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Formulation and evaluation of Risperidone orally disintegrating tablets

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ABSTRACT

Most people have difficulty swallowing, particularly the geriatric or pediatric population. Tablets have many advantages such as cost-effectiveness, compactness, least variability of contents of all oral dosage forms. Oral Disintegrating Tablets (ODT) are dissolving tablets that are solid oral dosage forms that break down into a swallowable form without additional water. There are many properties such as it should break down without additional water, easily transportable. Chemicals such as Mannitol, Sorbitol, Propyl paraben, Methyl paraben, Crospovidone, etc. are used for manufacturing ODTs. The formulation steps for the tablet are sieving, dry mixing, lubrication, and compression. ODTs are evaluated for friability, thickness, hardness and weight variation. Formulation-I contained 2mg Risperidone,121.60mg Mannitol anhydrous, 11.20mg sodium starch glycollate, 0.80mg methylparaben, 0.20mg propylparaben, 1.40mg Aspartame, 0.7mg Sunset yellow, 1.40mg Strawberry flavour, and 0.70mg Magnesium stearate. Each formulation from F-II to F-VII were made by changing the composition compared to F-I. Using a pH 1.2 buffer, Risperidone calibration curves were analyzed using HPLC. There were straight-line relationships for Risperidone standard solution in Media at a concentration of 0-10 μg/ml. Physico-chemical parameters such as Loose Bulk Density (LBD), Angle of Repose, Tapped Bulk Density (TBD), Drug content (%) and Compressibility index (%) were analyzed for FI- F-VII. The cumulative percentage drug release of F-I is 96.50, F-II is 99.65, F-III is 99.82, F-IV is 98.56, F-V is 98.25, F-VI is 99.73 and F-VII is 99.82. F-I - F-VII formulations were compared to marketed sample (ZISPER MD 2mg). Stability Data of Risperidone F-VII Orally disintegrating Tablets at two different temperatures were carried out.

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INTRODUCTION

Dysphagia or difficulty swallowing affects about one third of the population. Patients with difficulty swallowing are most likely to be geriatric or pediatric. Schizophrenic patients can also have difficulty swallowing because of hand tremors, dysphasia, fear of choking, and underdeveloped nervous and muscular systems [1].

Pediatric Dosage Forms

Pharmacists are constantly adapting to maximize patient compliance, which is the most important fac-

tor in pediatric drug administration. In accordance with WHO guidelines, an ideal drug delivery system for children must be easy to administer, palatable, able to be titrated and administered based on weight, as well as contain safe, well-established and stable excipients [2].

Liquid Dosage Forms

As a result of the variable dosing and palatable nature of liquid oral dosage forms, they were considered the best way to administer medications to children [3].

Solid Dosage Forms

There is a considerable difference between administering drugs as pure chemical substances and administering them as prepared preparations.

Advantages of tablets

Tablets can provide the following primary benefits

The unit dosage form is the least variable oral dosage form in terms of dosage precision and content variability.

Among all oral dosage forms, this has the lowest cost.

Their lightness and compactness make them the most desirable [4].

Disadvantages

Tablets still have some disadvantages despite all their advantages. In addition to their advantages, tablets also have some disadvantages:

Drugs that are amorphous or flocculent and low-density resist compressed into dense compacts.

In the case of poorly wetting, slow dissolving, intermediate or large dosages, or high absorption in the gastrointestinal tract, formulation and manufacture of tablets that are adequate in bioavailability may be difficult or impossible.

Orally Disintegrating Tablets

Children who swallow tablets can suffer from aspiration risks and swallowing difficulties, which can cause complications with traditional tablets. Pediatric patients are typically less at risk of aspirating with oral disintegrating tablets (ODTs). Oral disintegrating tablets are solid oral dosage forms that disintegrate without additional water in the oral cavity into a form that can be swallowed. Due to their non-water or chewing requirements, ODTs are beneficial. There are many advantages to these drugs, including superior taste, increased bioavailability, improved efficacy, improved stability, variable dosing, and lowered costs. Furthermore, more than half of patients prefer ODTs to tablets or other forms of dosage.

Ideal properties of orally disintegrating tablets

Tablets that disintegrate orally should follow,

- Swallow without the need for water or other liquids.
- Within a few seconds, it dissolves or disintegrates in saliva.
- Taste good.
- If administered, Mouth residue will be minimal.
- Transport and portability are important [5].

Techniques for preparing orally disintegrating tablets

In order to formulate oral disintegrating tablets, several techniques have been reported [6].

