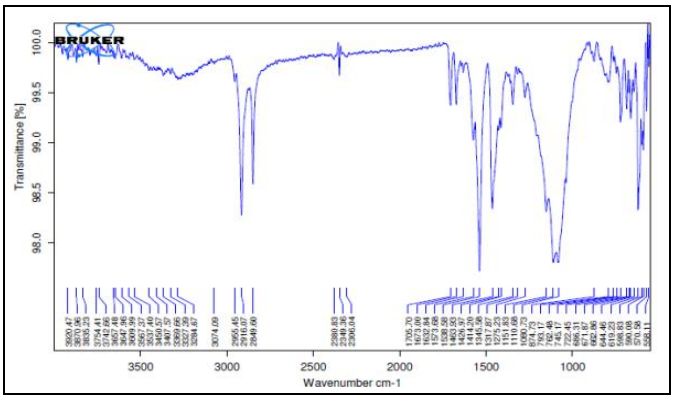

FIG. 2: FTIR SPECTRA OF OPTIMIZED FORMULATION

Vilazodone was mixed with various proportions of excipients showed no color change at the end of two months, providing no drug-excipient interactions.

Evaluation:

Characterization of Pre-compression Blend: The pre-compression blend of Vilazodone was characterized concerning the angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio. The angle of repose was less than 28 º, Carr's index values were less than 11 for the pre-compression blend of all the batches indicating good to fair compressibility. Hausner's ratio was less than 1.25 for all batches indicating good flow properties.

TABLE 2: PHYSICAL PROPERTIES OF PRECOMPRESSION BLEND

Formulation code	Angle of repose (Θ)	Bulk density (gm/cm^3)	Tapped density(gm/cm^3)	Carr's index (%)	Hausner's ratio
F1	30.48 ± 0.02	0.515 ± 1.47	0.610 ± 0.01	15.57 ± 1.4	1.18 ± 0.01
F2	31.24 ± 0.04	0.523 ± 0.45	0.612 ± 0.01	14.95 ± 0.66	1.17 ± 0.02
F3	30.86 ± 0.03	0.518 ± 0.25	0.613 ± 0.02	15.35 ± 0.3	1.18 ± 0.01
F4	33.28 ± 0.01	0.517 ± 1.05	0.617 ± 0.03	15.66 ± 0.10	1.185 ± 0.15
F5	32.19 ± 0.02	0.525 ± 0.99	0.611 ± 0.01	14.91 ± 0.33	1.175 ± 0.03
F6	31.10 ± 0.02	0.522 ± 0.36	0.623 ± 0.02	14.56 ± 0.20	1.170 ± 0.01
F7	39.23 ± 0.01	0.527 ± 0.45	0.618 ± 0.01	16.53 ± 1.6	1.198 ± 0.21
F8	32.21 ± 0.01	0.516 ± 0.24	0.622 ± 0.05	14.96 ± 0.15	1.186 ± 0.03
F9	33.54 ± 0.04	0.522 ± 0.25	0.615 ± 0.04	15.64 ± 0.26	1.175 ± 0.02
F10	34.65 ± 0.08	0.526 ± 0.65	0.614 ± 0.01	15.62 ± 0.72	1.187 ± 0.13
F11	36.27 ± 0.06	0.522 ± 0.34	0.621 ± 0.04	14.87 ± 0.35	1.185 ± 0.06
F12	35.24 ± 0.07	0.525 ± 0.11	0.619 ± 0.02	15.32 ± 0.09	1.197 ± 0.07

All the values represent n = 3

Evaluation of Tablets:

Physical Evaluation of Vilazodone Immediate Release Tablets: The results of the weight variation, hardness, thickness, friability, and drug content of tablets are given in the table. All the tablets of different batches complied with the official requirement of weight variation as their weight variation pass the limit.

The hardness of the tablets ranged from 2.28 ± 86 - 2.96 ± 68 kg/cm^{2,} and the friability values were < than 0.39 ± 66%, indicating that the tablets were compact and hard. The thickness of the tablets ranged from 2.01 ± 22 -2.08 ± 57.

All the formulations satisfied the content of the drug as they contained 98 - 100% of vilazodone and good uniformity in drug content was observed. Thus all physical attributes of the prepared tablets were found to be practically within control limits.

