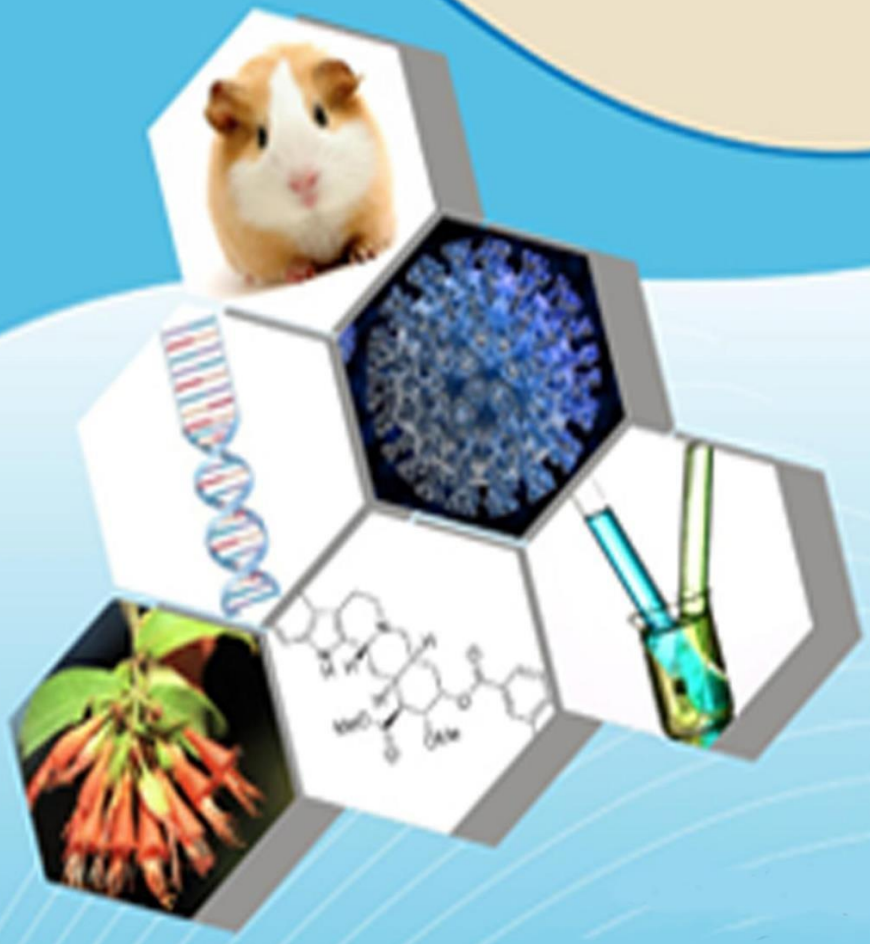
ISSN : 2347-2251

Indo-American Journal of Pharma and Bio Sciences



iajpb.editor@gmail.com
editor@iajpb.com

www.iajpb.com

ISSN 2347-2251 www.iajpb.com
Vol. 20, Issuse 4, 0ct 2022

Indo-American Journal of Pharma and Bio Sciences

FORMULATION AND EVALUATION OF ITRACONAZOLE IMMEDIATE RELEASE TABLETS

R.Mohanthi*, D.Ramya, K.Venkat Krishna,
Guide: Dr. P. Silas., Ph.D

Article Info

Received: 19-07-2022 Revised:20 -8-2022 Accepted: 22-09-2022

ABSTRACT

The current study aimed to develop and evaluate a novel super disintegrant containing chitosan silicate conjugate and chitosan thioglycolic acid conjugate for the rapid release and absorption of the anti-fungal medication itraconazole following oral administration, and to compare it to other commercially available super disintegrants such as sodium starch glycolate. The Charring point, Viscosity, and Fourier transforms of chitosan thioglycolic acid and chatoyant silicate conjugates, which were used to make the tablet, were determined. Medicine compatibility was tested using techniques including Fourier transform infrared spectroscopy and differential scanning calorimetry, and no negative interactions were found between the drug and its intended receivers. In this study, we analyzed the post-compression properties of rapid release tablet formulations made utilizing the direct compression technique. This research found that the disintegration time of tablets given orally is shorter than that of those delivered sublingually, leading to faster absorption and greater bioavailability. Since formulation F-6 needed less time to wet and absorbed more moisture than tablets with the same proportions of SSG, CTC, and starch, it was deemed the best option. The in vitro dissolving tests showed that after 30 minutes, F-6 had disintegrated to its full potential thanks to the extraordinary disintegration capacity of the Chitosan silicate conjugate. The procedure for releasing was first-order and non-Fictional. F-6 was found to be stable after being put through a battery of stability tests, passing with flying colors in terms of both visual appeal and its capacity to dissolve and disintegrate in vitro.