- Tablet Moulding
- Freeze drying / lyophilization
- Sublimation
- Spray drying
- Mass extrusion
- Direct compression

MATERIALS AND METHODS

Risperidone was procured from JPN Pharma Private Limited, Cellulose, Microcrystalline from Ankit pulps and boards Private Limited, Mannitol from Quingdao bright moon sea wood, Sorbitol-Roquette, Propyl paraben and Methyl paraben purchased from Rasula pharmaceuticals and fine chemicals, Starch, pre-gelatinized was from Universal starch chem allied ltd., Croscarmellose sodium from Prachin chemicals, Crospovidone-International fine chemicals, Sodium starch glycolate-Vasa pharma chem pvt ltd., Magnesium stearate - Accent microcell pvt ltd., Sunset yellow-Roha dye chem. Pvt ltd

Equipment used in each company were Blister Packing Machine - Elmach packages pvt ltd, Mumbai, India, Single pan electronic balance; Dissolution Test Apparatus - Electro Lab, Mumbai, India; 12 Station D/B Tooling compression Machine Blister Packing Machine - Fluid pack, Ahmedabad

Formulation steps for tablets (Direct compression)

Table 2 shows how oral disintegrating tablets of Risperidone (2 mg) were prepared using direct compression (without granulating step). Formulation

codes FI-FVII were prepared using direct compression. Sieving, dry mixing, lubrication, and compression are the steps involved in Direct Compression Method tablet production [7].

Sieving

In Table 4, the active ingredient and the other ingredients (described in formulation codes F-I to F-VII) were passed through sieve number 40.

Dry mixing

To ensure uniform mixing of the active ingredient and all the ingredients, all the ingredients were placed in poly bags and mixed for 10 mins.

Lubrication

It was mixed with the powder mixture, magnesium stearate, talc and sieve # 60 for 5 minutes in a polybag to achieve a uniform blend.

Compression

A tablet shape of 7.14 mm was then used to compress the powder mixture into tablets. One machine compresses tablets using rotary punches.

Packing Details

Packing specifications for the prepared tablets were as follows: 10 tablets were packaged in PVC-Aluminum blister packets.

Evaluation of orally dispersible tablets

Thickness

Tablet thickness is the only overall dimensional variable once tablet size and shape are determined. An established thickness standard should not be exceeded by more than 5%. Packaging and consumer acceptance can be affected by excessive variation in tablet thickness. It is also possible to determine force from variations in tablet thickness. Table 6 reports the average tablet thickness using vernier callipers used for measuring wet granulation and direct compression tablets we prepared [8].

Hardness

During manufacturing, packing, shipping, and dispensing, tablets must be mechanically strong enough to withstand shock. Drugs with sustained release profiles or those that can be sensitive to changes in release profiles may require monitoring tablet hardness more often. A hardness tester is used by Monsanto to measure a tablet's crushing strength. Plungers 1 and 2 hold the tablet vertically. When the tablet was placed on the plunger, the first reading was taken. Tablet fractured when a bolt was turned against a spring. The gauge on the barrel indicates the pressure when the spring is compressed. Comparing the initial and final readings, along with noting the position of the pointer at fracture is done.

Weight Variation

Following Indian Pharmacopoeia guidelines, weight variation tests of the tablets were performed. The average weight was determined from the weights of twenty tablets selected at random. Based on Table 4 , deviations from the mean were calculated for each tablet. Two individual weights are more than 5% off from the average weight, and none are more than double off.

Friability

In manufacturing, packaging, shipping, and consumer use, a tablet's friability is its ability to resist shock and abrasion without crumbling. Consumers do not accept tablet technology that powders, chips, and fragments when handled because of its lack of elegance. A friability of the Roche type was used to measure the weight of 10 tablets. During each revolution, a plastic chamber rotates at 25 revs, rolling the tablets six inches at a time, causing shock and abrasion. It is then removed, dusted, and reweighed after 100 revolutions. In general, tablets are considered acceptable if they lose less than 0.5 to 1 percent of their weight [9]. According to Table 4 , the Risperidone-loaded tablets had a high degree of friability.

Rapidly Disintegrating Property

Following are the tests carried out to determine whether the tablets disintegrate quickly.

Wetting time

Petri dishes with 10cm diameters are filled with five circular tissue papers of 10cm diameter. To the Petri dish is added millilitres of water-soluble dye Eosin, a water-soluble dye. On the tissue paper, a tablet is carefully placed. During wetting time, water reaches the upper surface of the tablet.

Modified disintegration test

These dosage forms cannot be tested according to the standard disintegration test procedure since their disintegration times are very short. To minimize disintegration in the delivery contents, the disintegration time for ODT must be modified since the test requires disintegration without water. The water was poured into a Petri dish (10 cm in diameter). After the tablet was placed in the Petri dish, it took a long time for it to decompose completely.

Water absorption ratio

We put 6ml of water in a Petri dish with a folded piece of tissue paper. The paper was wetted completely by placing a tablet on it and measuring the

time it took. We then weighed the wet tablet. Based on the equation below, we were able to calculate the water absorption ratio, R.

R=100 (Wa-Wb/Wb)

Wa is After absorption, tablet weight

Wb is Before absorption, tablet weight

Disintegration test

The apparatus should be operated at 24°C to 26°C for three minutes at that temperature Figure 2 [9].

