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Physicochemical Properties of Oxaliplatin and Their Impact on Formulation Development

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ABSTRACT

The physical, chemical, and biological characteristics of active pharmaceutical ingredients are revealed by preformulation investigations, which are an essential stage in the drug formulation process. Oxaliplatin, a platinum-based anticancer drug used in colorectal cancer treatment, is the subject of this study preformulation. The main factors assessed are UV spectroscopy, melting point determination, partition coefficient, solubility, infrared spectroscopy, X-RD, and HPLC are examples of preformulation studies for antitumor agents. Oxaliplatin is appropriate for aqueous formulations due to its high water solubility and adequate stability. With a melting point of 200°C, the drug's crystalline nature was discovered by thermal research, indicating its stability under typical storage settings. Fourier-transform infrared spectroscopy compatibility studies showed positive interactions with excipients frequently seen in injectable formulations.

Keywords: *Antineoplastic agent, Preformulation, colon cancer, oxaliplatin, physiochemical properties*

1. INTRODUCTION

Preformulation developed in the end of 1950 and beginning of 1960 shift in accentuation within modern drug item improvement. It was improvement in scientific techniques that prodded the principal programs that may bear the name preformulation [1] It moreover gives guide to detailing improvement Preformulation includes the utilization of bio drug standards to the physic synthetic boundaries of the medication fully intent on planning an ideal medication conveyance framework. Portrayal of the medication particle is the very significant stage at the preformulation period of item improvement. Consequently Preformulation studies are a significant apparatus right on time in the improvement of the two Programming interface and medication items [2] Oxaliplatin showed antitumoral activity against a number of human colon cancer cells in vivo as well as in vitro [3]. tests conducted to evaluate the physical and chemical qualities about the eloxatin too find out their suitability of polymers that be most important to that event about mechanism for delivering drugs are presented in this work. In the solid state, oxaliplatin proved sufficient for standard pharmaceutical manufacturing settings, remaining stable even under light and heat exposure [4].

ANTINEOPLASTIC AGENT (OXALIPLATIN)

Colon cancer can now be treated with the first approved platinum-based anticancer drug. Leading reason for mortality from carcinoma globally, is oxaliplatin [5]. In February 1999, the FDA received an NDA to a first-line therapy in colon cancer. Two multicenter, randomized, controlled clinical trials were included in the NDA. In one trial, 200 Participants were paired at random to get a chronomodulated infusion based on leucovorin and oxaliplatin, after that 5-FU per day for five days [6]. As the standard of cancer treatment, platinum-based chemotherapeutics have been applied extensively in medical facilities [7]. All bodily tissues store oxaliplatin, which is linked to plasma proteins. While just a little portion of the oxaliplatin dose is removed in feces, over 50% of it is excreted in urine by the kidneys [8]. Future trials are assessing the IV injection of Calcimycin (calcium and magnesium salts) both prior the following how oxaliplatin is administered which happened to be beneficial in a retrospective research [9].

let describe some evaluation parameter used in preformulation for antineoplastic agents.

PREFORMULATION PARAMETER

- Organoleptic properties
- UV spectroscopy
- Standard graph
- Melting point
- Solubility
- Partition coefficient
- Infrared spectroscopy
- XRD

2. MATERIAL AND METHOD

MATERIAL

Drug sample was purchased from YARROW CHEM PRODUCTS 215, second floor, Swastik Disha corporato park, opp. Shreyas Talkies, L B S Marg, Ghatkopar(west), Mumbai – 400085.

METHOD

ORGANOLEPTIC PROPERTIES

By the physical observation determine organoleptic properties of antineoplastic agent (oxaliplatin).

UV SPECTROSCOPY

In this process we used UV spectrophotometer, cuvette, volumetric flasks measuring cylinders, beakers. To perform UV spectroscopy first weigh 10 mg of the drug and dissolve it in 10 ml of solution. This solution is called the stock solution, which will have a concentration of 100 µg/ml. From this stock solution, take 1 ml and prepare a standard solution. After that, prepare different dilutions (2µg/ml, 4µg/ml, 6µg/ml, 8µg/ml, 10µg/ml) of this standard solution. These standard solutions are used to generate a calibration curve.

STANDARD GRAPH

In UV spectroscopy, a calibration plot used for measuring an unknown sample's concentration is called a standard graph**.** Whatever dilution we have made, we have to place it in a cuvette and run in the UV spectrophotometer. The standard graph is then plotted with absorbance on y- axis and x- axis. The standard graph should be a straight line.