***In*-vitro Dissolution:** The drug release rate from tablets was studied using the USP type II dissolution test apparatus. The dissolution medium was 500 ml of pH 6.8 phosphate buffer at 50 rpm at a temperature of 37 ± 0.5 ºC. Samples of 5 ml were collected at different time intervals up to 1 h and have analyzed after appropriate dilution by using UV spectrophotometer at 241 nm.

TABLE 3: EVALUATION OF VILAZODONE IMMEDIATE RELEASE TABLETS

Formulation code	Average weight (mg)	Thickness (cm)	Hardness (Kg/cm^2)	Friability (%)	Content uniformity (%)	*In-vitro* disintegration time (Min)
F1	198.18	2.02 ± 98	2.65 ± 25	0.42 ± 95	99.18	4.3
F2	196.68	2.05 ± 84	2.84 ± 96	0.56 ± 64	97.27	4.4
F3	199.25	2.01 ± 22	2.82 ± 88	0.38 ± 84	100.68	4.6
F4	197.37	2.06 ± 31	2.90 ± 76	0.51 ± 72	101.85	4.8
F5	200.99	2.08 ± 14	2.55 ± 22	0.63 ± 38	96.39	2.8
F6	201.76	2.02 ± 96	2.28 ± 86	0.54 ± 99	99.47	3.3
F7	199.55	2.01 ± 65	2.47 ± 65	0.48 ± 57	98.25	4.1
F8	198.68	2.06 ± 77	2.96 ± 68	0.56 ± 75	96.44	3.6
F9	199.91	2.08 ± 57	2.87 ± 46	0.39 ± 66	98.19	3.1
F10	200.77	2.03 ± 28	2.64 ± 33	0.41 ± 38	99.27	5.0
F11	202.38	2.04 ± 71	2.94 ± 75	0.46 ± 24	100.69	5.2
F12	199.43	2.05 ± 27	2.72 ± 68	0.53 ± 38	99.48	5.4

TABLE 4: *IN-VITRO* DATA FOR FORMULATION F1- 12

Time (Min)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
0	0	0	0	0	0	0	0	0	0	0	0	0
5	16.28	12.26	15.33	18.12	18.15	22.28	20.48	22.71	24.37	20.85	20.22	18.45
10	39.42	25.38	27.57	27.38	34.93	34.58	28.63	31.94	36.39	33.62	28.31	36.69
15	43.15	39.99	45.36	39.27	47.69	45.35	37.28	42.37	45.47	43.68	36.18	45.76
20	57.75	47.62	59.75	52.85	62.26	64.88	44.94	48.54	52.69	55.25	48.85	60.54
25	64.74	69.75	68.33	66.85	74.88	72.74	62.22	63.33	79.66	68.99	55.91	68.37
30	72.28	75.31	79.18	78.43	96.57	87.63	70.99	86.27	93.54	84.14	76.88	72.41