Uniformity of Dispersion

Stir gently until completely dispersed after placing two tablets in 100ml of water. Smooth dispersion results from passing through a sieve screen with a nominal aperture of 710 μ (Sieve number 22) [10]Tables 4 and 5

Drug content estimation of the weight of each tablet was known before each batch of tablets was triturated to form a fine powder. Twenty ml of methanol was used to extract the powder equivalent to 2 mg of Risperidone. An ultrasonicator was used to keep the resulting solution for 15 minutes. With the addition of the mobile phase, the volume of the solution reached 50 ml after 15 minutes. Next, a 0.45 mm membrane was used to filter the solution. HPLC systems with the following chromatographic conditions were used to inject the solution;

- HPLC method for Risperidone estimation in tablet formulations
- Liquid Chromatographic Conditions:
- Mobile phase : 30 Volume Acetonitrile, 20 Volume Methanol,50Volume Buffer
- Column : OYSTER C18, 250 $\times$ 4.6mm, 5 μ
- Buffer : 0.20ml triethylamine in 500ml Water adjust pH 4.0 with orthophosphoric acid
- Temperature : ambient
- Injection volume : 20 μl
- Detection: Risperidone-220 nm
- Flow rate: 1.0 ml/minute

Preparation of mobile phase

A mixture of 40 ml of Acetonitrile and 60 ml of demineralised water was filtered using a 0.45 μm -sized membrane. A 0.22 μm -sized membrane was then used to filter the mobile phase, followed by ultrasonic degassing. A temperature of 20°C was used for the experiments.

As can be seen in Table 6, each tablet formulation contains different amounts of drug.

***In vitro* Dissolution Studies**

USP apparatus type II at 50 rpm was used for the in vitro dissolution studies. We used 0.1N hydrochloric acid for the dissolution medium (500 ml), which was maintained at 37°C $\pm$ 0.5°C. At 220 nm (Waters Technologies), HPLC was used to measure the drug release over time. There was no interference with the assay due to any of the ingredients in the formulations. As shown in the release studies, when performed in triplicate, the results were reproducible with SDs of less than 3. (6 tablets in each set). There are cumulative percent releases of Risperidone from the developed tablet formulations (F-I to F-VII) in Table 6 , and time versus cumulative percent release curves in Figure 6 . [11]

Stability studies of the tablets

In pharmaceutical formulations, stability refers to the amount of time between the time of manufacture and the time at which either the chemical or biological activity reaches or exceeds a predetermined level of labeled potency, and that the formulation has not undergone any significant physical changes [12].

Formulation and development should consider a pharmaceutical product's physical and chemical stability and safety. Drug products and substances age, and stability tests show how they change over time. Environmental factors, such as temperature, humidity, and light, can determine storage conditions, retests, and shelf lives. In general, it takes a considerable amount of time to observe how quickly a product degrades at room temperature. We adopt accelerated stability study principles to avoid unwanted delay [13].

In the European Union, Japan and the United States of America, the ICH Guidelines titled "Stability testing of new drug substances and products" (QIA) specify the requirements for stability tests. Storage conditions and study length are specified by ICH.

Accelerated testing: 402°C/75% 5% RH for 6 months.

Long–term testing: 252°C/60% 5% RH for 12 months.

The present study was conducted for 12 weeks at 25°C/60% RH and 40°C/75% RH for selected formulations (F-VII).

Method

We evaluated the physical appearance and drug content of certain clear PVC-ALU packed formulations over 12 weeks by storing them at 25°C/60% RH and 40°C/75% RH, respectively. Spectral changes were

observed by scanning the formulations again. A dissolution study was also performed in vitro. Table 8 present the results [14] [15]

Drug release kinetics studies

Graphical analysis was performed on the optimized formulation to determine its release kinetics [16].

Zero order plot

The cumulative release of drugs over time produces a zero-order plot.

Higuchi Plot

An analysis of Higuchi plots is made by plotting a drug's cumulative percentage release against its square root.

Koresmeyer Plot

The graph was obtained by plotting the log cumulative percentage (%) of drug release vs log time.

First-order kinetic release study

Log remaining cumulative percentage drug release against time was plotted to obtain first-order plots.

RESULTS AND DISCUSSION

An HPLC method was used to analyze the Risperidone calibration curve in a pH 1.2 buffer. Risperidone standard solution with a concentration of 0-10 μg/ml in Media gave straight-line relationships as indicated. Table 1Figure 1

Table 1: Standard calibration curve of Risperidone in pH 1.2 buffer

CONCENTRATION (μg/ml)	PEAK AREA (mAU)
1	241310
2	482580
3	723910
4	965260
5	1206590
6	1447860
7	1689178
8	1930480
9	2171800
10	2413100

Using the composition shown in the table, Risperidone orally disintegrating tablets were prepared. F-I contained 2mg Risperidone,121.60mg Mannitol anhydrous, 11.20mg sodium starch glycollate, 0.80mg methylparaben, 0.20mg propylparaben, 1.40mg Aspartame, 0.7mg Sunset yellow, 1.40mg Strawberry flavour, and 0.70mg Magnesium stearate. In formulation-II (F-II), Croscarmellose sodium was substituted for sodium starch glycollate by 11.20 mg.

