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FORMULATION AND IN VITRO EVALUATION OF IMMEDIATE RELEASE TABLETS OF ANTIPSYCHOTIC DRUG RISPERIDONE

Ajay Kumar Saini*[1], Dr Vishal Garg[2], Dr Alok Upadhyay[3]

[1]Ph.D Research Scholar, Sunrise University, Alwar (Rajasthan), India

[2]Jaipur School of Pharmacy, Maharaj Vinayak Global University, Jaipur.

[3]Director Mascot College of Pharmacy, Bareilly

Corresponding Author E-mail - ajaysaini7889@gmail.com

ABSTRACT:

Risperidone is a novel antipsychotic with dopaminergic and serotonergic effects. The main pharmacological activities of risperidone include serotonin 5-HT2 receptor blockade and dopamine D2 antagonism. The main objective of this research is to develop various formulations of immediate release tablet of risperidone to increase solubility and bioavailability by using various Superdisintegrants such as Sodium Starch Glycolate, Croscarmellose and Crospovidone, by wet granulation method. The drug-excipients compatibility was determined by using UV and DSC thermogram. The powder blend and tablets of risperidone were evaluated for various pre and post compression parameters like physiochemical parameters, angle of repose, compressibility index, hausner's ratio, tablet hardness, friability, content uniformity and in vitro disintegration and dissolution studies and their results were found to be satisfactory. Outcomes of study indicates that maximum in vitro dissolution profile of formulation F6 were found to have equivalent percentage of drug release and concluded that F6 is better and similar to innovator product.

KEY WORDS: Risperidone, immediate release tablet, excipients, superdisintegrants

INTRODUCTION:

The tablet is the most widely used dosage form because of its convenience in terms of self administration, compactness and ease in manufacturing.[1] Many patients require quick onset of action in particular therapeutic condition and consequently immediate release of medicament is required.[2, 3] It is estimated that 50% of the population is affected by this problem, which results in a high incidence of ineffective therapy. Disintegrating agents are substances routinely included in the tablet formulations to aid in the breakup of the compacted

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mass when it is put into a fluid environment.[4, 5] They promote moisture penetration and dispersion of the tablet matrix.[6] In recent years, several newer agents have been developed known as "Superdisintegrants". These newer substances are more effective at lower concentrations with greater disintegrating efficiency and mechanical strength.[5, 6, 7] On contact with water the superdisintegrants swell, hydrate, change volume or form and produce a disruptive change in the tablet. Effective superdisintegrants provide improved compressibility, compatibility and have no negative impact on the mechanical strength of formulations containing high-dose drugs.[8]

Risperidone is a novel antipsychotic with dopaminergic and serotonergic effects. Chemically it is known as 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1- piperidinyl] ethyl] 6,7,8,9-tetrahydro2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one.[9] It is practically insoluble in water, freely soluble in methylene chloride, sparingly soluble in ethanol. Risperidone is indicated for acute and chronic schizophrenic psychoses and other psychotic conditions with positive and negative symptoms.[10, 11]

Risperidone is rapidly and very well absorbed after oral administration.Peak plasma concentrations are attained within 1-2hrs. The volume of distribution is 1-2 L/kg. Risperidone is extensively metabolized in the liver by CYP2D6 to a major active metabolism, 9-hydroxyrisperidone, which appears approximately eqi-effective with risperidone with respect to receptor-binding activity.[12]

MATERIALS:

Risperidone was received as a gift sample from Lupin Pharma Ltd, Aurangabad India. Sodium starch Glycolate, crosspovidone and cross Croscarmellose sodium was obtained from Akin laboratories, Hyderabad. Microcrystalline cellulose purchased from signet chemicals, Mumbai India. Magnesium stearate, Talc, Mannitol was purchased from SD fine chemicals limited, Mumbai, India.

