ORIGINAL ARTICLE

FUTURE JOURNAL OF PHARMACEUTICALS AND HEALTH SCIENCES

Published by Pharma Springs Publication Journal Home Page: https://pharmasprings.com/fjphs

Formulation and Evaluation of Fast Dissolving Oral Films of Risperidone

Ajith Reddy C*, Uma Sankar K, Kishore Babu M

Department of Pharmaceutics, Krishna Teja Pharmacy College, Chadalawada Nagar, Renigunta Road, Tirupathi-517506, Andhra Pradesh, India

Article History:

Received on: 10 Dec 2021
Revised on: 28 Dec 2021
Accepted on: 30 Dec 2021

Keywords:

Fast Dissolving,
Oral Films,
Risperidone,
In-vitro Dissolution,
Disintegration

ABSTRACT

The current research was primarily directed to develop and implement and evaluate rapidly disintegrating Risperidone using HPMC E15 and HPMC E5. The acceptable plasticizer but also its concentration were based on the basis of flexibility, tensile strength and stickiness of a film. The films are solvent casting process. The thicknesses of the films were in the range of 0.234 mm to 0.271 mm. The weights of films have been noticed being in the range of 83 to 91. Folding endurance of films had been noticed being in the scope of 38 ± 1 to 57 ± 2. The surface PH of all films have been encountered to really be neutral since there was no change in color inside the litmus paper. The disintegration time of such ready films were all in the scope of 19 sec to 32 sec.

*Corresponding Author

Name: Ajith Reddy C
Phone: +91 8500170013
Email: ajithreddy861998@gmail.com

eISSN: 2583-116X pISSN:

DOI: https://doi.org/10.26452/fjphs.v2i1.168

Production and Hosted by

Pharmasprings.com

INTRODUCTION

Even after of many of advance that have been made in variety delivery mechanism established for administering of varied drugs and via alternate paths such as oral, parenteral, transdermal, nasal, etc., the oral drug delivery is taken into account as one of the most efficient and also the preferred approach of administration [1]. More so than 70% of medicine can be found available in the market within form of oral drug delivery. Because of this problem roughly 50% of population mainly paediatric population and elderly individuals generally avoid orally ingested solid oral dosage. Keeping the convenience of administration but also trying to swallow in mind, drug research has resulted in the development of fast dissolving drug delivery [2]. Risperidone is effective for going to treat the positively and negatively symptoms of schizophrenia compared to first generation antipsychotics [3].

MATERIALS

Risperidone was a gift sample from Pharma train Hyderabad. HPMC E15, HPMC E5, Propylene glycol, Sorbitol, Aspartame, Tween 80, Citric acid and flavouring agent seemed to be actually bought from S.D. Fine chemicals, Mumbai.

METHODOLOGY

Compatibility Studies

Sample concentration in KBr must be within the limits of 0.2% to 1%. The thickness of the pellet is much greater than a liquid film, so sample with low concentration is required. Too high concentration generally leads to difficulties in obtaining clear pellets [4].

Formulation of Risperidone Fast Dissolving Films

Mouth dissolving film of Risperidone was prepared by solvent casting technique. Solution A was decided to make by solubilising HPMC-E15 polymer in five ml of liquid. Solution B was already decided to make by dissolving Risperidone, Aspartam, Sorbitol & citric acid in 5 ml of ethanol. The source of ideas 'A'

and 'B' have been combined and incensed for 30min and add Propylene glycol and tween 80 and flavouring agent and continue stirring for 10mins [Table 1]. The solutions company were poured it onto glass petri plate of 9 cm diameter but were located in the oven at 70°C until a wax coated film was created and after that solidified films have been cut into rectangular or circular pieces with 4.0 cm^2 (2.0 cm × 2.0 cm) large surface area. Desired quantity of Risperidone had been 10 mg (dose of drug) per 4.0 cm^2 feature films [5].

Morphological Properties

This measurement device has been quickly checked simply with testing process for physical features of films and assessment of surface by touch or consult [6].

Thickness Uniformity

All the portions were evaluated for thickness through using calibrated Vernier caliper [7].

Weight Uniformity of Films

Three films of each formulation trial of 2cm size have been taken and decided to weigh independently electronic balance and the average weights were determined by calculating [8].

Folding Endurance

The Multiple films of each composition trial of 2cm length have been captured and concluded to weigh independently electronic weighing balance and the estimate weights were the flexibility of films can also be measured quantitative and qualitative in terms of folding endurance. The one strip of film was cut (approximately 2*2cm) and again and again folded at the same position until burst. The number of times the film may be folded at the same position without bursting gave the value of folding endurance [9].

Surface pH

The surface pH was noted by trying to bring pH paper closer to the surface of the films and permitting it to equilibrium for 1min [5].

***In vitro* Disintegration Test**

In vitro disintegration rate is decided visibly in a glass baking dish 25ml water to roiling each 10 sec. The disintegration time is indeed the time whenever the film begins to break or disintegrates [10].