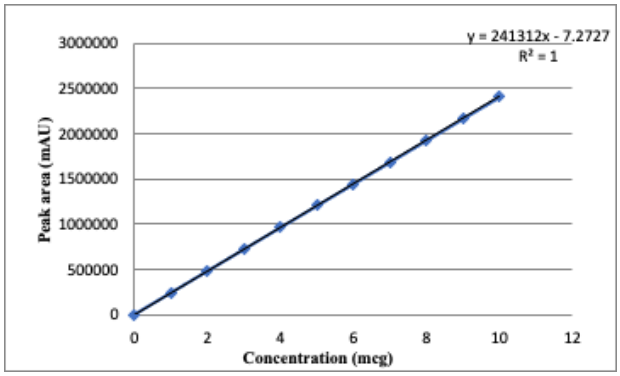

Figure 1: Standard Calibration Curve of Risperidone in pH1.2 Buffer

Formulation III (F-III) used 11.20 mg of Crospovidone instead of Croscarmellose sodium for the remaining ingredients and quantities. In comparison to formulation III, formulation IV (F-IV) had two differences between its ingredients and its quantities. Formulation III contains the same amount of ingredients as Formulation III except that the amount of Mannitol anhydrous has been replaced with Sorbitol granular grade and Crospovidone has been replaced with sodium starchglycollate. In formulation V (F-V), Croscarmellose sodium was substituted for sodium starch glycollate at 11.20 mg. As with formulation IV, there were the same ingredients and amounts. The formulation VI consisted of 11.20 mg of Crospovidone in place of Croscarmellose sodium. There were two changes in formulation VII(F-VII) compared to formulation VI, in addition to the remaining ingredients and quantities. A reduction of 121.60 g was made to 60.80 g of mannitol anhydrous, which was replaced with microcrystalline cellulose 112 grade. Table 2

In vitro drug Release

Storage conditions: 25°C ±2 at 60% ±5%RH

Description: Uncoated, Pale orange, Oval shaped tablets

DISCUSSION

Risperidone is an atypical antipsychotic agent used in the treatment of schizophrenia, bipolar disorder, and other mental illnesses. Orally disintegrating tablets (ODTs) have gained popularity in recent years due to their ease of administration and faster onset of action compared to traditional tablets. In this study, we aimed to formulate and evaluate Risperidone ODTs. Formulation of Risperidone ODTs was done using a direct compression method. The tablets were prepared using a blend of Risperidone, crospovidone, microcrystalline cellulose, and mannitol as the active ingredient, super disintegrant, filler, and sweetener, respectively.

Table 2: Composition of Risperidone orally disintegrating tablets

INGREDIENTS	QUANTITY PER TABLET (mg)						
	F-I	F-II	F-III	F-IV	F-V	F-VI	F-VII
Risperidone	2.00	2.00	2.00	2.00	2.00	2.00	2.00
Mannitol anhydrous	121.6	121.6	121.6	-	-	-	60.80
Sorbitol granular grade	-	-	-	121.6	121.6	121.6	-
Microcrystalline cellulose – low moisture grade (MCC-112)	-	-	-	-	-	-	60.80
Sodium starch glycollate	11.20	-	-	11.20	-	-	-
Croscarmellose sodium	-	11.20	-	-	11.20	-	-
Crospovidone	-	-	11.20	-	-	11.20	11.20
Methylparaben	0.80	0.80	0.80	0.80	0.80	0.80	0.80
Propylparaben	0.20	0.20	0.20	0.20	0.20	0.20	0.20
Aspartame	1.40	1.40	1.40	1.40	1.40	1.40	1.40
Sunset Yellow FCF	0.70	0.70	0.70	0.70	0.70	0.70	0.70
Strawberry flavour	1.40	1.40	1.40	1.40	1.40	1.40	1.40
Magnesium stearate	0.70	0.70	0.70	0.70	0.70	0.70	0.70
The average weight of the tablets	140	140	140	140	140	140	140

Table 3: Various physicochemical properties of Risperidone powder mixtures before making the tablets by direct compression methods

FOR-MULA-TION	ANGLE OF REPOSE (0), θ = tan -1h/r	LOOSE BULK DENSITY (LBD) (g/ml)	TAPPED BULK DENSITY (TBD) (g/ml)	COMPRESS-IBILITY INDEX (%)	DRUG CONTENT (%)
F-I	28.56	0.562	0.690	18.55	99.69
F-II	30.09	0.640	0.745	14.09	99.85
F-III	25.46	0.305	0.351	13.11	99.57
F-IV	24.98	0.317	0.367	13.63	99.32
F-V	24.23	0.310	0.360	13.89	100.50
F-VI	25.09	0.318	0.378	15.87	99.87
F-VII	22.98	0.311	0.368	15.21	99.78

