

DEVELOPMENT OF RISPERIDONE ORAL TABLET FOR THE TREATMENT OF MENTAL ILLNESS

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Abstract:

The oral tablet is a solid dosage form. The orally disintegrating tablet or orally dissolving tablet (ODT) is a drug dosage form, designed to dissolve on the tongue fairly than swallowed whole. The ODT is in the class of solid dosage forms. The ODT is available in over-the-counter (OTC) and prescription medications. ODT is best economic drug delivery with better patient compliance. ODT is safest and convenient formulation. The geriatric and pediatric patient compliance better in ODT than conventional tablet. The ODT is rapidly disintegrate and dissolved in saliva. The mental illness peoples swallow ODT easily and no need to take more water to dissolve the tablet. The objective was to prepare a risperidone ODT formulation using water soluble excipients, super-disintegrants. The various risperidone ODT formulation were prepared. The amount of risperidone in each formulation was 1mg. Six formulation were prepared (K1,K2,K3,K4,K5,K6). Formulations prepared were tested for flowability of granules, appearance, thickness, uniformity of weight, hardness, friability and disintegration time.

Keywords: Orally disintegrating tablet; Risperidone; Mental illness, Varicose veins, Sedentary, Compression stockings

Introduction

Mental illness also defined as mental health disorders, refers to a large series of mental health conditions such as disorders that affect mood, thinking and behavior. Examples of mental illness or psychiatric diseases and behavioural disorders include depression, anxiety disorders, schizophrenia, eating disorders and addictive behaviors. risperidone is used for the treatment of schizophrenia. Schizophrenia is a disorder that affects person's ability to think, feel and behave clearly. It is also indicated for bipolar disorder. Bipolar disorder is a disorder associated with episodes of mood swings ranging from depressive lows to manic (unusually irritable mood exists) high. The proper attitude, discipline helps to get rid of mental illness. The discipline, good understanding and respects with parents, elder brothers, senior peoples, younger sisters, colleagues, classmates, work place staffs, teachers, professors and all publics are preferred to get cured. Risperidone is a drug used to treat schizophrenia, the successful recovery of the patient is by the surrounding environment and patient supporters. Parents are evergreen supporters of all

human beings. Parents live calm with happiness in the house with each other to lead successful Indian family system both in the house and out of the house. Their children live with them happily. The certain mental and mood disorders such as depression, frustration can be cured successfully by this way. Frustration is opposition of emotional response, related to anger, annoyance and disappointment. Frustration causes from the perceived resistance to the fulfillment of a person's aim or goal and when goal is rejected. The cosmetic appearance such as varicose veins in legs may cause frustration. The risk factors of varicose veins include a sedentary lifestyle (long hour inactive such as seated long hour), weight gain, prolonged standing and pregnancy. Symptoms of varicose veins include aching, cramping, itching, swelling and fatigue. Varicose veins can occur in men or women of any age. Common treatment includes leg elevation while sitting or sleeping, compression dressings with single or multilayered systems, compression stockings, sclerotherapy, ablation of abnormal veins, surgery. Varicose veins cure is must at initial stage, with that of awareness, so the frustration and fear can be stopped. Fear of mind causes depression, so people can not able to judge their opinions. Antidepressants are used to treat frustration.

Material and Methods:

Materials

Risperidone was obtained from Madras Pharmaceuticals, Chennai, India. Other materials used in the study (methyl methacrylate copolymer (acrylic resin), Crosscarmelloe, Xylitol, Saccharin, methanol, ethanol, potassium dihydrogen phosphate, etc.) were of analytical grade and procured from SD Fine Chemicals, India. Purified water was used throughout the study.

Formulation preparation:

The composition of different ODT formulations of code K1, K2, K3, K4, K5 and K6 were shown in Table 1. Risperidone and methyl methacrylic resin used to form complex with ion exchange method. The risperidone complex formed in 0.1N HCl. The risperidone complex is mixed with superdisintegrant croscarmellose, xylitol, saccharin, starch to form the blend. The blend is lubricated with magnesium stearate and talc. The prepared granules compressed with tablet press. Each tablet contain 1mg of risperidone. The prepared tablet is evaluated for physical and chemical characters.