METHODS:

Formulation of Immediate Release Tablets of Risperidon: (Batch F1-F9)

9 Formulation batch of Risperidon Immediate Release (IR) tablets each weighing 100mg, were prepared by direct compression technique of (equivalent to 3mg risperidone in each tablet) along with a mixture of Sodium starch glycolate, Crosscarmellose sodium and Crospovidone, at different concentrations viz. 2% to 6% as these superdisintegrants work best

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in between range of 2% to 8%. Batches were also prepared using combination of Superdisintegrant.

The powder blend of drug and excipients were evaluated by pre-formulation study such as Bulk density, Tapped density, Angle of repose, Carr's Index, Hausner's ratio. Finally the powder blends of each batch were compressed in to tablet by using 8 station single rotary compression machines. The composition of different formulations of immediate release tablet is shown in Table 1.

Pre Compression Parameters: [13, 14, 15]

Pre-formulation studies are the initial step in the development of dosage forms of any drug substance. Pre-formulation studies act an important criterion to understand the potential pharmaco-kinetics of a drug substance in humans as well as in animals. The various official pre compression parameters to be determined are bulk density, tapped density, Carr's index, Hausner's ratio and angle of repose for dosage form formulation.

Post Compression Parameters: [16-20]

1. Appearance of tablets:

Randomly picked tablets from each formulation batch examined under lens for shape and in presence of light for color other defects like absence of chipped, cracked and swelling.

2. Thickness: The thickness of the prepared tablets was tested using vernier calipers. The test was done in triplicate and average was determined.

3. Friability: The friability study of the 20 tablets from each batch was determined by Roche friabilator. Weighed tablet samples are placed into friabilator and subjected to combined effects of abrasion and shock by revolving at 25 rpm for 4min for 100 revolutions. Percentage friability was calculated from the loss in weight as given in formula as below. The weight loss should not be more than 1%.

% friability= Initial weight-Final weight / Initial weight x 100

Table 1: Formulation Development of Risperidone by Different Concentration of Super-disintegrants

S. No	Ingredients	Weight per Tablet (mg)								
		F1	F2	F3	F4	F5	F6	F7	F8	F9

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1	Risperidone	3	3	3	3	3	3	3	3	3
2	**Sodium starch glycolate**	2	4	6	-	-	-	-	-	-
3	**Cross Povidone (PVP K30)**	-	-	-	2	4	6	-	-	-
4	**Cross carmellose sodium**	-	-	-	-	-	-	2	4	6
5	MCC (Avicel) PH102	30	28	26	30	28	26	30	28	26
6	Mannitol	20	20	20	20	20	20	20	20	20
7	Magnesium Stearate	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
8	Talc	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
9	Lactose Mono Hydrate	(QS)	(QS)	(QS)	(QS)	(QS)	(QS)	(QS)	(QS)	(QS)
Total (mg)		100	100	100	100	100	100	100	100	100

F: Formulation, MCC: Micro-crystalline Cellulose

4. Weight variation: 20 random tablets were weighted individually by using electronic balance and average weight was determined.

5. Wetting Time: Wetting is closely related to inner structure of tablets. Petri dish method was used to determine wetting time.

6. Water Absorption Ratio: The weight of the tablet prior to placement in the petridish was noted (w_b) utilizing a CAS digital balance. The wetted tablet was removed and reweighed (w_a). Water Absorption ratio, R, was then determined according to the following equation: $R = 100 \times (w_a - w_b)/ w_b$

where w_b and w_a were tablet weights before and after water absorption, respectively

7. *In-vitro* Disintegration time: This test was performed using tablet disintegration apparatus. 6 tablets from each batch placed in the six tubes of the basket and operate the apparatus using 0.1N HCl maintained at 37±0.5ºC as the immersion fluid. Then time noted down to complete disintegration of tablets.

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8. Content Uniformity: Risperidone content in tablets was calculated by powdering 10 tablets from each batch. Powder equivalent to 10 mg of Risperidone was dissolved in Methanol. 1 ml of filtrate was further diluted to 100 ml with 0.1 N HCL and it was determined by spectroscopy at 280 nm.