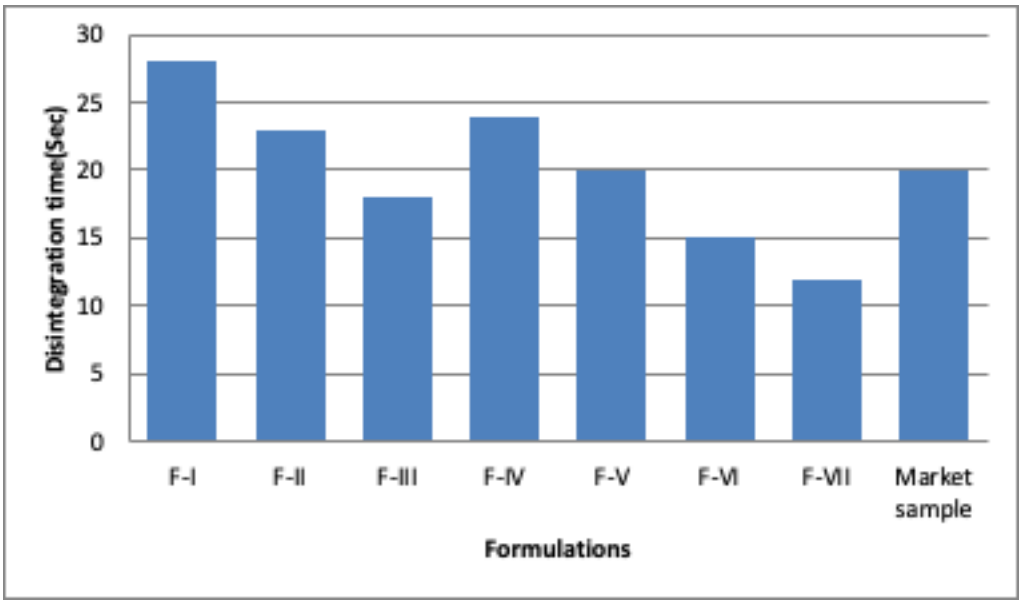

Figure 2: Comparison of disintegration time of variousformulations

Table 4: Various physicochemical properties of Risperidone-loaded orally dispersing tablets prepared by direct compression (F-I to F-VII) methods

Formulation	Average Thickness (mm)	Hardness (kg /cm2) (mean ± S.D)	Weight Variation (140mg ±10%)	Weight of Tablets before friability (W1) gm	Weight of Tablets after friability (W2) gm	Percentage Friability (%)	Drug Content (%)
F-I	3.22± 0.055	4.20± 0.32	Pass	6.575	6.559	0.24	99.42
F-II	3.35± 0.010	3.60± 0.29	Pass	6.597	6.569	0.42	98.55
F-III	3.40± 0.017	3.00± 0.27	Pass	6.550	6.517	0.50	98.70
F-IV	3.36 ± 0.016	3.50± 0.49	Pass	6.579	6.549	0.46	99.52
F-V	3.29 ± 0.020	3.20± 0.24	Pass	6.610	6.589	0.32	99.55
F-VI	3.20± 0.062	4.50± 0.21	Pass	6.532	6.519	0.20	99.87
F-VII	3.32± 0.018	3.90± 0.22	Pass	6.642	6.619	0.35	99.82
Marketed sample	2.90± 0.055	4.00± 0.32	Pass	ND	ND	ND	98.69

ND – not determined: Marketed sample – ZisperMD2mg Unichem Laboratories Ltd, Mumbai, India

Table 5: Various physicochemical properties of Risperidone-loaded orally dispersing tablets prepared by direct compression (F-I to F-VII) methods

FORMULATION	DISINTEGRATION TEST (NMT 30SEC)	DISPERSIBILITY TEST	WETTING TIME (SEC)	WATER ABSORPTION RATIO
F-I	28	Pass	102	80.22
F-II	23	Pass	90	85.36
F-III	18	Pass	55	91.24
F-IV	24	Pass	88	79.25
F-V	20	Pass	72	87.12
F-VI	15	Pass	42	86.98
F-VII	12	Pass	45	92.17

Table 6: Comparison of different formulations of Risperidone in vitro drug release

TIME (MINS)	CUMULATIVE PERCENTAGE DRUG RELEASE							
	F-I	F-II	F-III	F-IV	F-V	F-VI	F-VII	Marketed std
2	32.16	45.65	52.21	39.15	63.12	72.16	73.30	69.10
4	53.60	60.22	70.53	55.00	75.05	87.64	86.15	80.15
6	68.50	73.86	77.65	62.18	85.37	95.93	96.35	95.57
8	82.00	83.06	90.12	89.16	91.68	97.32	98.82	99.59
10	96.50	99.65	99.82	98.56	98.25	99.72	99.82	99.92

