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Solubility Enhancement of Luliconazole by Solid Dispersion

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Abstract: *Solubility is important parameter for a drug which affects absorption of drug and bioavailability which leads to alter the therapeutic effectiveness. It plays vital role in dissolution process. Most of drugs are practically insoluble in water. Water is the choice of solvent in pharmaceutical industry. The drug should be soluble in GIT for absorption. Therefore various techniques are used to enhance the solubilty of drug. In this study solubility of drug luliconazole in water enhance by using polymer PVP K-30. This technique has shown improvement in solubility of drug. The polymer PVP K-30 is used to improve the solubility of drug. The drug and polymer is used in ratio 1:2 w/w. The best release was 30% in 60 min as compared to pure drug 1% in 60 min.*

Keywords: Luliconazole, PVP K-30, solubility, solid dispersion, UV spectroscopy, FTIR, XRD, DSC

I. INTRODUCTION

Solubility is the property of a chemical compound, referred to as a solute, to dissolve in a solid, liquid, or gaseous solvent and produce a homogenous solution of the solute in the solvent. The solvent is often a liquid, which could be a single substance or a mixture of two liquids. It is rare to discuss a solution that is in a gas; solid solutions are more typical. From being entirely miscible (infinitely soluble), like ethanol in water, to being only marginally soluble, like silver chloride in water, the degree of solubility varies significantly. Chemicals that are just very slightly soluble are commonly referred to as being insoluble.

A saturated solution is one in which the solvent and the solute are in an equilibrium state.Molarity, molality, parts, %, volume fraction, and mole fraction are some of the ways it can be portrayed. It is the quantitative measure of the amount of dissolved solute in a saturated solution at a particular temperature. In terms of quality, it refers to transparent, uniform molecular dispersion, which is the result of two or more compounds continuously interacting to produce one phase

The simultaneous and antagonistic processes of dissolving and phase joining (such as the precipitation of solids) lead to solubility, which happens when a system is in dynamic equilibrium. In the case of an immediate release agent, solubility is determined by the highest dose strength. When a medication dissolves in 250 mL or less of aqueous solutions with a pH range of 1 to 7.5, it is said to be very soluble. The estimated volume of 250 mL comes from normal bioequivalence testing methods, which call for giving a medicinal product to fasting human volunteers with a glass of water. All medications have been separated into four categories: class 1, high soluble and high permeable; class II, low soluble and high permeable; class III, low soluble and high permeable; and class IV, low soluble.

In order to complete a movement and achieve the desired pharmacological reaction, solubility is crucial. Drug solubility also serves:

- To improve bioavailability
- Reduce target specificity
- Low bioavailability in animal studies
- Compounds precipitating during serial dilution in buffer, biochemical assays, functional assays, and cell-base assays are some potential complications that could arise from low aqueous solubility

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II. IMPORTANCE OF SOLUBILITY

Due to its ease of administration, high patient compliance, cost-effectiveness, lack of sterility restrictions, and flexibility in the creation of dosage forms, oral ingestion is the most practical and frequently used method of drug delivery. Because of this, many generic medication manufacturers are more likely to create bioequivalent oral drug formulations.

The poor bioavailability of oral dose forms, however, presents the biggest design problem. Aqueous solubility, drug permeability, dissolving rate, first-pass metabolism, presystemic metabolism, and sensitivity to efflux mechanisms are some of the variables that affect oral bioavailability. Poor solubility and inadequate permeability are the two most common causes of low oral bioavailability.

Other dosage forms, such as parenteral formulations, also heavily rely on solubility. One of the key factors in reaching the desired drug concentration in the systemic circulation and the necessary pharmacological response is solubility. When taken orally, poorly water soluble medications may need high dosages to attain therapeutic plasma concentrations. The main issue in developing formulations for new chemical entities as well as generics is low water solubility.

III. SOLID DISPERSION

In order to hasten the oral absorption and disintegration of medications with low water solubility. "Sekiguchi and Obi" developed solid dispersions in 1961. In order to improve a drug's ability to dissolve and form solid solution (molecular level mixing) or eutectic (non-molecular level mixing) products, the drug is combined with a solid hydrophilic matrix that is highly soluble.

A collection of solid products with at least two separate components, often a hydrophilic matrix and a hydrophobic medication, are referred to as solid dispersion. Either the matrix is crystalline or amorphous. The medication can be spread molecularly, in crystalline or amorphous particles (clusters)

Application of solid dispersion:

1) To provide a uniform dispersion of a small amount of medication in solid form.
2) To make the medication more stable.
3) To dispense solid dosages of liquid (up to 10%) or gaseous substances.
4) To create a sustained released dosage form for a fast release main dose.
5) To lessen the pre-systemic inactivation of medicines like progesterone and morphine
6) To create a prolonged release regimen employing poorly soluble or insoluble carriers for soluble medicines..