Keywords: Itraconazole, Anti-fungal, Super disintegration and in vitro dissolution

INTRODUCTION

Patients are more likely to take their medication as prescribed when given it orally, making this the preferred administration route. For reasons including mobility, small size, and ease of manufacture, tablets remain the most used dosage form. Fast-acting medications are best administered as immediate-release capsules or tablets.duration that is short-lived. Without the need for timed release coatings or any other mechanisms1, these tablets are made to disintegrate and release their contents. Super disintegrants such cross linked polyvinyl-pyrrolidone (cross providence), sodium starch glycolate, carboxymethylcellulose (croscarmellose sodium), etc. were used extensively in the development of these tablets.

Department: Department of pharmaceutics,
University College Of Pharmaceutical Sciences, Palamuru University, Telangana, Mahabubnagar, 509001.
mohanthi3@gmail.com

ISSN 2347-2251 www.iajpb.com
Vol. 20, Issuse 4, 0ct 2022
Indo-American Journal of Pharma and Bio Sciences

When used orally, these super disintegrates (sometimes called "rapidly dissolving tablets") are designed to dissolve quickly in the stomach, releasing 85 percent of the drug or more within 15 minutes. Very quick dissolving tablets are those that release more than 85% of the drug in less than 15 minutes.36 Tablets are a popular form of drug administration due to their inexpensive cost, rapid onset of action, and ease of use. Companies that provide this dosage form to their target demographic of patients have a chance to enhance sales and preserve their position as market leaders. Direct compression is used because it is more cost-effective and reduces the time required to make the tablets, whereas wet granulation is not suitable for temperature labile and moisture sensitive active ingredients28 and lengthens the cycle time. When consumed as intended, the contents of immediate-release tablets are absorbed quickly by the body (GIT).

METHODS FOR THE PREPARATION OF IMMEDIATE RELEASE TABLETS

- Direct compression technique
- Wet granulation technique

DIRECT COMPRESSION TECHNIQUE 33, 42

In direct compression, the drug is combined with a variety of receivers, lubricated, and then immediately crushed into a tablet. In this formulation, the medicine component for dissolving is exposed when breaking the tablet apart. Flow properties and cohesiveness under pressure of the mixture to be compressed must be adequate. Most drugs may be promptly compressed into pills of adequate quality. Both the disintegrate itself and its proportion to the other components are significant. Not only should you consider the tablet's hardness and its capacity to absorb water, but also its particle size distribution, contact angle, pore size distribution, and particle size distribution. Each of these factors has a role in the breakdown. In a manufacturing scenario, the disintegration addition technique requires little effort and costs little money to implement.

WET GRANULATION TECHNIQUE 33, 42

In wet granulation, the powder is agglomerated softly with the help of a liquid binder. The granules become too hard if they are over-wet, and they become too soft and friable if they are under-wet. Not all drugs

ISSN 2347-2251 www.iajpb.com
Vol. 20, Issuse 4, 0ct 2022
Indo-American Journal of Pharma and Bio Sciences

are suitable for use in aqueous solutions because of the danger of chemical degradation. The process begins with measuring and combining the active ingredient with the receivers by weight. The powder is combined with aqueous preparations of cornstarch, natural gums like acacia, cellulose derivatives such methyl cellulose, gelatin, and other liquid binders, and then well stirred to produce the wet granulate. Granules are made by pressing the moist substance through a mesh. Either a conventional tray-dryer or a fluidized-bed drier may be used to dry the granules. Tablets are crushed after dry granules are screened to a smaller size, lubricants are added, and the mixture is appropriately blended.

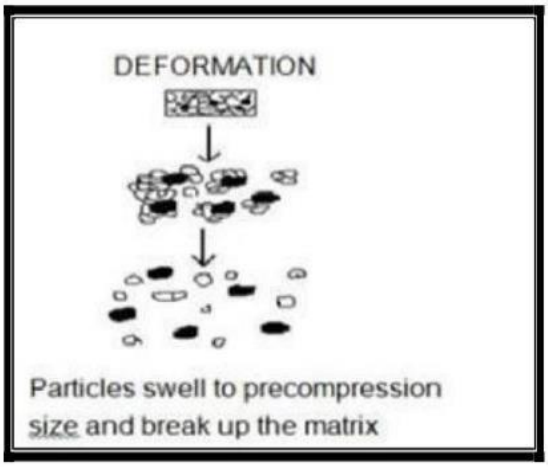
MECHANISMS

B YSUPERDISINTEGRATION

DEFORMATION

After been bent by tablet compression, disintegration particles restore their original shape when coming into touch with the medium. As the distorted particlesgrow in size, the tablet crumbles.