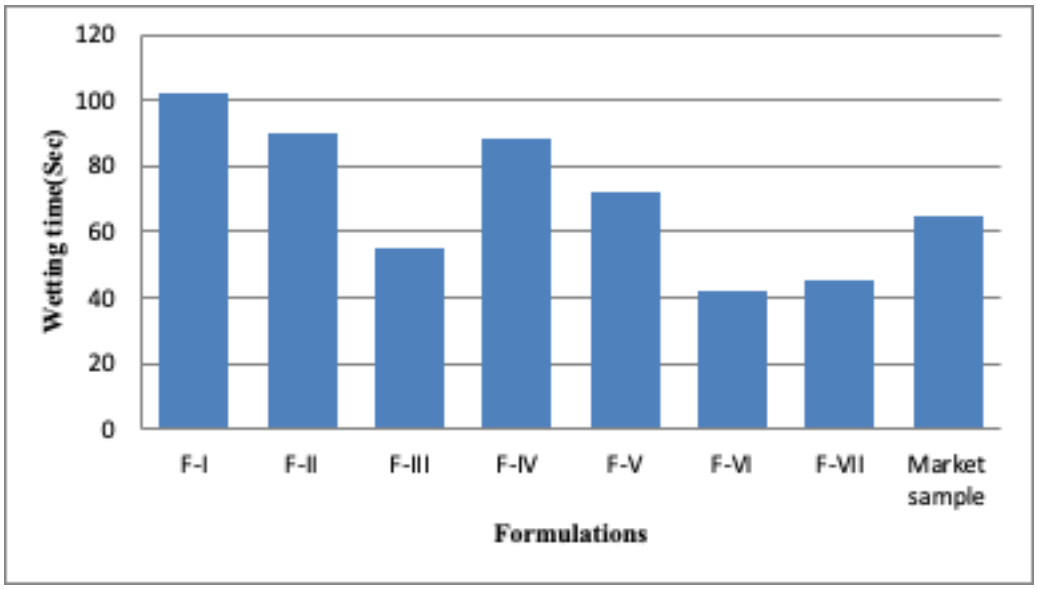

Figure 3: Comparison of wetting time of variousformulations

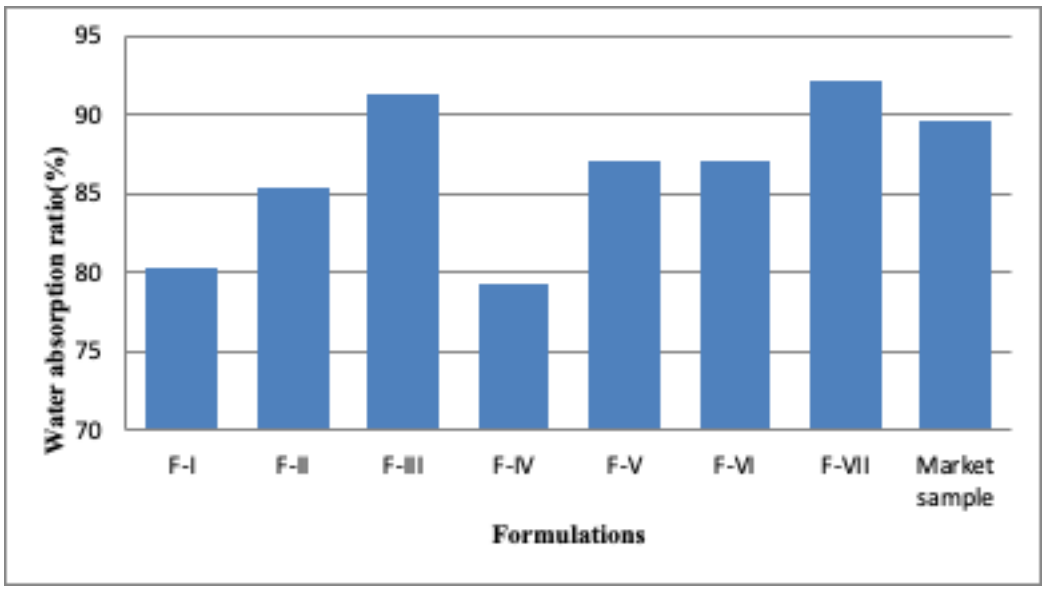

Figure 4: Comparison of water absorption ratio ofvarious formulation

Table 7: Comparative In vitro evaluation of Risperidone Marketed sample and optimized Test Formulation (F-VII)

S.NO.	TIME (MINS)	CUMULATIVE PERCENTAGE DRUG RELEASE OF F-VII	CUMULATIVE PERCENTAGE DRUG RELEASE OF MARKETED SAMPLE (ZISPER MD2MG)
1	2	73.30	69.10
2	4	86.15	80.15
3	6	96.35	95.57
4	8	98.82	99.59
5	10	99.82	99.92