Advantages:

1.Drug particle size is reduced when a new carrier is used in solid dispersion, which enhances the drug's solubility and bioavailability.
2. Enhance particle wettability: Solid dispersion enhances particle wettability.
3. Increased porosity: Compared to solid dispersions containing reticular polymers, thosecontaining linear polymers form larger, more porous particles, which increases the rate of dissolution
4. Enhance dissolution, which enhances solubility and bioavailability in the end.

Disadvantages:

1. Difficult to incorporate in dosage form formulation.
2. The presence of moisture causes instability.

4. Solubility Enhancement

1.Oraganoleptic properties:

Drugs was tested for organoleptic properties such as appearance, colour, odour, taste, etc.

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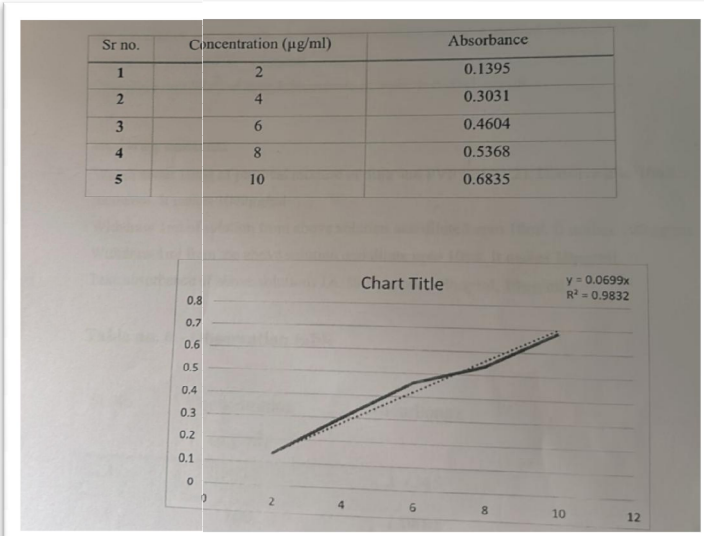
1. Preformulation Study:

Calibration of Luliconazole:

Sr no.	Concentration (µg/ml)	Absorbance
1	2	0.1395
2	4	0.3031
3	6	0.4604
4	8	0.5368
5	10	0.6835



Saturation solubility of Drug Luliconazole :

1. Add appropriate drug into 5ml distilled water drug is added till the solution gets turbid.
2. Stir for 1 hour and then filter.
3. Then take the absorbance of filtrate.

Absorbance of filtrate is 0.2870

Add this value into linear equation Y=mx+c

Where, m slope

C-intercept

By calculation and taking mi.e. slope from calibration curve method which is 0.069 Value was obtained Y = 4.1mu*g / m * l

Therefore Solubility of drug luliconazole in water is 0.0041 mg/ml.

Drug Content :

Weigh about 10mg of physical mixture of drug and PVP K30 (1:2). Dissolve into 10ml methanol. It makes 1000mu*g / m * l

Withdraw Iml of solution above solution and diluted upto 10ml. It makes 100mu*g / m * L Withdraw Iml from the above solution and dilute upto 10ml. It makes 10mu*g / m * L

Take absorbance of above solutions i.e. 1000mu*g / m * l 100mu*g / m * l 10mu*g / m * l4.1.

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Sr No.	Concentration (µg/ml)	Absorbance
1	1000	3.7245
2	100	1.0885
3	10	0.0266

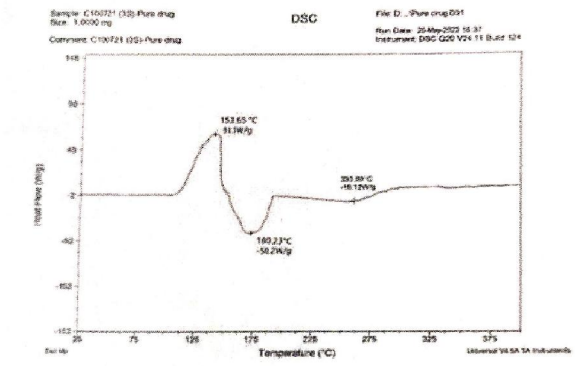
Drug content= 0.0038mg

Dissolution :

The dissolution of drug luliconazole and PVP K 30 is done by using paddle dissolution apparatus. Physical mixture of drug and PVP K 30 is mixed in the 90ml water. Temperature is maintained at 37.5°C. The paddle is rotated at 100 rpm. Then the sample is withdrawn after 5 min and the absorbance is taken. Similarly 5ml of sample is withdrawn after 15, 30 and 45 min respectively at the same time 5ml of water is added. The absorbance of sampe is taken at 299nm.

Diffrential scanning colourimetry (DSC) :

The melting point of pure Luliconazole is 152°C. The thermograms of the pure drugs characteristic, sharp exothermic peak at 153.65°C, for pure drug, sharp endothermic peaks at 180.230C for pure drug (Luliconazole). This conclude that the peaks are associated with the melting point of the drug and indicates the amorphous nature of the drug. The DSC thermogram of pure Drugs as shown in figure 9.