Figure 1.3: Deformation mechanism of super disintegrating agent



ELECTROSTATIC REPULSION

An other mechanism postulated to account for disintegration is the growth of the "non sellable" dissolve dosage form. Guyot Hermann proposed a notion of particle repulsion to explain the dissolution of dose forms by non-swelling particles. The presence of water is necessary for disintegration, which is triggered by electrostatic repulsion between particles. The scientific community has come to recognize the significance of wicking over repelling.

ISSN 2347-2251 www.iajpb.com
Vol. 20, Issuse 4, 0ct 2022
Indo-American Journal of Pharma and Bio Sciences

Researchers have proposed a plethora of different processes that might be at play in most disintegrations. The likelihood of interdependencies among these central activities increases as a result.

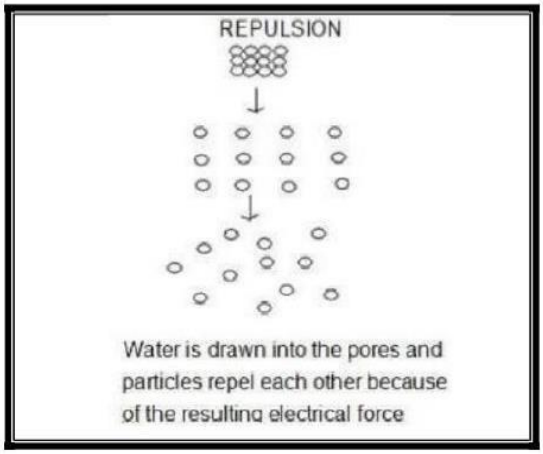


Figure 1.4: Electrostatic repulsion mechanism of super disintegrating agent

REVIEW OF LITERATURE

Ahmed JA *et al.*., (2015) dtopics included the design, creation, and assessment of instant release tablets. The benefits and drawbacks of quick release dosage forms and their optimal qualities were also discussed.

B.K. Satheesh babu *et al.*., (2019) The purpose of this research was to synthesize and characterize a transverse rate-controlling membrane and then determine how it affected medication penetration across the membrane. Conjugation with thioglycolic acid for synthesis of chatoyant conjugate. The melting point and charring temperature of our chitosan conjugate were determined using Fourier transmission-infrared spectroscopy and differential scanning calorimetry, respectively. Chitosan and chitosan conjugate were blended together at varying concentrations to produce membranes with controllable drug diffusion rates. Ethyl cellulose, at 20% w/v, was employed to provide a reservoir for the drug gel in a transverse delivery system because to the membrane's buffering properties. Ethyl cellulose was utilized at a weight-to-volume (w/v) ratio of 2% to provide an impermeable backing layer. Ethanol, water, sodium alginate, and sodium carboxymethylcellulose were used to create the carvedilol gel. The prepared rate-controlling membranes were evaluated using a wide variety of

ISSN 2347-2251 www.iajpb.com
Vol. 20, Issuse 4, 0ct 2022
Indo-American Journal of Pharma and Bio Sciences

metrics, including thickness, folding endurance, swelling index, moisture content, moisture uptake, water vapor transmission rate, tensile strength test, measurement of gel strength, in vitro permeation study, ex vivo permeation study, compatibility study using Differential scanning calorimetric, and stabilitystudy.

The super disintegrants were used in the creation of the itraconazole sublingual tablets by **Brahmbhatt H et al., 2014.** By using a polymer (chatoyant), we were able to postpone the flushing action of saliva, allowing for more efficient drug absorption. The pills' chemical and physical properties were examined. Combined formulations of chitosan and super disintegrates were reported to speed up medication release compared to either component used alone, as determined by permeation studies. 23

Kauffman, C. A. notes that the addition of itraconazole and fluconazole to the antifungal arsenal has made therapy for endemic and opportunistic mycoses less toxic and more easily administered (1996). Itraconazole is now often used to treat patients with moderate to severe histoplasmosis, blast mycosis, or sporotrichosis. Although itraconazole was formerly the go-to drug for treating coccidioidal meningitis, fluconazole has now supplanted it as the drug of choice. Multiple large-scale collaborative trials have indicated that fluconazole is useful in treating candidemia, localized mucocutaneous and visceral candidiasis, and cryptococcal meningitis.