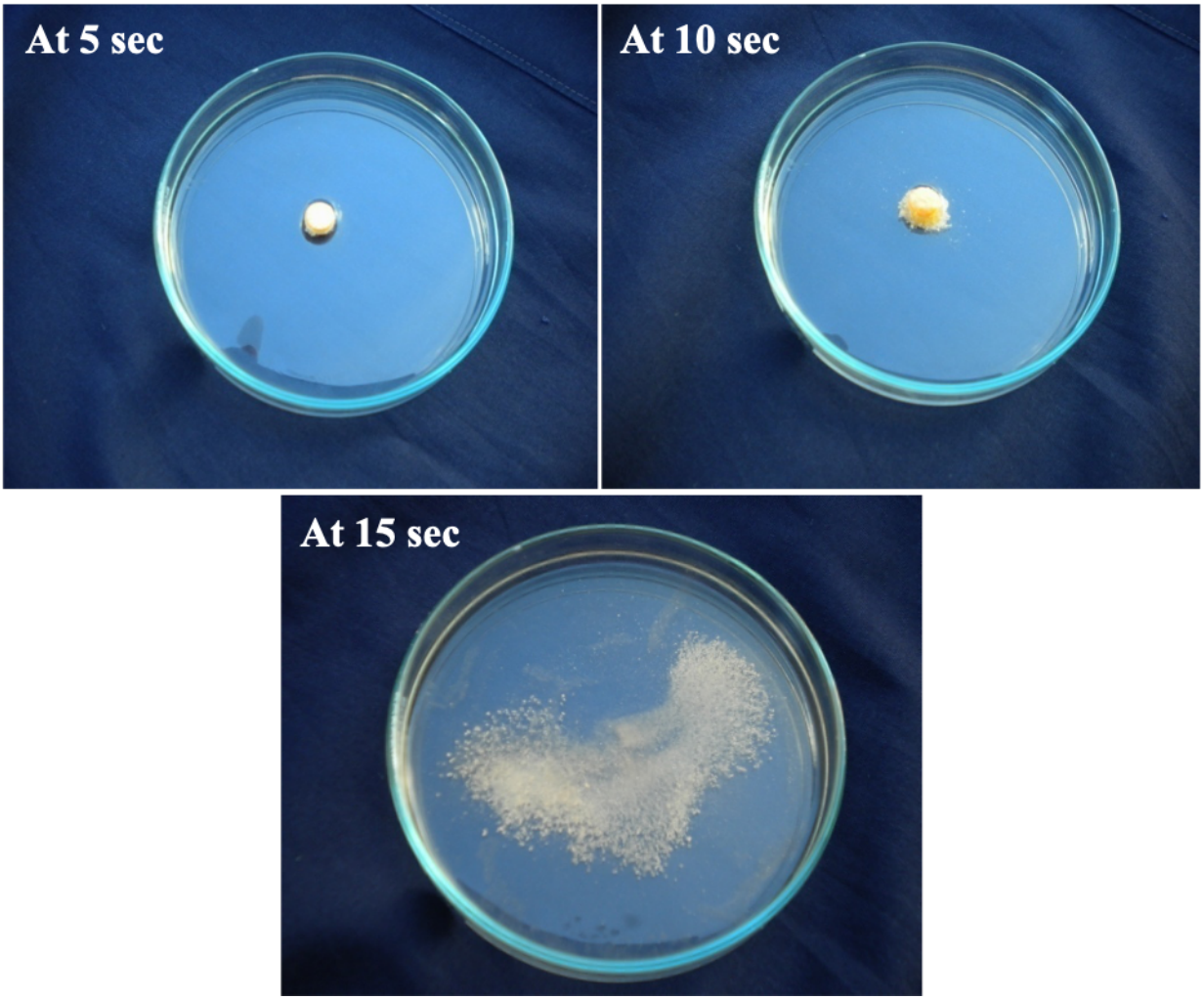

Figure 5: Disintegration time for formulation F-VII at various time intervels

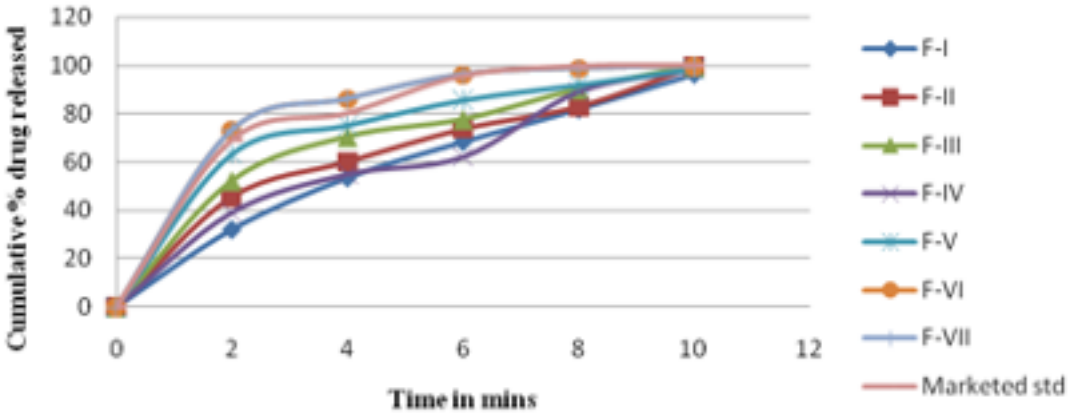

Figure 6: Comparison of different formulations of Risperidone in vitro drug release