***In vitro* Dissolution Studies**

The dissolution medium consists entirely of 900 mL 6.8pH phosphate-buffer solution, retained at 37±0.5°C and agitated at 50 rpm. One film has been used in each test. Samples of dissolution medium (5ml) have been withdrawn with syringe equipped with pre-filter at known intervals and release of drug was evaluated UV-spectrophotometer at 280nm. The quantity forced to withdrawn at every intervals was supplemented with newly quantity of dissolution medium. Cumulative percentage drug discharge of Risperidone was calculated and obtained by plotting on that time [11].

Mathematical Modeling for Drug Release Profile

The data acquired from the *in vitro* dissolution tests obtain the kinetic track record analysis [4].

Zero-order kinetics: $Q_t = Q_o + K_o t$

First-order kinetics: $Q_t = log\ Q_o + K_1 t/2.303$

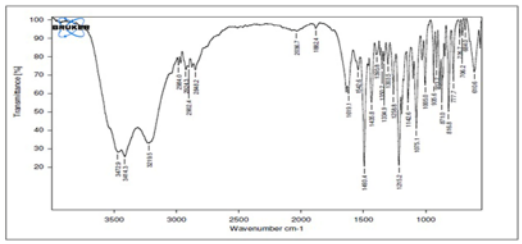
Stability Studies

The stability study had been performed as per ICH guidelines for such period with one month at various accelerated temperature [12] and humidity conditions of 40°C ± 2°C / 75% ± 5% RH.

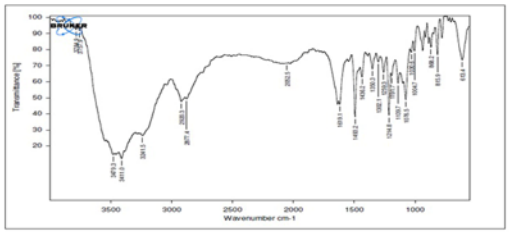
RESULTS AND DISCUSSION

FT-IR Studies

From drug excipient compatibility trend analysis, we referred to the omission of conversations among both pure drug and excipients [Figure 1].



FTIR Spectra of Risperidone



FTIR Spectra of Mixture of Compounds

Figure 1: FTIR Spectrum of Drug and Mixture of Compounds

The inspection by condition monitoring of films and so by feel or touch, it explains that films are having surface texture and they are elegant. The thicknesses of the films were in the range of 0.234 mm to 0.271 mm. The weights of films have been noticed being in the range of 83 to 91. Folding endurance of films had been noticed being in the scope of 38± 1 to

Table 1: Formulation of Risperidone Fast Dissolving Films

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Risperidone	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
HPMC E15	25	30	35	40	45	50	10	20	30
HPMC E5	-	-	-	-	-	-	30	20	10
Propylene glycol	10	10	10	10	10	10	10	10	10
Sorbitol	34	29	24	19	14	9	19	19	19
Aspartame	5	5	5	5	5	5	5	5	5
Tween 80	5	5	5	5	5	5	5	5	5
Saliva stimulating agent (citric acid)	5	5	5	5	5	5	5	5	5
Flavouring agent	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Total wt. (mg)	85	85	85	85	85	85	85	85	85

Table 2: Evaluation Parameters of Risperidone FDF

Formulation code	Thickness (mm)	Weight variation	Folding endurance	% Assay	Disintegration time (sec)
F1	0.234	87	42	99.13	19
F2	0.271	91	51	98.79	24
F3	0.263	83	38	99.82	21
F4	0.247	85	57	100.17	27
F5	0.257	87	54	99.48	32
F6	0.234	90	49	101.07	28
F7	0.238	86	45	100.29	26
F8	0.265	91	39	99.37	23
F9	0.268	87	48	100.53	27

Table 3: *In-vitro* drug release data of formulation F1 to F9

Time (min)	% Drug Release								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
3	24	23	35	27	26	24	39	63	65
6	31	35	46	35	39	31	61	76	86
9	38	41	58	49	51	53	83	83	95
12	53	50	72	63	68	68	97	95	100
15	64	59	79	75	80	81	98	99	-
18	71	70	85	86	89	95	98	-	-
21	78	82	92	97	97	99	-	-	-
24	82	89	99	99	100	-	-	-	-
27	85	94	-	-	-	-	-	-	-
30	91	97	-	-	-	-	-	-	-

Table 4: r^2 Values for Best Formulation F9

Formulation code	Zero order	First order
F9	0.789	0.999

Table 5: *In-vitro* Release Profile of F9 Formulation Stability Studies

Time	Initial	1 Month
0	0	0
3	65	64
6	86	87
9	95	95
12	100	100

57 ± 2. The surface PH of all films has been encountered got really be neutral since there was no change in colour inside the litmus paper [Table 2]. The disintegration time of such ready films were all in the scope of 19 sec to 32 sec.