The melting point of pure Luliconazole is 1520C and melting point of polymer PVP K. 30 15 150°C. The thermograms of the physical mixture characteristic, sharp exothermic peak at 139.8°C, for physical mixture, sharp endothermic peaks at 146°C for physical mixture (Luliconazole: PEG 6000). This conclude that the peaks are associated with the melting point of the drug and indicates the amorphous nature of the drug. The DSC thermogram of physical mixture as shown in figure 10.

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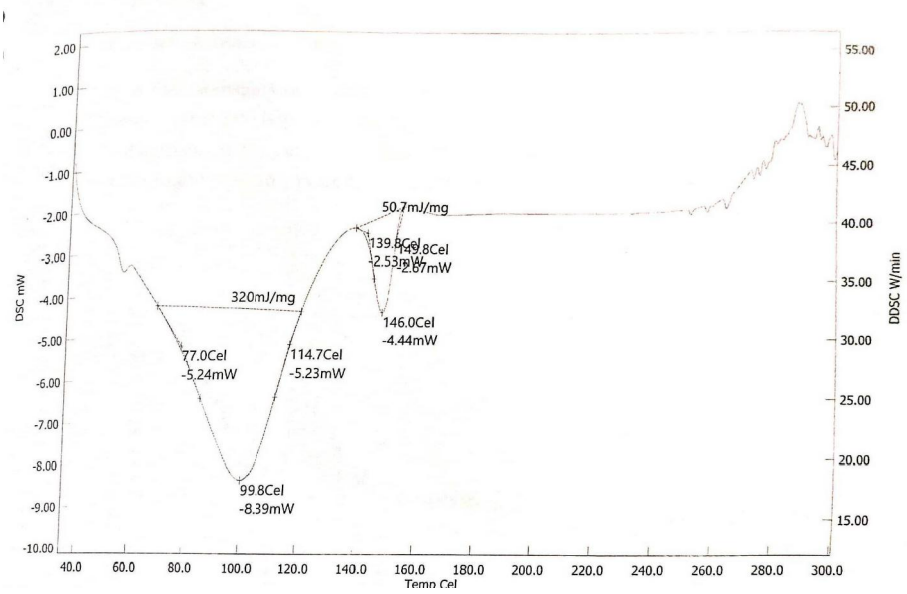
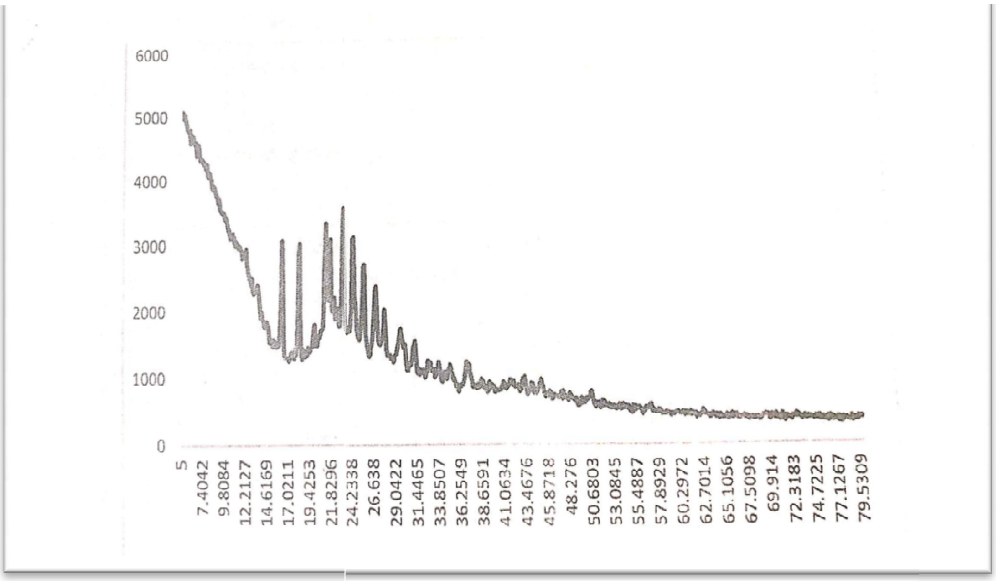


X ray Diffraction (XRD):

Xray diffraction studies where conducted to determine the stabilizer influence on existing luliconazole state and analyse potential changes in crystalline state after drug formulation as solid dispersion (fig 11). Luliconazole shows characteristics peak at 2 theta 11.2109, 11.3111, 16.3199, 16.4201, 16.5202, 18.2232, 18.2232, 18.3234, 21.4289, 21.9297, 23.3322,



IV. CONCLUSION

Luliconazole is a topical antifungal drug with lower bioavailability problem due to its poor aqueous solubility, improving the solubility could increase the dermal bioavailability and thus polymer PVP K 30 was added to enhance the solubility of drug in aqueous medium.

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Evaluations were done to observe the solubility of drug after addition of PVP K. 30. It was observed and therefore concluded that the solubility of drug increase by adding polymer by saturation solubility study of drug and physical mixture..

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