9. *In vitro* Dissolution test: The release rate of drug from Risperidone immediate release tablets was determined using dissolution apparatus II (Paddle type). The dissolution test was run using 900 ml of 0.01N of Hydrochloric Acid in water, at 37±2°C and 50 rpm. A sample (10 ml) of the solution was withdrawn at regular interval of 5 min up to 30 minutes. The samples were replaced with fresh dissolution medium of same quantity. The samples were filtered through a 0.20µm PTFE membrane filter (hydrophilic) and measure the absorbance at 280nm using UV spectrophotometer.

RESULT AND DISCUSSION:

PRE-FORMULATION STUDY: Pre-formulation study is the first step to determine whether the specific drug content is suitable for the decided formulation or not. The aim was to formulate the tablet formulation with wet granulation method, so it was mandatory to know about the suitability of bulk density, tapped density, Carr's index, Hausner's ratio and angle of repose as these were the official requirement while choosing any material for its dosage form formulation. **Table 2** indicates the outcomes data of Bulk Density, Tapped Density, Hausner's ratio, Carr's index and Angle of Repose for various formulation batches. The result of evaluation parameters clearly indicates its suitability to be the material of choice for formulation.

Table 2 Pre-compression Characteristics of Powder Blend of Batch F1 to F9

Batch No.	**Bulk Density** (gm/ml)	**Tapped Density** (gm/ml)	**Angle of Repose** (ɵ)	**Carr's Index** (%)	**Hausner's ratio**
F1	0.526	0.612	26.76	14.0	1.16
F2	0.662	0.763	22.54	13.23	1.15
F3	0.695	0.823	24.65	15.2	1.18
F4	0.782	0.869	28.12	11.0	1.11
F5	0.560	0.631	24.68	11.25	1.12
F6	0.628	0.714	25.16	14.27	1.17
F7	0.51	0.71	28.16	12.39	1.16

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F8	0.58	0.75	22.66	11.29	1.16
F9	0.64	0.68	25.42	13.12	1.15

POST COMPRESSION EVALUATION: The entire tablet formulations batches were subjected for organoleptic, physical and chemical evaluations. Shape, thickness, hardness, friability, weight variation, *in-vitro* disintegration time, *in vivo* disintegration time, wetting time, water absorption ratio, Risperidon content, *in vitro* dissolution studies, model fitting of release profile and stability studies were carried out

7.3.1.2 Thickness and Diameter Test:

Average tablet thickness (Table 3A) was found to be consistent throughout the batch. Tablet thickness ranges between 3.42 mm to 3.54 mm for 100 mg weighing tablets.

7.3.1.3 Hardness Test:

Hardness values observed were not less than 3.2 kg/cm2 & not more than 3.63 kg/cm2. Hardness was maintained to be within 2.00 kg/cm^2 to 4.20 kg/cm^2, as these tablets are rapidly disintegrating. The lower standard deviation values indicated that the hardness of all the formulations were almost uniform in specific method and possess good mechanical strength with sufficient hardness.

7.3.1.4: Weight Variation Test:

20 tablets from each batch were randomly selected to calculate average weight and standard deviation. All the formulations show uniform weight (as per IP-2010) with low standard deviation values (Table 3A). It was found between 96 mg to 104 mg for 100mg weighing tablets, indicating the uniformity of the tablets weight.

7.3.1.5 Friability Test:

The study results are shown in Table 3A, was found well within the approved range (<1%) in all the formulation. The effect of superdisintegrant's concentration on friability of immediate release tablet was minimum.

7.3.1.6 Wetting Time:

Wetting is closely related to inner structure of tablets. The record of the wetting time was shown in Table 3B. Wetting time was more for the batches prepared with less concentration of disintegrants. Poor wetting was also observed in the batches without superdisintegrants. Good wetting may be due to ability of swelling and also capacity of absorption of water of

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Superdisintegrants and it ranges between 28 to 45 seconds which is depend on the concentration of superdisintegrants in the tablets.