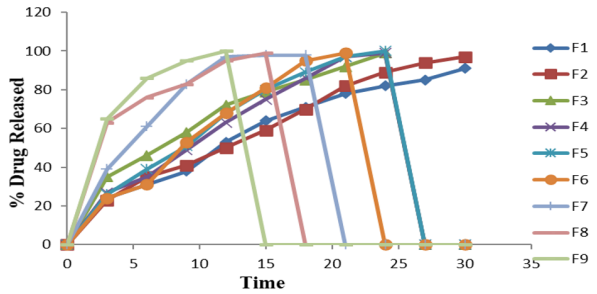


Figure 2: Dissolution Profile for F1 to F9 Formulations

Stability Studies

Selected formulation F9 was strip packed and stored at 40°C ± 2°C / 75% ± 5% RH [Table 3, Table 4] or indeed a duration of 1 month [Table 5]. Samples were evaluated now since storage for 1 month as well as assessed [Figure 2, Figure 3].

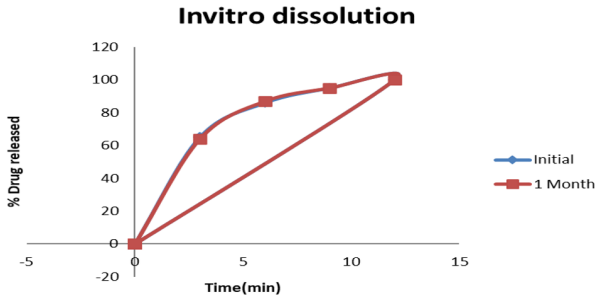


Figure 3: *In-vitro* Release Profile of F9 During Stability Studies

CONCLUSION

Risperidone orally disintegrating films were successfully prepared with HPMC E15CPS and HPMC E15 & HPMC E5 combination. The disintegration time of the prepared films were in the range of 21sec to 32sec. The F9 formulation *in vitro* disintegration time was below of 27 sec. It was concluded that formulations F9 were found to be satisfactory batch and were optimized for the desirable properties.

ACKNOWLEDGEMENT

I would like to thanks to Dr. M. Kishore Babu Garu, Principal of Krishna Teja Pharmacy College, Chadalawada Nagar, Renigunta Road, Tirupathi-517506, Andhra Pradesh, India.

Funding Support

The authors declare that they have no funding support for this study.

Conflict of Interest

The authors declare that there is no conflict of interest.

REFERENCES

[1] Parul Saini, Anoop Kumar, Pankaj Kumar Sharma, and Sharad Visht. Fast Disintegrating Oral Films: A Recent Trend of Drug Delivery. *International Journal of Drug Development and Research*, 4(4):80–94, 2012.

[2] Rajni Bala, Pravin Pawar, Sushil Khanna, and Sandeep Arora. Orally Dissolving Strips: A New Approach to Oral Drug Delivery System. *International Journal of Pharmaceutical Investigation*, 3(2):67–76, 2013.

[3] A Arya, A Chandra, V Sharma, and K Pathak. Fast dissolving oral films: an innovative drug delivery system and dosage form. *International Journal of ChemTech Research*, 2(1):576–583, 2010.

[4] Smita V. Pawar and M. S. Junagade. Formulation and Evaluation of Mouth Dissolving Film of Risperidone. *International Journal of PharmTech Research*, 8(6):218–230, 2015.

[5] R. C. Mashru, V. B. Sutariya, M. G. Sankalia, and P. P. Parikh. Development and Evaluation of Fast-Dissolving Film of Salbutamol Sulphate. *Drug Development and Industrial Pharmacy*, 31(1):25–34, 2005.

[6] Francesco Cilurzo, Irma E. Cupone, Paola

Minghetti, Francesca Selmin, and Luisa Montanari. Fast dissolving films made of maltodextrins. *European Journal of Pharmaceutics and Biopharmaceutics*, 70(3):895–900, 2008.

[7] S Kalyan and M Bansal. Recent trends in the development of oral dissolving film. *International Journal of PharmTech Research*, 4(2):725–733, 2012.

[8] Misao Nishimura, Katsuhiko Matsuura, Tadao Tsukioka, Hirotaka Yamashita, Naoki Inagaki, Tadashi Sugiyama, and Yoshinori Itoh. In vitro and in vivo characteristics of prochlorperazine oral disintegrating film. *International Journal of Pharmaceutics*, 368(1-2):98–102, 2009.

[9] Hao Zhang, Jie Zhang, and James B. Streisand. Oral Mucosal Drug Delivery. *Clinical pharmacokinetics*, 41(9):661–680, 2002.

[10] Zainab E Jassim, Mais F Mohammed, and Zainab Ahmed Sadeq. Formulation and Evaluation of Fast Dissolving Film of Lornoxicam. *Asian Journal of Pharmaceutical and Clinical Research*, 11(9):217–223, 2018.

[11] Poonam A. Padamwar and Poonam P. Phasate. Formulation and evaluation of fast dissolving oral film of bisoprololfumarate. *International Journal of Pharma Sciences and Research*, 6(1):135–142, 2015.

[12] Ashish Jain, Harish C Ahirwar, Shivam Tayal, and Pradeep K. Mohanty. Fast dissolving oral films: A tabular update. *Journal of Drug Delivery and Therapeutics*, 8(4):10–19, 2018.

Cite this article: Ajith Reddy C, Uma Sankar K, Kishore Babu M. Formulation and Evaluation of Fast Dissolving Oral Films of Risperidone. Future J. Pharm. Health. Sci. 2022; 2(1): 35-39.