METHODOLOGY

Table 2.1: List of Chemicals/Solvents.

ISSN 2347-2251 www.iajpb.com
Vol. 20, Issuse 4, 0ct 2022

Indo-American Journal of Pharma and Bio Sciences

CHEMICALS	SOURCE/MANUFACTURER
Itraconazole	Gift sample from Spansules Pharmatech Pvt. Ltd., Hyderabad
Mannitol	Strides Arco lab Ltd., Bengaluru
Avicel PH 102	Strides Arco lab Ltd., Bengaluru
Chitosan	Himedia Labs Pvt. Ltd., Mumbai
Thioglycolic acid	Qualigens Fine Chem., Mumbai
Colloidal silicon dioxide	Strides Arco lab Ltd., Bengaluru
Sodium hydroxide	Himedia Labs Pvt. Ltd., Mumbai
Sodium starch glycolate	Strides Arco lab Ltd., Bengaluru
Pregelatinized starch	Strides Arco lab Ltd., Bengaluru
Magnesium stearate	Strides Arco lab Ltd., Bengaluru
Methanol (HPLC grade)	Spectrochem Pvt. Ltd., Mumbai
Formic acid (HPLC grade)	Spectrochem Pvt. Ltd., Mumbai
Methanol	Merck Specialities Pvt. Ltd., Mumbai
Sodium chloride	Himedia Labs Pvt. Ltd., Mumbai

Table 2.2: List of Instruments.

INSTRUMENTS	MANUFACTURER/MODEL
Analytical balance	Shimadzu
pH meter	Systronics μ pH system 362
Magnetic stirrer	REMI Instruments Ltd.
U.V/Visible spectrophotometer	Shimadzu UV 1800
Dissolution test apparatus	Electro lab TDT 08L (USP)
Tablet hardness tester	Pfizer
Friabilator	Lab India
Disintegration test apparatus	Lab India
FT-IR spectrophotometer	Shimadzu FT-IR 8400
HPLC	Shimadzu (Prominence)
Melting point apparatus	Sigma
Digital Ultra sonicator	LABMAN Scientific Instruments
Tablet punching machine	Kamavathi RSB-4 Minipress
Digital viscometer	Brookfield LV DV-II+ Pro viscometer
Differential scanning calorimeter	DSC 60-plus Shimadzu

ANALYTICAL METHODS FOR THE DETERMINATION OF ITRICONAZOLE

Determination of absorption maxima

An amount of itraconazole equal to 100 mg was weighed out and diluted in 100 ml of 0.1N HCl to make a 1 mg/ml solution (SS-1). Ten milliliters of the

ISSN 2347-2251 www.iajpb.com
Vol. 20, Issuse 4, 0ct 2022
Indo-American Journal of Pharma and Bio Sciences

aforementioned SS-1 solution were diluted with 0.1 N HCl to produce a final volume of 100 milliliters, yielding a concentration of 100 micrograms per milliliter (SS-II). There are only 10 ng/ml of active ingredient in this solution since it was diluted to that degree. The resulting solution was put through a series of scans in a UV-Visible Spectrophotometer (Shimadzu UV 1800) between 200 and 400 nanometers. In 0.1 N HCl, the drug's maximum absorbance was observed at 223 nm.

Standard calibration curve of Itraconazole by RP-HPLC

INSTRUMENT: Shimadzu (Prominence)

COLUMN: Cosmosil C-18 analytical column (250 mm × 4.6 mm inner diameter, 5 µm particle size).

MOBILE PHASE: Formic acid (0.1%): Methanol (60:40)

FLOW RATE: 0.6 ml/min

INJECTION VOLUME: 20 µl

DETECTION WAVELENGTH: 223 nm (U.V detector)

Principle of RP-HPLC

In analytical chemistry, high-performance liquid chromatography (HPLC) is a method used to isolate and determine the concentrations of individual compounds. RPC is a catch-all term for any chromatographic technique in which the stationary phase is hydrophobic (RPC). Liquid chromatography, also known as reversed-phase chromatography.
In this method, the solid support (mobile phase) is covalently linked to alkyl chains, making the stationary phase hydrophobic and non-polar and increasing its attraction to hydrophobic and non-polar molecules. In contrast to normal phase chromatography, reversed phase chromatography employs a hydrophilic or polar stationary phase. In reversed-phase chromatography, water is often used as the mobile phase, or solvent. The hydrophobic and non-polar molecules in the mobile phase will prefer to adsorb to the stationary phase, which is also hydrophobic and non-polar, whereas the hydrophilic and polar molecules will flow through the column and be eluted first due to the polarity of the mobile phase. A nonpolar organic solvent may be used to reduce the polarity of the mobile phase, allowing for