7.3.1.7 Water Absorption Ratio:

The results of Water Absorption Ratio are shown in Table 3B. Good water absorption indicates good swelling of the tablet which may be due to the presence of superdisintegrants. It was observed that all the formulations with superdisintegrants showed good water absorption ratio.

7.3.1.8 Drug Content Uniformity:

The percent drug content of the tablets was found in between 97.52% to 99.56% of Risperidon. Drug content of all the formulations was found to be within the limits (Table 3B) specified in IP 2010, indicating the uniformity of the tablets prepared by wet granulation method.

7.3.1.9 *In vitro* Disintegration Time:

The internal structure of tablets, which is pore size distribution, water penetration into tablets and swelling of disintegration substance are suggested to be the mechanism of disintegration. (Table 3C, fig 1)

The effect of superdisintegrant's concentration on disintegration of immediate release tablet was observed by analyzing various graph plotted between concentration of superdisintegrant's and disintegration time.

7.3.1.10 *In-vitro* Dissolution Studies:

All the nine batches were subjected for the in vitro dissolution studies using tablet dissolution test apparatus USP type II (Lab India DS 8000). The samples were withdrawn at different time intervals (1, 2, 4, 6, 8, 10, 12, 14 & 16min) and analyzed at 280nm. Cumulative drug release and cumulative % drug retained were calculated on the basis of mean amount of Risperidon present in the respective tablet. The results of In-vitro dissolution Studies of all tablers in Phosphate buffer pH 6.8 are shown in Table 3C and 4

The effect of superdisintegrant's concentration on dissolution of immediate release tablet was observed by analyzing various graph plotted between concentration of superdisintegrant's and % drug release.

Table 4 and Fig 2, show data of % Risperidone release of immediate release tablet prepared from wet granulation tablet of Risperidone with three superdisintegrant's in different concentration.

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Table 3A Evaluation of Tablet Parameters-1 (Batch F1 to F9)

Batch No.	Weight Variation (mg)	Hardness (kp)	Thickness (mm)	Friability (%w/w)
F1	102 ± 3.34	3.42 ± 0.02	3.52 ± 0.01	0.64 ± 0.02
F2	101 ± 2.60	3.20 ± 0.01	3.46 ± 0.03	0.72 ± 0.01
F3	99 ± 3.70	3.42 ± 0.03	3.42 ± 0.02	0.32 ± 0.02
F4	102 ± 2.95	3.33 ± 0.02	3.5 ± 0.06	0.44 ± 0.02
F5	100 ± 2.34	3.63 ± 0.03	3.52 ± 0.04	0.38 ± 0.01
F6	101 ± 3.20	3.51 ± 0.03	3.53 ± 0.02	0.65 ± 0.02
F7	104 ± 1.70	3.59 ± 0.04	3.55 ± 0.01	0.58 ± 0.02
F8	96 ± 3.95	3.15 ± 0.03	3.54 ± 0.02	0.50 ± 0.01
F9	102 ± 3.12	3.52 ± 0.01	3.42 ± 0.01	0.62 ± 0.01

Table 3B Evaluation of Tablet Parameters-II (Batch F1 to F9)

Batch No.	Wetting Time (s)	Water Absorption Ratio	Drug Content Uniformity
F1	39-43	71.12 ± 0.02	99.02 ± 0.15
F2	40-45	75.17 ± 0.02	98.45 ± 0.24
F3	39-42	74.1 ± 0.01	97.52 ± 0.20
F4	40-45	76.52 ± 0.02	97.85 ± 0.18
F5	36-39	78.1 ± 0.03	98.12 ± 0.38
F6	35-37	79.06 ± 0.02	99.4 ± 0.12
F7	30-34	74.51 ± 0.01	98.24 ± 0.27
F8	28-33	78.5 ± 0.01	99.56 ± 0.36
F9	37-42	78.67 ± 0.02	97.68 ± 0.16