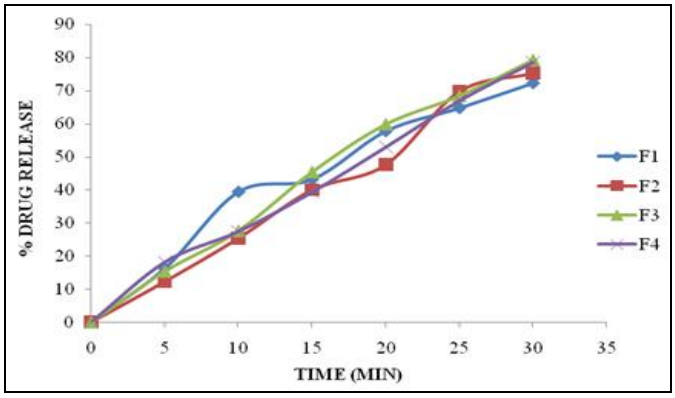

FIG. 3: *IN-VITRO* DISSOLUTION DATA FOR FORMULATION F1-F4

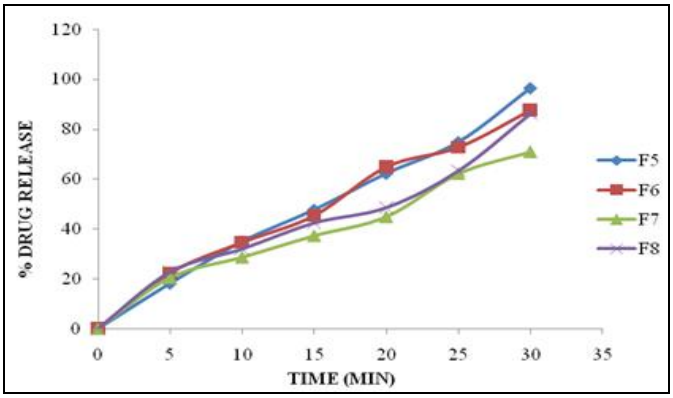

FIG. 4: *IN-VITRO* DISSOLUTION DATA FOR FORMULATIONS F5-F8

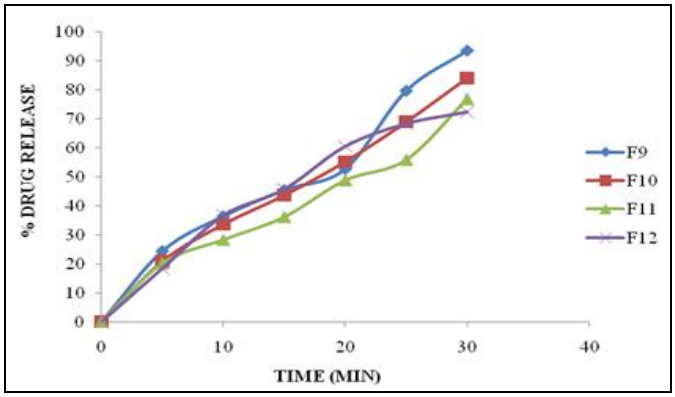

FIG. 5: *IN-VITRO* DISSOLUTION DATA FOR FORMULATIONS F9-F12

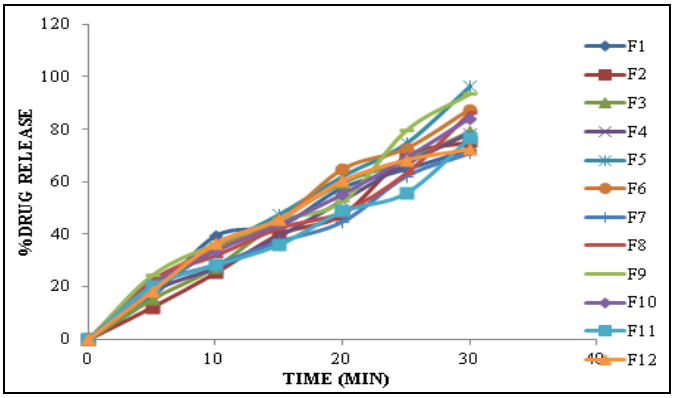

FIG. 6: *IN-VITRO* DISSOLUTION DATA FOR FORMULATIONS F1-F12

Among all the formulations F5 formulation containing drug and exploited showed good result that is 96.57% in 30 min, at the concentration of 20 mg and F5 formulation showed less disintegration time (2.8 min). Hence, from all the formulations, it is evident that F5 formulation is the better formulation.

CONCLUSION: In the present study, vilazodone 10 mg tablets have been formulated and developed using direct compression technique, to provide a safe, highly effective method for treating severe depression while reducing undesirable adverse effects.

The results suggest that suitably formulated immediate release tablets of vilazodone with a superdisintegrants (cross-povidone, cross-carmelrose sodium, sodium starch glycolate, and Locust beam gum) can be achieved. Pre-formulation studies of vilazodone were performed. The FTIR analysis revealed that the super-disintegrants and excipients used were compatible with vilazodone. Immediate release tablets vilazodone is to be prepared by direct compression technique using superdisintegrants, namely cross-povidone, croscarmellose sodium, sodium starch glycolate, locust beam gum.

Among all the formulations, the formulation containing croscarmellose sodium as a super disintegrant is fulfilling all the parameters satisfactorily. It has shown excellent (Less) *in-vitro* disintegration compared to other super-disintegrants. A part from all formulations F5 formulation showed maximum drug release 96.57% at the end of 30 min.

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CONFLICT OF INTEREST: The authors validate that the contents of this article have no conflict of interest.

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