ISSN 2347-2251 www.iajpb.com
Vol. 20, Issuse 4, 0ct 2022
Indo-American Journal of Pharma and Bio Sciences

the elution of hydrophobic substances from the column.
The greater the concentration of organic solvent needed to elute the molecule, regardless of whether the stationary phase is hydrophobic or non-polar, the stronger the binding of the molecule to the stationary phase. By permitting the mobile phase to run down the column at high pressure (50-350 bar), RP-HPLC facilitates more rapid and precise separations.Elution is the name given to the process of separating the constituents.

Preparation of mobile phase

The solution was prepared by combining 60 parts Methanol with 40 parts Formic acid (0.1% in HPLC grade water) and then filtering it through 0.45 m filter paper in a vacuum suction pump. Ultrasonication was used to remove the air bubbles.

Standard stock solution

A volume of mobile phase equal to 50 ml was added to a volumetric flask containing 100 mg of itraconazole, and the mixture was stirred for 5 minutes. The mobile phase was used to achieve the correct volume for the standard stock solution (1000 g/ml) (Stock Solution-I)

Working standard solution

Micropipetting 10 ml from the aforementioned Stock Solution-I, we diluted it to 100 ml with mobile phase to get 100 g/ml (Stock Solution-II). Smaller volumes of SS-II solution (0.1 ml, 0.15 ml, 0.2 ml, 0.25 ml, 0.3 ml, 0.35 ml, 0.4 ml, 0.45 ml, and 0.5 ml) were pipetted into larger volumetric flasks (10 ml). The solutions were then put through RP-HPLC to acquire concentrations in the range of 1-5 g/ml, and their respective areas were calculated.

CHARACTERIZATION OF THE SYNTHESIZED CHITOSAN CONJUGATES

a) Charring point

About 5 mg of chitosan, CSC, and CTC was placed in a one-end-sealed glass capillary tube, and the melting points were measured. Once the melting point equipment was set up, the capillary tube holding the sample was inserted and the temperature was raised slowly. The charring point of a given

ISSN 2347-2251 www.iajpb.com
Vol. 20, Issuse 4, 0ct 2022
Indo-American Journal of Pharma and Bio Sciences

sample was recorded as the temperature in degrees Celsius at which full charring occurred.

b) Viscosity

The Brookfield LV DV-II+ Pro viscometer was used to measure the viscosity of 2% solutions of chatoyant, CSC, and CTC. This apparatus was operated using Rheocalc V 2.7. When using a viscometer, spindle LV-4 (spindle number 64) was employed and was submerged in polymer solution up to the line. Spindle speeds of 20, 50, 60, and 100 rpm were maintained for 15 seconds each, and the viscosity readouts were recorded.

c) Fourier transforms infrared spectroscopy (FT-IR)

To do this, pellets of chitosan, CSC, and CTC were formed and scanned by an FT-IR spectrophotometer from 3600 to 400 cm1 to get their infrared spectra.

PRE-FORMULATION PARAMETERS

Drug–incipient compatibility Studies

The physical, chemical, and biological properties of the medicine and the recipients employed in the production of the product must be taken into account throughout the design and formulation of the dosage form. In order to create a product that is stable, effective, appealing, and safe, it is necessary to ensure compatibility between the active component and other receivers. Pre formulation factors were used to investigate drug–recipient compatibility. These included: a) Fourier transforms infrared spectroscopy (FT-IR); b) Differential scanning calorimetry; and c) pharmacokinetic modeling (DSC)

a) Fourier transforms infrared spectroscopy (FT-IR)

The FT-IR spectra of the drug and other recipients were collected and analyzed using a Shimadzu FT-IR 8400 spectrophotometer to verify the stability (compatibility) of the drug in the formulation. The current investigation made use of the potassium bromide pellet technique. Dry potassium bromide crystal powder was extensively incorporated into the samples. In order to create a disc, the mixture was compacted. The spectrum from 4000/cm to 750/cm was recorded when the disc was put in the spectrophotometer.

