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COMPARATIVE STUDY OF DIFFERENT BRANDS OF RESPERIDONE MARKETED FORMULATION

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Abstract:
The proposed method for the determination of resperidone in solid dosage form was found to be precise, Selective, rapid and economical.The proposed methods can be used for the drug analysis in routine quality control & method proves to be More economical than the published Standard methods. resperidone is a safe and effective new antipsychotic that has a high binding affinity for both serotonin and dopamine receptors.1 Several well-designed controlled clinical trials have been conducted to establish the antipsychotic efficacy of resperidone. In a previously published report we had mentioned the rationale for using a once-a-day dosage schedule for resperidone based on the elimination half-life of resperidone and its active metabolite, 9-hydroxyresperidone, to enhance compliance. Since that time, the use of resperidone once daily has been studied and recommended. In the setting of a community day treatment program, we had switched patients from a twice-a-day resperidone dosage schedule to a once-daily dosage and found it to be effective. In a retrospective chart review published earlier, we found no increase in side effects such as neuroleptic-induced extrapyramidal symptoms or sedation in patients taking once-daily resperidone. We found the once-daily dosage to be safe, and patient compliance was enhanced. We now report a retrospective chart review of patients who had been on once-daily resperidone treatment for an extended period of time. The aim of this study was to assess the efficacy, extrapyramidal side effects, and tolerability of resperidone in these patients over an extended period of time. The Food and Drug Administration (FDA)-approved indications for oral resperidone(tablets & oral solution) include the treatment of schizophrenia (in adults and children aged 13 and up), bipolar acute manic or mixed episodes as monotherapy (in adults and children aged 10 and up), bipolar acute manic or mixed episodes adjunctive with lithium or valproate (in adults), and autism- associated irritability (in children aged 5 and up). Also, the long-acting resperidone injection has been approved for the use of schizophrenia and maintenance of bipolar disorder (as monotherapy or adjunctive to valproate or lithium) in adults. There are also many varied non-FDA-approved uses for resperidone. This activity outlines the indications, mechanism of action, administration methods, significant adverse effects, contraindications, and monitoring, of resperidone, so providers can direct patient therapy in treating conditions for which it is indicated as part ofthe inter professional team.

KEYWORDS: *Hardness, Friability, Thickness, Friability, brand*

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INTRODUCTION:

Poor quality medicine, especially among multisource generics, has become a global issue as it has defied most existing international and national regulations. The World Health Organization (WHO) estimated that 30% of the medicines in circulation in low-and middle-countries are substandard and counterfeit due to very weak policies, regulation and policy enforcement systems for medicine. Poor quality medicine poses serious public health challenge to endusers globally. Antipsychotics, such as resperidone, have become one of the major targets for counterfeiters due to its increasing use in the relief of symptoms of mental health disorders. Resperidone, sold under the brand name Resperdal among others, is an atypical antipsychotic used to treat schizophrenia and bipolar disorder.It is taken either by mouth or by injection (subcutaneous or intramuscular).The injectable versions arelong-acting and last for 2–4 weeks. Resperidone is a selective blocker of dopamine (D2) and serotonin 5-HT2 receptors. It acts as an atypical antipsychotic agent which has been shown to improve both positive and negative symptoms in the treatment of schizophrenia. It is used widely in the treatment of mania and schizophrenia, and its therapy is associated with serum amino transferase elevations, and in rare instances, has been linked to clinically apparent acute liver injury.

MATERIALS AND METHODS:

MATERIALS:

Sample Collection: Three brands of resperidone (2 mg) tablets (coded R1 – R3) used in this study were purchased from retail pharmacy outlets. These were stored under appropriate conditions and tested within their expiration dates.

Instruments/Reagents used in the study: UV/Vis Spectrophotometer, analytical weighing balance, Dissolution tester, disintegration tester , Friabulator and Monsanto Hardness Tester were used in this study. Distilled water, Conc Hcl were also used. All reagents were of analyticalgrade.