Flowability of granules: The flow property of granules evaluated for compressibility index (Carr's index) and hausner's ratio by flow funnel method. The granules pour through a vertical funnel to a maximum cone height (h). The radius of heap measured. The formula for angle of repose is $\tan \theta = h/r$

Bulk density and tapped density measured by cylinder method. The 100 ml measuring cylinder filled with known amount of powder. The initial volume noted in the cylinder as bulk volume, after 100 taps in tapped density tester, the tapped volume of packing was noted. The bulk and tapped density calculated by mass/volume formula.

Carr's index of granules = $((\text{Tapped density} - \text{bulk density}) \times 100) / \text{Tapped density}$.

Hausner's ratio is an index of ease of powder flow. Hausner's ratio = $\text{Tapped density} / \text{Bulk density}$

Appearance of tablet: The tablet appeared as white round plain tablet

Thickness The tablet: The thickness in millimeters (mm) measured individually for 10 preweighed tablets used to found thickness in screw gauge. The average thickness and standard deviation of the tablets were found.

Uniformity of weight: Twenty tablets were weighed individually, which are selected at random and calculate the average weight.

Drug Content: The Ultra violet spectroscopy used to evaluate risperidone quantity per tablet, taken 20 tablets, grinded in mortar and pestle become powder. The 2mg risperidone equivalent powder taken and with serial dilution and filtration through 0.45 micron filter paper, then the quantity of risperidone analysed in ultra violet spectroscopy. The analysis done for three times. The λ_{max} used for UV estimation is 286 nm. The risperidone content found in the range of 90-96 percentage in the formulation K1-K6.

Hardness: The multicheck hardness tester used to found the hardness test of the tablet

Friability: The roche friabilator used to found the friability of the tablets. The weighed quantity of tablet tested in friabilator with 25 rotation per minute, upto 4 minutes.

$$\% \text{ Friability} = ((W_1 - W_2) \times 100) / W_1$$

Where W_1 = Initial weight of the tablet before the test, W_2 = Final weight of the tablet after the test; The friability found less than 1% w/w.

In vitro disintegration time: These six tablets were tested in water at 37 °C using a tablet disintegration apparatus. Noted the time required for disintegration of the tablets and passing completely through the sieve. The six tablets disintegrated not less than 10 seconds.

In vitro dissolution study: The USP paddle method dissolution testing apparatus used to determine the dissolution time of the ODTs. The dissolution test is performed using 900 ml of 0.1 N HCl at 37±0.5 °C at 100 rpm. The dissolution study found to be not less than 30 seconds. The drug release seen increased slightly from K1 to K6.

In vitro dispersion time: Added ODT in 50 ml of phosphate buffer solution (pH 7.4) at 37±0.5 °C. Noted the time required for complete dispersion of tablets. The dispersion time found to be not less than 50 seconds. There is no significant variation of in vitro dispersion time of trial K1 to K6.

Water absorption ratio:

Note the weight of the tablet to kept before in the petri dish (W_b). Note the weight of the tablets after wetting (W_a).

$$\text{Water absorption ratio} = 100 \times (W_a - W_b) / W_b$$

The water absorption ratio is found 60 percentage.

Conclusion:The prepared risperidone ODT provides the desired physicochemical characters, and provide taste masking and easy disintegration in the buccal cavity. The further clinical study is useful for economic product development. The suitable analytical method and packaging material such as high-density polyethylene bottles are required for the stability management of the risperidone ODT.

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I express my sincere thanks to my parents.

Table 1. Composition of ODT formulations (% w/w)

S.No	Materials	Code					
		K1	K2	K3	K4	K5	K6
1	Risperidone	10	10	10	10	10	10
2	Acrylic resin	2.5	5	7.5	10	12.5	15
3	Crosscarmelloe	15	15	15	15	15	15
4	Xylitol	2	2	2	2	2	2
5	Saccharin	5	5	5	5	5	5
6	Starch	14.5	12	9.5	7	4.5	2
7	Magnesium sterate	0.5	0.5	0.5	0.5	0.5	0.5
8	Talc	0.5	0.5	0.5	0.5	0.5	0.5
Total		50	50	50	50	50	50

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