ISSN 2347-2251 www.iajpb.com
Vol. 20, Issuse 4, 0ct 2022

Indo-American Journal of Pharma and Bio Sciences

b) Differential scanning calorimetric (DSC)

Using a Shimadzu crimper, we crimped the lids of aluminum pans containing 1-3 mg of medication and recipient samples. As a control, we utilized a similar but empty pan with the same kind of seal used on the sample. Nitrogen was used as the purging gas, and the thermal behavior of the samples was studied by exposing them to temperatures between 100 and 300 degrees Celsius and scanning the temperature range at a rate of 10 degrees Celsius per minute.

FORMULATION OF TABLETS

DIRECT COMPRESSION METHOD

Direct compression was used in the making of the instant release pills. Before combining, both the medicine and the patients were carefully measured and weighed, and then sieved using No. 40 mesh. Beneficiaries and the drug were blended together in a glass mortar and pestle for around 10 minutes. After that, we threw in some giants and lubricants. Everything that was used may be compressed immediately. We used a Karnavathi-rotary tablet compression machine to compact the homogenous mixture into tablets. Table 3 displays the results of the various formulation attempts.

Table 2.3: Formulation of Immediate release tablets for Itraconazole

Ingredients	Formulations												
	F-1	F-2	F-3	F-4	F-5	F-6	F-7	F-8	F-9	F-10	F-11	F-12	F-13
Itraconazole	100	100	100	100	100	100	100	100	100	100	100	100	100
Mannitol	75.2	72.7	70.2	75.2	72.7	70.2	75.2	72.7	70.2	75.2	72.7	70.2	80.2
Avicel PH 102	18	18	18	18	18	18	18	18	18	18	18	18	18
Sodium starch glycolate	5	7.5	10	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----
Chitosan silicate conjugate	-----	-----	-----	5	7.5	10	-----	-----	-----	-----	-----	-----	-----
Chitosan thioglycolic acid conjugate	-----	-----	-----	-----	-----	-----	5	7.5	10	-----	-----	-----	-----
Starch (Pregelatinized)	-----	-----	-----	-----	-----	-----	-----	-----	-----	5	7.5	10	-----
Aerosil	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Magnesium stearate	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Total (mg)	200	200	200	200	200	200	200	200	200	200	200	200	200

RESULTS AND DISCUSSION

ANALYTICAL METHODS FOR THE DETERMINATION OF ITRACONAZOLE

Determination of λmax
Sample: Itraconazole
Concentration: 10 µg/ml
Solvent: 0.1 N HCl
Highest peak: 223 nm
λma : 223 nm

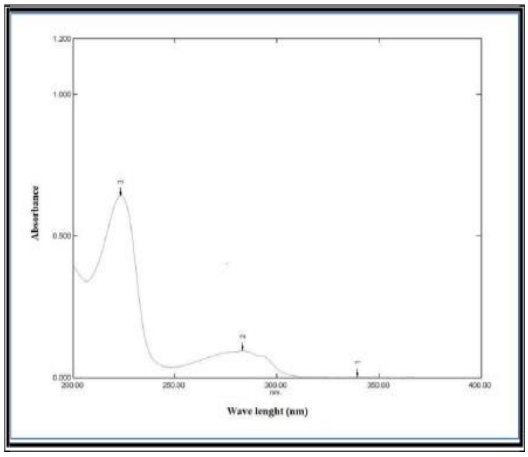


Figure : UV spectra of Itraconazole.

Shimadzu UV 1800 U.V/Visible Spectrophotometer was used to scan a solution of 10 g/ml Itraconazole in 0.1 N HCl from 200 nm to 400 nm. There was a consistent maximum absorbance at 223 nm for this medication.

Standard calibration curve of Itraconazole by RP-HPLC

As shown in figure, a calibration curve was generated using the mean peak areas of various concentrations of Itraconazole in working standard solutions, and the results are shown in table 3.1.

Table 3.1: RP-HPLC data of Itraconazole.

S.NO	Concentration (µg/ml)	Mean peak area± S.D*
1	0.0	0
2	1.0	49644±172.30
3	1.5	65619±177.58
4	2.0	77189±238.78
5	2.5	94972±70.50
6	3.0	122630±108.09
7	3.5	142162±347.06
8	4.0	157146±412.08
9	4.5	169195±319.01
10	5.0	193795±265.68