METHODS:

Preliminary test

General Appearance: Organoleptic analysis was performed on each sample. The shape, colour and coating type of the different brands of risperidone tablets were examined and recorded.

Packaging and Labeling Inspection: The labeling on the primary and secondary packages of the tablets was properly examined for the following details: name and strength of active ingredient, batch number, brand name, manufacture and expiry dates. The manufacturers' addresses were also noted.

***In Vitro* Official Tests**

Uniformity of Weight: Twenty tablets from each brand of risperidone were selected and weighed with analytical balance individually. The determinations were done in triplicates. The weights were recorded and the mean, standard deviation, and percentage standard deviation were calculated using the formula.

$$\text{Weight Variation} = \frac{I_w - A_w}{A_w} \times 100\%$$

Where Iw = individual weight of tablets Aw = average weight of tablets.

Preparation of standard stock solution)

A 10 ml volume of concentrated hydrochloric acid was dissolved in 500 ml of distilled water and made up to 1000 ml with distilled water to give 0.1 N HCl.

Determination of maximum wavelength (λmax) of absorption

An aliquot from the stock solution was scanned in the UV-Visible spectrophotometer at different wavelengths to determine the maximum wavelength of absorption. Maximum wavelength obtained was 241 nm.

Determination of standard calibration curve

The serial dilutions (0.1, 0.2, 0.3, 0.4, 0.5, 0.6 µg/ml) obtained from resperidone stock solution were passed through the UV-Visible spectrophotometer and their absorbance was read at 241 nm.

Assay of Content of Active Ingredients

Ten tablets from each brand of resperidone were weighed and crushed to powder in a mortar. The percentage drug content was calculated for each batch.

Disintegration Test

The disintegration test for the different brands of resperidone was carried out according to the method described in the IP.

Dissolution Test

The dissolution test for the different brands of resperidone tablets were carried out according to USP dissolution apparatus (paddle type).

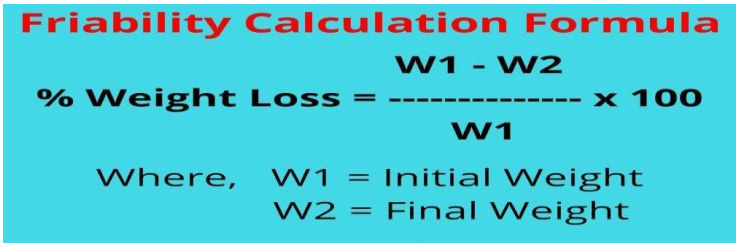
***In Vitro* Unofficial Tests**

Hardness/Crushing Strength Test

Ten tablets were randomly selected from each brand of resperidone. One tablet was placed between the jaws of a hardness tester and adjusted by pushing forward the movable jaw inside, turning the plunger clockwise. The value on the scale that coincides with the pointer was noted and pressure applied till the tabletbreaks. The value on the scale was recorded. The procedure was repeated for all tablets.

Friability Test

Ten tablets were selected at random. Each batch of ten tablets was weighed. The tablets were placed in the friabilator and rotated for 4 min at 25 revolutions. The tablets were removed, de-dusted and reweighed.



RESULT AND DISCUSSION:

Table 1 : Result of labelling and inspection test

Drug Name	Mfg Date	Exp Date	Batch No	Company Name
Risdone-1	May 2021	Apr 2024	112101491	Intas Pharma Ltd
Respidone-2	Oct 2020	Sep 2023	73TRE003	Torrent Pharma Ltd
Rispond-3	Mar 2021	Feb 2024	RATP0044	Micro Lab Ltd

Table 2 : Result of weight variation, Hardness, %Friability, Disintegration time ofdifferent brand of resperidone.