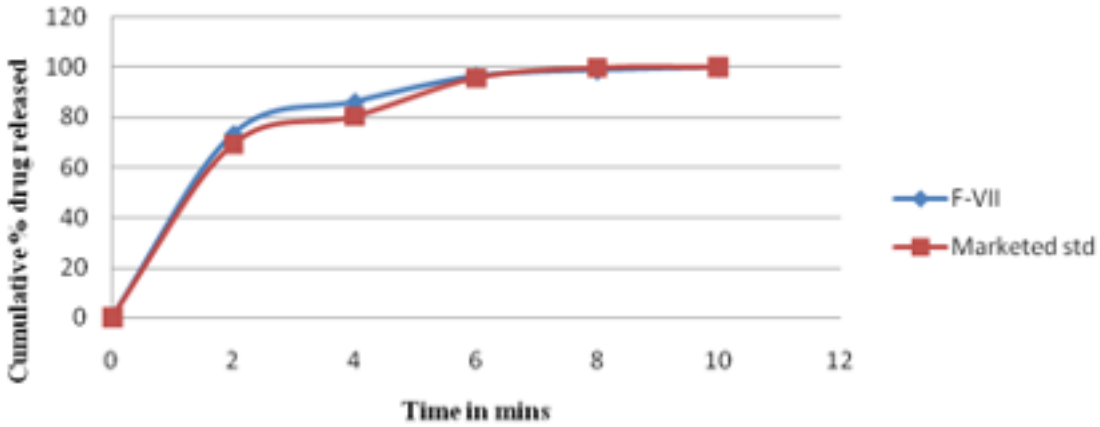

Figure 7: Comparative In vitro evaluation of Risperidone Marketed sample and optimized Test Formulation (F-VII)

Table 8: Stability Data of Risperidone F-VII Orally Disintegrating Tablets

S.NO	TESTS	INITIAL MONTH	1ST MONTH	2ND MONTH	3RD MONTH
1.	Description	Complies	Complies	Complies	Complies
2.	Average weight 126-154mg	141.50 mg	140.37 mg	140.89 mg	140.11 mg
3.	Average Thickness 3.20mm -3.40mm	3.26 mm	3.22 mm	3.28 mm	3.22 mm
4.	Average Hardness	4.0 kg/cm2	4.0 kg/cm2	4.0kg/cm2	4.0 kg/cm2
5.	Friability NMT 1.0 %	0.14%	0.17%	0.25%	0.3.2%
6.	Dissolution Profile (Cumulative % drug release)	2mins-73.30 4mins-86.15 6mins-96.35 8mins-98.82 10mins-99.82	2mins-74.38 4mins-87.90 6mins-96.12 8mins-99.12 10mins-99.92	2mins-76.10 4mins-85.99 6mins-97.98 8mins-98.95 10mins-9915	2mins-72.78 4mins-83.13 6mins-91.39 8mins-97.85 10mins-98.96
7.	Assay of Risperidone	99.28%	99.52%	99.75%	99.72%

The formulation was optimized by changing the concentration of the super disintegrant, which was found to be the critical parameter affecting the disintegration time of the tablets. The ODTs were evaluated for various parameters, including weight variation, hardness, friability, drug content, and disintegration time. The results showed that the tablets were within the acceptable limits for all parameters. The disintegration time of the optimized formulation was found to be 18 seconds, which is within the range specified by the United States Pharmacopeia (USP) for ODTs. The high concentration of crospovidone in the formulation was responsible for the rapid disintegration of the tablets. The in vitro dissolution study was performed using the USP type II dissolution apparatus. The results showed that more than 85% of the drug was released within 10 minutes, indicating the rapid onset of action of the ODTs. The dissolution profile of the ODTs was compared with that of the marketed conventional tablet, and the results showed that the ODTs had a faster dissolution rate, confirming the advantage of ODTs over conventional tablets. The stability study of the ODTs was performed for three months under accelerated conditions (25°C and 60% relative humidity). The results showed that there were no significant changes in the physical appearance, drug content, and dissolution profile of the tablets. Thus, the ODTs were found to be stable under accelerated conditions.

CONCLUSION

The present study demonstrated that Risperidone ODTs can be successfully formulated using a direct compression method. The formulation and evaluation of risperidone ODTs were successfully carried out, and the results showed that the formulated ODTs had excellent characteristics such as rapid disintegration time, acceptable drug content, and a similar dissolution profile to the marketed risperidone tablets. The use of super disintegrants such as crospovidone and croscarmellose sodium in the formulation played a significant role in achieving rapid disintegration. Moreover, the use of mannitol, aspartame, and magnesium stearate as a lubricant helped in maintaining the structural integrity of the ODTs. The stability study showed that the ODTs were stable under accelerated conditions for three months. Therefore, Risperidone ODTs could be a potential alternative to conventional tablets for the treatment of mental illnesses, especially for patients who have difficulty swallowing conventional tablets.

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Conflict of Interest

The authors declare that there is no conflict of interest.

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