Table 3C Evaluation of Tablet Parameters-III (Batch F1 to F9)

Form. Code	*In-vitro* Disintegration time (sec)	*In-vitro* Drug Release after 15 Min
F1	46 ± 2.24	80.95 ± 0.374
F2	42 ± 1.22	86.55 ± 0.769
F3	32 ± 2.78	92.48 ± 0.588
F4	48 ± 2.41	85.19 ± 0.844
F5	40 ± 2.21	91.54 ± 0.586
F6	32 ± 1.22	95.48 ± 0.486
F7	44 ± 2.35	86.12 ± 0.662

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F8	40 ± 2.38	90.60 ± 0.588
F9	34 ± 2.4	88.2 ± 0.486

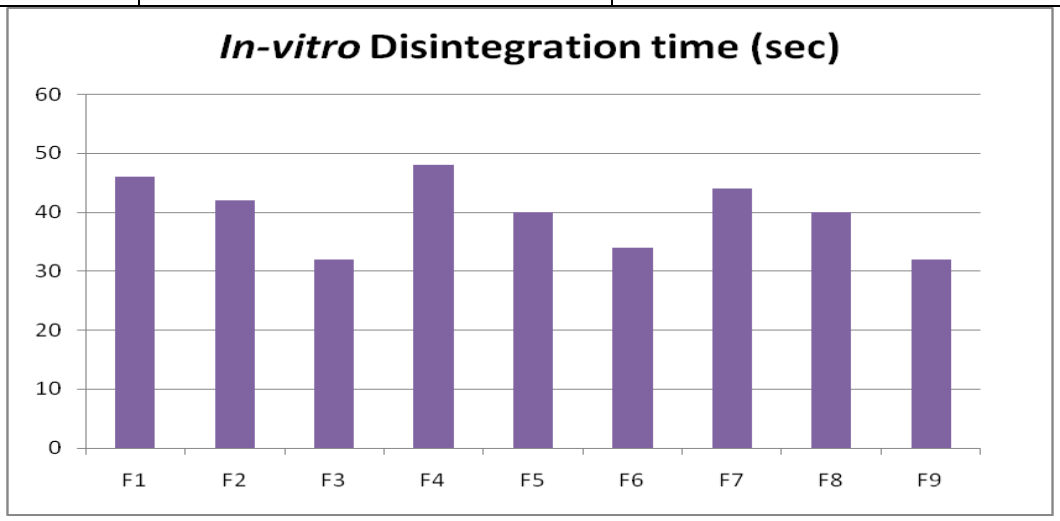

Fig: 1 Comparison of disintegration time of Immediate Release tablets of Risperidone (Batch F1 to F9)