Sample	Weight Variation	Hardness	% friability	Disintegration Time(min)
Risdone-1	200±2.4	4.21	1.00%	1.0
Respidone-2	201±3	5.67	0.9%	2.3
Rispond-3	198±1.3	5.12	0.3%	1.7

Table 3: Result of the general appearance for the tested brand of resperidone

Product Name	Coating	Colors	Dosage Form
Risdone-1	Coated	Peach	Tablet
Rispond-2	Coated	White	Tablet
Respidon-3	Coated	White	Tablet

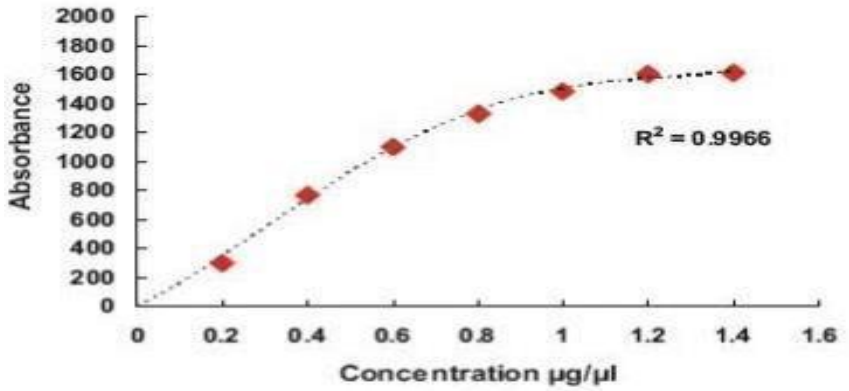


Fig no 1: Standard calibration curve of resperidone

In-vitro dissolution Studies:

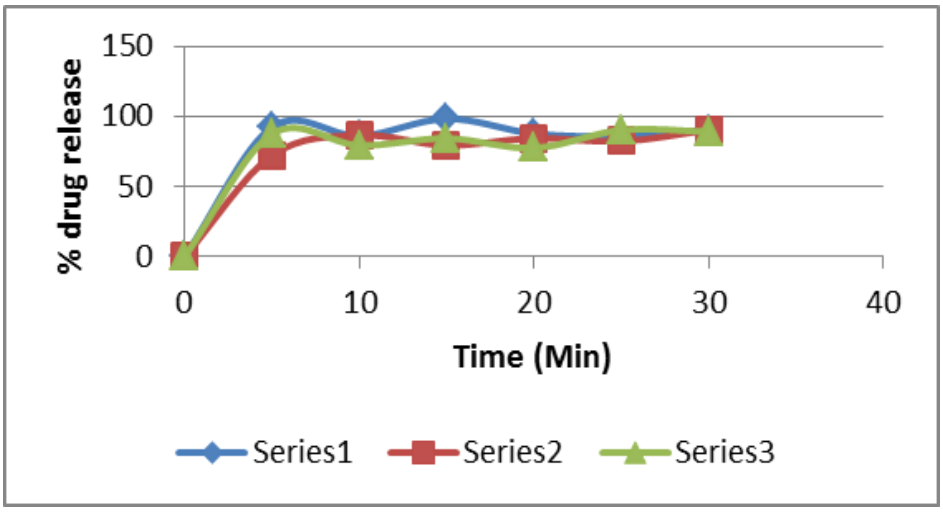


Fig no 2: graph of % drug release against time of resperidone

SUMMARY AND CONCLUSION:

The proposed method for the determination of resperidone in solid dosage form was found to be precise, Selective, rapid and economical.The proposed methods can be Used for the drug analysis in routine Quality control & method proves to be More economical than the published Standard methods. Resperidone is a safe and effective new antipsychotic that has a high binding affinity for both serotonin and dopamine receptors.1 Several well-designed controlled clinical trials have been conducted to establish the antipsychotic efficacy of risperidone. Since that time, the use of risperidone once daily has been studied and recommended. In the setting of a community day treatment program, we had switched patients from a twice-a-day risperidone dosage schedule to a once-daily dosage and found it to be effective. We found the once-daily dosage to be safe, and patient compliance was enhanced. The aim of this study was to assess the efficacy, extrapyramidal side effects, and tolerability of risperidone in these patients over an extended period of time. Also, the long-acting risperidone injection has been approved for the use of schizophrenia and maintenance of bipolar disorder (as monotherapy or adjunctive to valproate or lithium) in adults.

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