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FORMULATION AND EVALUATION OF SUSTAINED RELEASE LEVOFLOXACIN MATRIX TABLET

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ABSTRACT
Matrix tablets are sorts of controlled drug delivery system, which discharge the drug in nonstop way by both c controlled also dispersion-controlled components To control the arrival of the drug. which are having distinctive solvency properties, the drug is scattered in swellable hydrophillic substance. a dissolvable matrix of unbending non swellable hydrophobic material or plastic material, one of the last confounded methodologies two the produce of supported discharge measurements frame include the immediate pressure of mix of drug, retardant material and added substance to define a tablet in which the drug is installed in a matrix of the retardant on the other hand drug and retardant drained might be granulated preceding pressure, the materials most broadly utilized as a part of getting ready matrix systems incorporate both hydrophilic and hydrophobic polymer generally accessible hydrophilic polymers incorporate hydroxypropyl methyl cellulose (HPMC), hydroxypropyl cellulose (HPC) at that point hydroxyehtylcellulose (HEC) at that point thickener sodium alginate polyethylene oxide and crossconnected homopolymers and copolymers of acrylic corrosive. It is usely provided in micronized frames since little molecule estimate is a basic to the fast developmentof coagulated layer on the tablet surface (Jaimini and Kothari.

KEYWORDS: Matrix tablets, dispers, io hydrophilic, HPMC.

INTRODUCTION

Introduction of matrix tablet as managed discharge (SR) have offered another reprieve through for controlled drug delivery system in the field of pharmaceutical innovation it prohibits complex generation technique, for example, covering pelletization amid assembling and drug discharge rate from the measurement frameis controlled masculine by the sorts and extent of polymer utilized as a part of the arrangement hydrophilic polymer matrix generally utilized for planning a SR dose shape .in view of expanded entanglement and cost associated with showcasing of new drug elements .has concentrated on improvement of maintained or controlled discharge drug delivery system.

Types of matrix systems

The matrix system can be classified in to three categories depending on the kind ofretarding agents or polymeric materials.

- Hydrophobic matrix system
- Hydrophilic matrix system
- Fat-wax matrix system

Advantages of matrix tablet

1. Simple to manufacture.
2. The use of sustained release formulations avoids the towering bloodconcentration.
3. Minimized the narrow and systemic side effect.
4. Development in treatment value.
5. Minimized drug accumulation with chronic dosing.
6. Sustained release formulation has the potential to improve the patientcompliance.
7. Decrease the toxicity by slowing drug incorporation.
8. Amplify the stability by protecting the drug form hydrolysis or otherderivative changes in GI.
9. Can be made to release high molecular weight compounds.
10. Use of less total drug

Disadvantages of matrix tablet

- The remaining matrix must be evacuated after the drug has been released.
- High cost of readiness.
- The released rate is influenced by different factors, for example, food and therate travel through the gut.
- The drug release rates fluctuate with the square course of time.

Release rate constantly lessened because of an expansion in diffusional opposition and additionally a reduction in

viable territory at the dispersion front, anyway a significant managed impact can be created using moderate release rate, which in numerous application are indistinct from zero

Polymers used in matrix tablet

Hydrogels

- Polyhydroxyethylemethylacrylate (PHEMA)
- Cross-linked polyvinyl alcohol (PVA)
- Cross linked polyvinyl pyrrolidone (PVP)
- Polyethylene oxide (PEO)
- polyacrylamide (PA)

Soluble polymers

- Polyethylenated (PEG)
- Polyvinyl alcohol (PVA)

Biodegradable polymers

- Polylactic acid (PLA)
- polyglycolic acid (PGA)
- polycaprolactone (PCL)
- Polyanhydrides

Non-biodegradable polymers

- Polyethylene vinyl acetate (PVA)
- polydimethylsiloxane (PDS)
- Polyether urethane (PEU)
- Polyvinyl chloride (PVC)
- Cellulose acetate (CA)
- Ethyl cellulose (EC)

Mechanism of drug release from matrix tablet

Drug in the outside layer presented to the showering arrangement is broken up first and after that diffuse out of the matrix. this procedure proceed with the interface between the washing arrangement and the drug advancing toward the inside. It takes after that for this framework to be dispersion controlled, the rate of disintegration of drug particles inside the matrix must be significantly quicker than the dissemination rate of broke up drug the matrix.