*S. D = Standard Deviation, n = 3

ISSN 2347-2251 www.iajpb.com
Vol. 20, Issuse 4, 0ct 2022

Indo-American Journal of Pharma and Bio Sciences

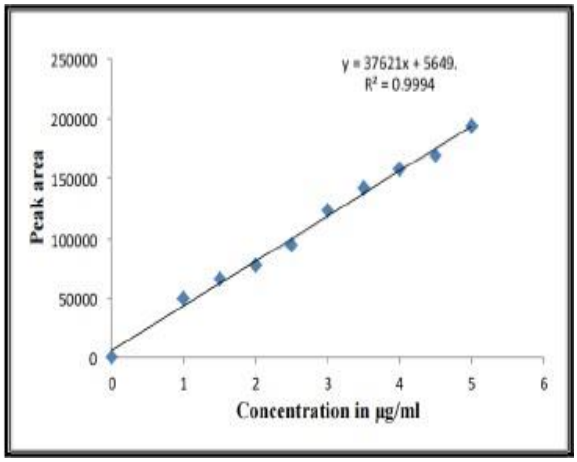


Figure: Standard calibration curve of Itraconazole by RP-HPLC.

Reverse phase high performance liquid chromatography was used to analyze solutions of itraconazole diluted with the mobile phase (formic acid-0.1% and methanol in the ratio 60:40), with the absorbance measured at 223 nm. The retention time and theoretical plate number were found to be within acceptable ranges. After plotting the calibration curve, a linear relationship was discovered to exist, with a regression coefficient of 0.9994 and a slope of 37621.

CHARACTERIZATION OF THE SYNTHESIZED CHITOSAN CONJUGATES

a) Charring point

Charring points were determined to be 242°C - 244°C for chitosan, 132°C - 136°C for chitosan silicon conjugates, and 201°C - 218°C for chitosan thioglycolic acid conjugates.

b) Viscosity
c) FT-IR analysis
d) DSC analysis

PRE-FORMULATION PARAMETERS

Drug-Excipients compatibility study
a) FT-IR analysis
b) DSC analysis

EVALUATION OF IMMEDIATE RELEASE TABLETS

PRE-COMPRESSION PARAMETERS

The drug and excipient blend were evaluated for pre compression parameters like bulk density, tapped density, angle of repose, Hausner's ratio and Carr's index. The studies revealed that the powder mixture had good flow properties and compressibility which are desirable for further processing into tablets.

POST COMPRESSION PARAMETERS

Prepared tablets were evaluated for thickness, diameter, hardness, friability and weight variation and was found that all the tablets had uniform thickness and diameter with acceptable differences, friability of less than 1% and weight variation was carried out and the results were found to be within the limits. Assay values of respective formulations were uniform with acceptable deviations when analyzed by reversed phase high performance liquid chromatography.

In-vitro dissolution time for formulations and marketed product

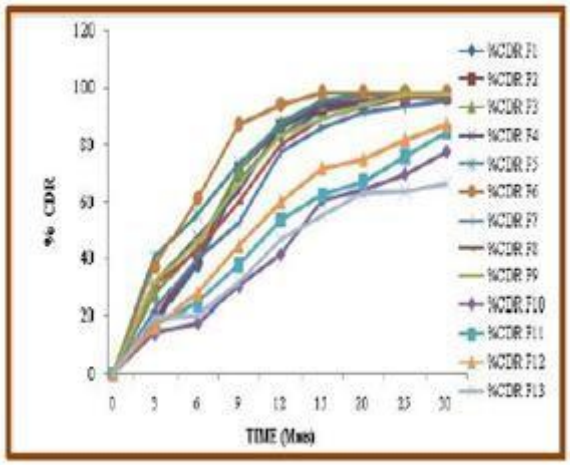


Figure 3.20: Comparison of In vitro % CDR of all formulations.

The time required for the manufactured tablets to dissolve in vitro was measured. It has been shown that CSC tablets disintegrate faster than those manufactured from SSG, CTC, or starch. Tablets formulated with CSC as a super disintegrate were shown to have shorter disintegration periods when

ISSN 2347-2251 www.iajpb.com
Vol. 20, Issuse 4, 0ct 2022
Indo-American Journal of Pharma and Bio Sciences

higher quantities of CSC were used. The

ISSN 2347-2251 www.iajpb.com
Vol. 20, Issuse 4, 0ct 2022
Indo-American Journal of Pharma and Bio Sciences

manufacturing process for the CTC tablet made its dissolution time longer than that of the CSC tablet. In comparison to CSC-produced tablets, those prepared with other super disintegrates (such as SSG) took longer to dissolve. Since CSC has a lower viscosity than SSG and CTC, its dissolution time is much shorter.

STABILITY STUDIES

Stability studies for formulation F-6 were performed and showed no significant differences in their appearance, disintegration time and drug release on dissolution and hence was to be stable after 60 days of storage.