MELTING POINT

The Thiele tube method is a technique used to determine the melting point of a substance. In this process, a Thiele tube, a capillary tube (containing the sample), a thermometer, and a heating medium (oil) are used. First, the sample is ground into a fine powder and filled into a capillary tube, which is then attached to the thermometer. After filling the Thiele tube with oil, its side arm is heated to create convection currents for uniform heating. The temperature is gradually increased, and the points at which the sample begins to melt and completely melts are recorded. To ensure more accurate results, the process is repeated, and the average melting point is determined.

SOLUBILITY

To perform a solubility test in the seven solvents - water, ethanol, chloroform, benzene, acetone, polyethylene glycol and methanol begin by preparing small beakers, each containing about 10 mL of one solvent. Weigh 1-2 grams of the substance to be tested and add it to each solvent. Stir the mixtures gently using a stirring rod for uniformity. Observe whether the substance dissolves completely, partially, or not at all in each solvent. Record your observations, noting whether the solution is completely soluble, partially soluble, or insoluble.

PARTITION COEFFICIENT \ (p)

Partition coefficient (p) is calculated using the shaking flask technique, which represents the distribution of a compound between two immiscible phases. In this method, we take 25 mL of the organic phase (chloroform) and 25 mL of the aqueous phase (distilled water). These two phases are placed in a separating funnel, and 10 mg of the drug is added to the mixture. The mixture is then shaken for 30 minutes using a mechanical stirrer to allow the drug to distribute between the two phases. After shaking, the mixture is left to reach equilibrium, during which the drug distributes itself between the phases. Once the phases are separated, the drug concentration in both phases is measured using UV spectroscopy.

INFRARED SPECTROSCOPY

The method of IR spectroscopy begins with sample preparation, where the sample is finely ground and mixed with potassium bromide to form a transparent pellet. This pellet is then placed in the IR spectrometer, and infrared radiation is passed through it. The sample absorbs specific wavelengths of the radiation due to molecular vibrations, and the remaining radiation is measured by a detector, producing an IR spectrum. The spectrum is analyzed to identify the functional groups and chemical structure of the solid sample based on the characteristic absorption bands.

XRD

XRD involves grinding the sample into a fine powder, placing it on a flat holder, and setting up the instrument with a selected scan range, step size, and speed. The sample is scanned to collect a diffraction pattern, which is analyzed using software to identify peaks and match them to a database for crystallographic information. Finally, the sample holder is cleaned, and the instrument is turned off, completing the process quickly and efficiently.

RESULT AND DISCUSSION

Organoleptic properties

Figure 1. and **Table 1.** Helps to explain the physical appearance of oxaliplatin

Table No.1: organoleptic properties of oxaliplatin

S.NO.	Physical property	Result	Conventional
1.	Physical form	Snowy to Pale yellow Powder	White to Pale yellow Powder
2.	Odor	Odorless	Odorless
3.	Taste	-	Bitter, Metallic
4.	Color	White to pale yellow	White to pale yellow

Figure 1. oxaliplatin drug

UV spectroscopy

Model – UV 1900i, made by SHIMADZU

The lambda max of the oxaliplatin was found to be 322nm. The Calibration curve of oxaliplatin are shown in Figure . 2

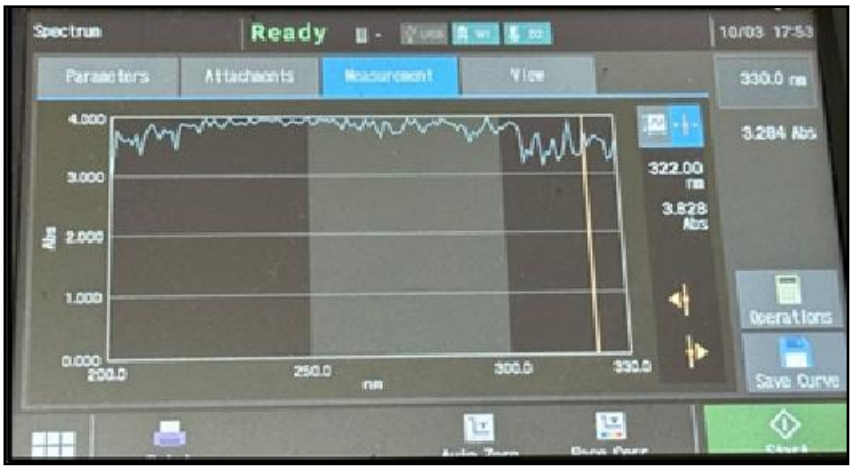


Figure 2. calibration curve of oxaliplatin

STANDARD GRAPH

The lambda max of the oxaliplatin was found to be 322nm. Following lambda max determination, the calibration curve and absorption will be assessed using UV spectroscopy. The absorption and concentration data were provided below in the **Table 2.** And Standard graph of oxalilatin are shown in **Figure 3**