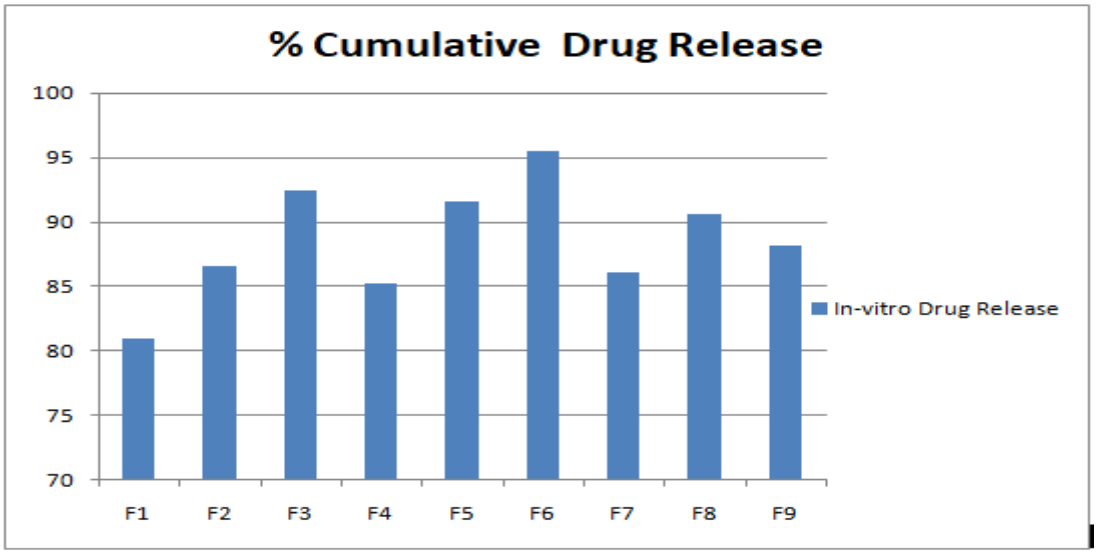

Fig. 2 % drug release of Immediate Release Tablet (Batch F1 to F9)

Table 4 shows *in -vitro* release data of formulations (Batch F1 to F9)

Time	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	14	16	25	14	12	21	18	15	18
2	17	21	36	22	24	30	25	24	28
4	22	26	45	30	32	42	31	34	44
6	28	37	54	38	43	53	40	44	52
8	35	42	68	44	51	65	48	52	66
10	52	60	82	58	60	80	60	60	78

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12	65	70	82	74	73	92	75	74	88
14	78	85	87	87	90	92	88	88	92
16	80	90	94	90	94	96	90	94	92

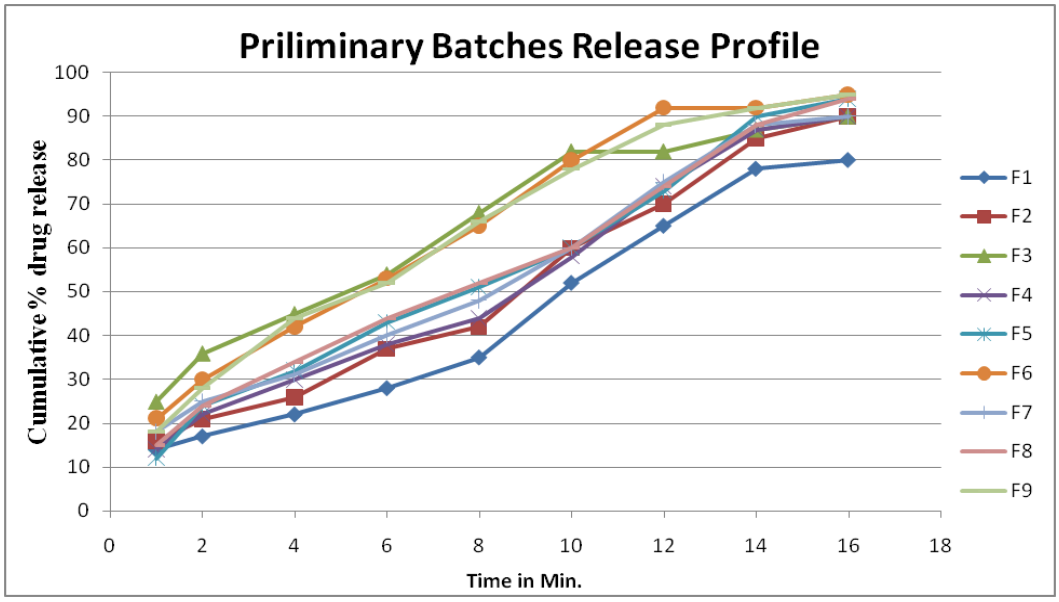

Fig. 3: Comparison of % drug release of IR Tablet prepared from Risperidone with different Super Disintegrants in Different Concentration (Batch F1 to F9)

Effect of Super-disintegrants on Drug Release:

Table 5: Data of various parameters of model fitting for Optimized formulations Batch F1-F9