SUMMARY AND CONCLUSION

This study aimed to provide a protocol for the synthesis, characterization, and assessment of chitosan conjugates for use as super disintegrants. The conjugation was described using the charring point and the viscosity. Combining data from Fourier transform infrared spectroscopy and differential scanning calorimetry, it was proven that conjugation fits the aforementioned physical conditions. Sharp peaks in Fourier transform infrared spectroscopy and endothermic peaks in differential scanning calorimetry confirmed the formation of conjugates. The safety of the medicine and the individual patients was checked using techniques including differential scanning calorimetry and Fourier transform infrared spectroscopy. Their compatibility was supported by the facts, thus it appeared like they were a solid fit. The compressibility and flow characteristics of the drug excipient mix were evaluated in advance of compression, and they were found to be satisfactory. Afterwards, we made immediate release tablets out of the synthesized conjugates to see how well they worked as super disintegrants, and we compared their super disintegration capabilities to those of commercially available super disintegrants. Super disintegrates like sodium starch glycol ate are readily accessible for purchase and use in this scenario. We were happy with the results of our tests on tablets manufactured with different quantities of chitosan silicate conjugate, chitosan thioglycolic acid conjugate, sodium starch glycolate, starch, and without super disintegrate.

Among all formulation F-6 showed the least disintegration time. The in vitro dissolution studies also suggested that from F-6 maximum drug was released within 30min due to super disintegrating property of chitosan silicate conjugate. The release mechanism followed first order, non-Fickian and

ISSN 2347-2251 www.iajpb.com
Vol. 20, Issuse 4, 0ct 2022
Indo-American Journal of Pharma and Bio Sciences

diffusion-controlled release. F-6 was subjected to stability studies and was found to be stable with respect to its appearance, invitro dissolution and disintegration time.

The present research study concluded that the synthesized CSC has better duper disintegrating property than SSG and CTC, hence used as super disintegrant in the preparation of immediate release tablets to achieve rapid onset of action.

REFERENCES

1. Ahmed JA et al.., a review on immediate release dosage form. International Journal of Pharmacy and Pharmaceutical Research 2015; 2(3): 1-17.
2. Bookish B, Malakar A. Formulation and evaluation of allylestrenol immediate release tablets. International Journal of Pharmaceutical Sciences and Research 2012; 3(6): 1679-1683.
3. Brahmbhatt H, Patel K, Makwana P, Chauhan N, Jain H et al.., Formulation and evaluation of sublingual tablet for Itraconazole. Journal of Drug Delivery and Therapeutics 2014; 4(4): 19-23.
4. Bonthagarala B, Nama S, Kothamasu S, Badamuddala M, Donthiboina S. Formulation and evaluation of sumatriptan succinate floating bilayered tablets. Discovery 2014; 17(49): 23-25.
5. B.K Satheesh babu. Synthesis and characterisation of chitosan conjugates; Design and evaluation of membrane moderated type drug delivery system. Indian journal of pharmacy 2019;4 (2)
6. Charde M, Jayani S, Pandey D, Chakole RD. Formulation and evaluation of immediate release tablets of metformin hydrochloride on laboratory scale. International Journal of Advances in Pharmaceutical Analysis 2011; 1(2): 45- 47.
7. Challa BR, Awen BZS, Chandu BR, Shaik RP. Method development and validation for Itraconazole determination in human plasma by HPLC with tandem mass spectrometry detection and its application to bioequivalence study. Brazilian Journal of Pharmaceutical Sciences 2011; 47(1): 14-22.
8. Dash S, Murthy PN, Nath L, Chowdhury P. Kinetic modelling on drug release from controlled drug delivery systems. Acta Polonies Pharmaceutica – Drug Research 2010; 67(3): 217-223.
9. Deshmkh H, Chandrashekhara S, Nagesh C, Murade A, Usgaunkar S. Super disintegrants: A recent investigation andcurrent approach. Asian Journal of Pharmacy and Technology2012; 2(1): 19-10. El-barghouthi M, Rashid AEI, Al-Ramawi,Badwan A. A novel super disintegrating agent made fromphysically modified chitosan with silicon dioxide. Drug Development and Industrial Pharmacy 2008; 34:373-383
11.http://www.merckmanuals.com/professional/clinicalpharmacology/pharmacok inetics/drug-absorption.
12.https://www.drugs.commonographItricoanzolehydrochloride.html
13.https://www.cdc.gov/fungal/diseases/blastomycosis/definition. html
14.https://www.cdc.gov/fungal/diseases/aspergillosis/index.html
15.https://en.wikipedia.orgwikiReversed-phase_chromatography