Table 2. ultraviolet spectroscopy absorption and concentration of oxaliplatin

S.NO.	CONCENTRATION (µg/ml)	ABSORPTION
1	2	0.053
2	4	0.155
3	6	0.225
4	8	0.296
5	10	0.382

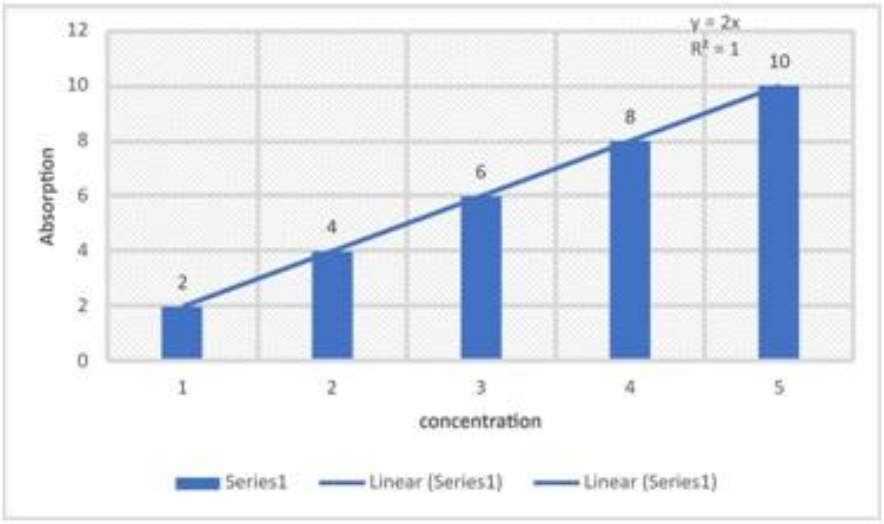


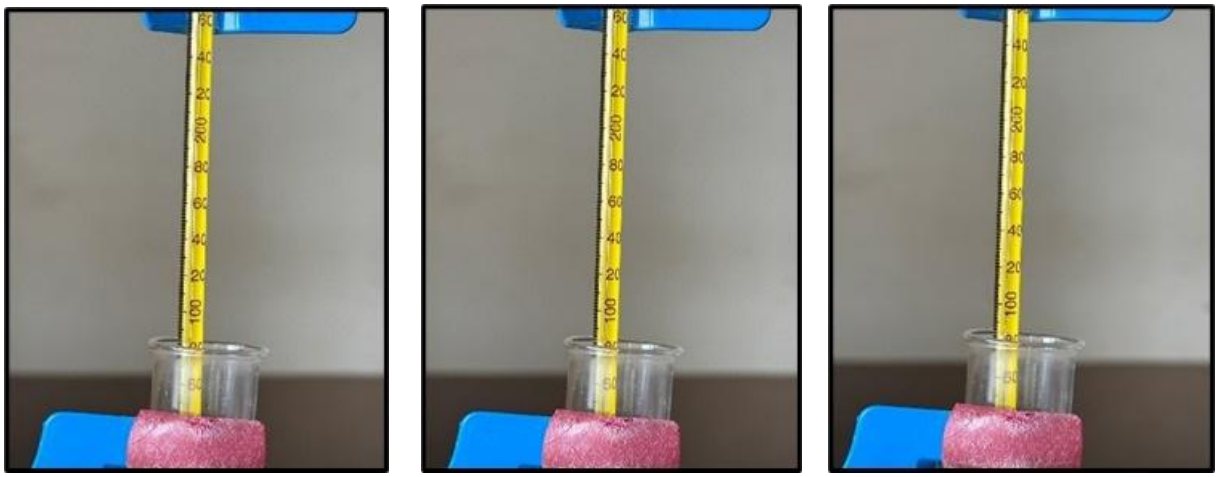
Figure 3. standard graph of oxaliplatin

MELTING POINT

The melting point of oxaliplatin results were tabulated in **Table 3.** And shown in **figure 4.**

Table 3. Melting point of oxaliplatin drug

S. NO.	Parameter	Result
1	Observed melting point ºC	199-200ºC
2	Average Melting point	200ºC



(a) 199ºC **(b) 201ºC** **(c) 200ºC**

Figure 4. Melting of oxaliplatin

SOLUBILITY

The solubility result of oxaliplatin with different solvents are tabulated in **Table 3.** And shown in **figure 5.**