Batch	Zero order		First order		Peppas		Hixon		Best fit model
F6	R^2	K	R^2	K	R^2	K	R^2	K	Zero order
	0.958	6.01	0.946	0.087	0941	0.58	0.412	0.078	

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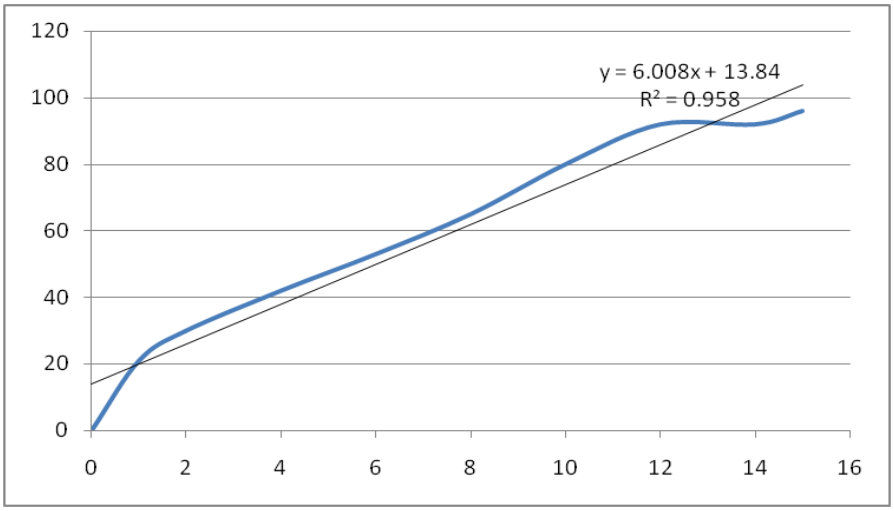

Fig 4: Plot Showing Zero order release kinetics of formulations F6

CONCLUSION:

The present work was aimed to develop immediate release tablet of risperidon by using direct compression technique using varying concentration of Sodium Starch Glycolate, Crospovidone, Cross carmellose sodium. Tablets were evaluated for various physicochemical parameters such as appearance, thickness, hardness, weight variation, friability, disintegration and in-vitro drug release.

Batch F1, F2, F3 were prepared with 2%, 4% and 6% Sodium starch glycolate as a superdisintegrant, showed the cumulative percentage of drug release 80.95%, 86.55%, 92.48%, respectively at 15 minutes. Formulation F3 containing 6% Sodium starch glycolate shows maximum drug release (92.42 %,) at 15 minutes. This result indicated that the optimum concentration of Sodium starch glycolate was 6%.

The formulation F4, F5, F6 were prepared with 2%, 4% and 6% Crospovidone as a superdisintegrant, showed the cumulative percentage of drug release 85.19% , 91.54% , 95.48 respectively at 15 minutes. Formulation F6 containing 6% Crospovidone shows maximum drug release (95.48 %,) at 15 minutes. This result indicated that the optimum concentration of Crospovidone was 6%.

The formulation F7, F8, F9 were prepared with 2%, 4% and 6% Croscarmellose sodium as a superdisintegrant, showed the cumulative percentage of drug release 86.12% , 90.60%, 88.2% respectively at 15 minutes .Formulation F8 containing 4% Croscarmellose sodium shows maximum drug release (90.6 %,) at 15 minutes. This result indicated that the optimum concentration of Croscarmellose Sodium was 4%.

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From the results, the release rates of superdisintegrants were in the order:

Crospovidone > Sodium starch glycolate > Croscarmellose sodium

The maximum percentage of drug release was achieved by the formulation containing Crospovidone 6% as a superdisintegrant. It may be due to the results in the rapid disintegration of tablet in dissolution medium resulting in maximum drug release. Among nine formulations, formulation (F-6) was selected as a best formulation because of its less friability, lowest disintegration time and highest drug release.

CONFLICTS OF INTERESTS:

Authors have no conflict of interest.

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