Table 3. solubility result of oxaliplatin with different solvent

Solvents	Solubility	Observation	Remarks
Water	Soluble	Clear solution	Best solvent for IV administration
Ethanol	partially soluble	Partially dissolve	Not ideal due to poor solubility
Chloroform	Insoluble	No visible dissolution	Not compatible (polar and nonpolar)
Acetone	Slightly soluble	Small amt. of drug dissolve	Limited use in formulation
Benzene	Insoluble	No visible dissolution	Incompatible with oxaliplatin

Polyethylene glycol	Soluble	Clear solution	Used to improved solubility of formulation
Methanol	Very slightly Soluble	Slightly cloudy solution	Not ideal due poor solubility

Figure 5. solubility of oxaliplatin

PARTITION COEFFICIENT

Model – UV 1900i, made by SHIMADZU

Table 4. absorption of oxaliplatin in aqueous phase and organic phase

S. No.	Separated phase	UV absorption
1	Aqueous phase	0.558
2	Organic phase	3.613

Figure 6. (A) soluble in water, (B) less soluble in chloroform

INFRARED SPECTROSCOPY

Model – 00524 made by SHIMADZU

The oxaliplatin IR spectra are displayed in **Figure 7.**

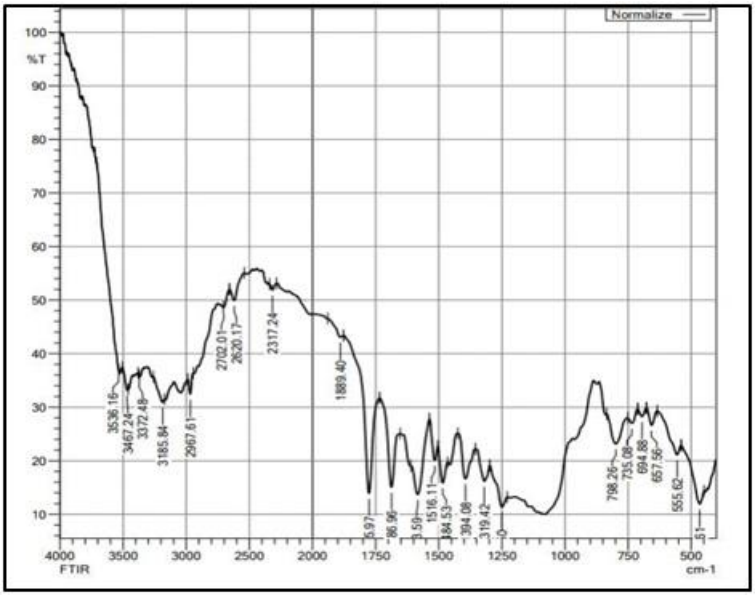


Figure 7. Oxaliplatin infrared spectrum

XRD

Make and Model: Bruker D8 advance A25

Figure 8. show the XRD of oxaliplatin

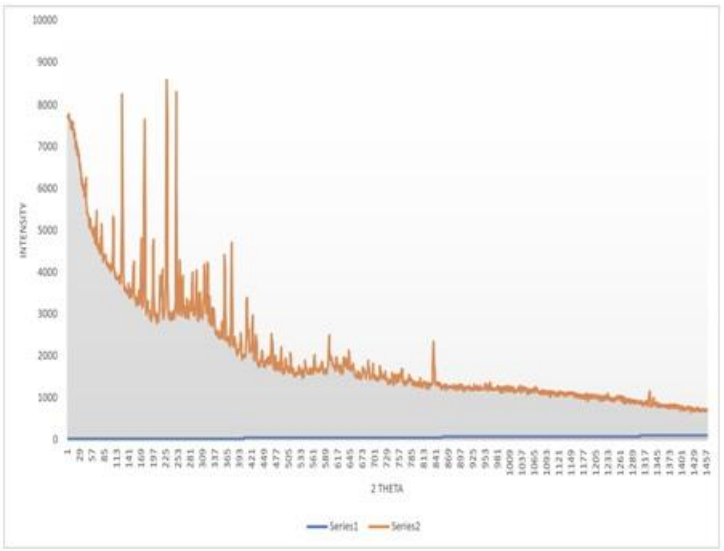


Figure 8. XRD of oxaliplatin

3. CONCLUSION

To create an ideal formulation, preformulation studies of the antineoplastic drug oxaliplatin concentrate on its safety, compatibility with a and physicochemical characteristics. Oxaliplatin is a platinum-based substance that dissolves in water. It requires aware handling as well as storage because it is sensitive to light yet it shows stability in aqueous solutions. Its characteristic appearance, color, and odor were revealed by organoleptic examination, which aided in identification and quality control. A standard crystalline fingerprint was produced by X-ray diffraction analysis, which is crucial for detecting

polymorphism consistency during formulation and storage.

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