PREFORMULATION STUDY: Preformulation is a phase of research and development process where the new drug substances are characterize for their physical, chemical and mechanical properties in order to develop stable, safe and effective dosage form. Preformulation may include organoleptic properties, melting point, solubility, identification of dug by chemical and spectrophotometric method.

Characterization for physiochemical properties of drug

A) Organoleptic Properties

Organoleptic properties of drug were determined by direct observation of drug sample under optical microscope for its appearance color and crystal morphology.

Table 1: List of Sensory characters.

S. No.	Sensory characters	Result
1.	Colour and Morphology	White crystal
2.	Odor	Odorless
3.	Form	crystalline powder
4.	Taste	Bitter

B) Solubility Study: The drug sample was qualitatively tested for its solubility in various polar, semi polar and non polar solvents**.** Solubility of the drug was determined by taking about 10 mg of drug sample in a test tube containing 2.0 mL of solvent and shaking for 10 min at room temperature and observed for its solubility.

Table 2: Solubility of Levofloxacin.

S. No.	Solvent used	Observation
1	Distilled Water	+++-
2	0.1 N HCl	++++
3	Ethanol	++++
4	Methanol	++++
5	Chloroform	+++-
6	0.1 N NaOH	++++
7	Phosphate Buffer pH 6.8	+++-

C) Melting point

It is one of the parameters to judge the purity of drugs. In case of pure chemicals, melting points are very sharp and constant. Since the drugs contain the mixed chemicals, they are described with certain range of melting point. The melting point was determined by capillary tube method in which small quantity of finely powder drug was placed into a capillary tube (closed at one end) and placed in the melting point determining apparatus (Chemline CL-725) containing silicon oil. The temperature of the castor oil was gradual rise automatically upon increasing the temperature. The temperature was noted down at which powder started to melt and the temperature at which the drug powder was melted completely.

Table 3: Melting point of the Levofloxacin.

S. No.	Melting Point of Standard Drug	Melting Point of Sample Drug	Average Melting Point of Sample Drug
1.		220 ºC -225ºC	
2.	224 ºC	220 ºC -222ºC	220 ºC -225ºC
3.		220 ºC -225ºC	

A) Identification TestFT-IR Spectroscopy

Infra- red spectrum is an important record which gives sufficient information about the structure of a compound. This technique provides a spectrum containing a large number of absorption band from which a wealth of information can be derived about the structure of an organic compound. The region from 0.8 µ to 2.5 µ is called Near Infra-red and that from 15 µ to 200 µ is called Far infra-red region Approx 5 mg of drug was mixed with KBr and prepared their pallet. Pallet was analyse using FT-IR spectrophotometer (Bruker, USA).

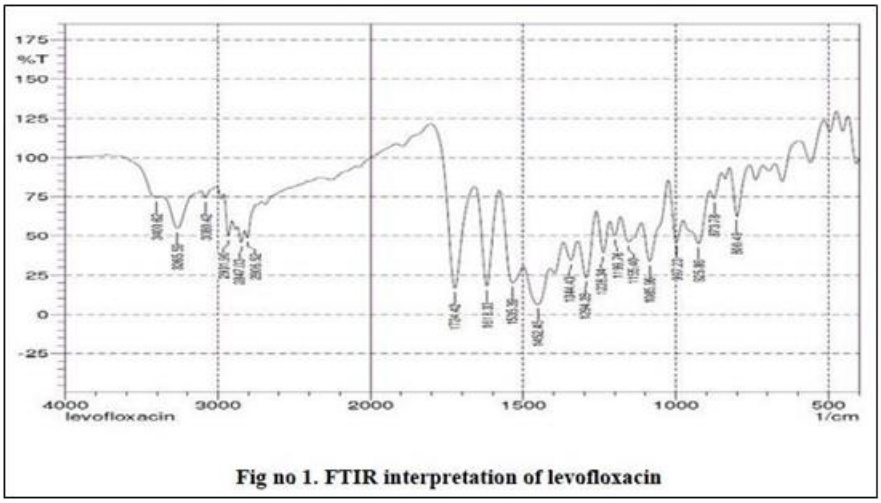

Fig no 1. FTIR interpretation of levofloxacin

Figure 1: FT-IR Spectrum of Levofloxacin (standar).

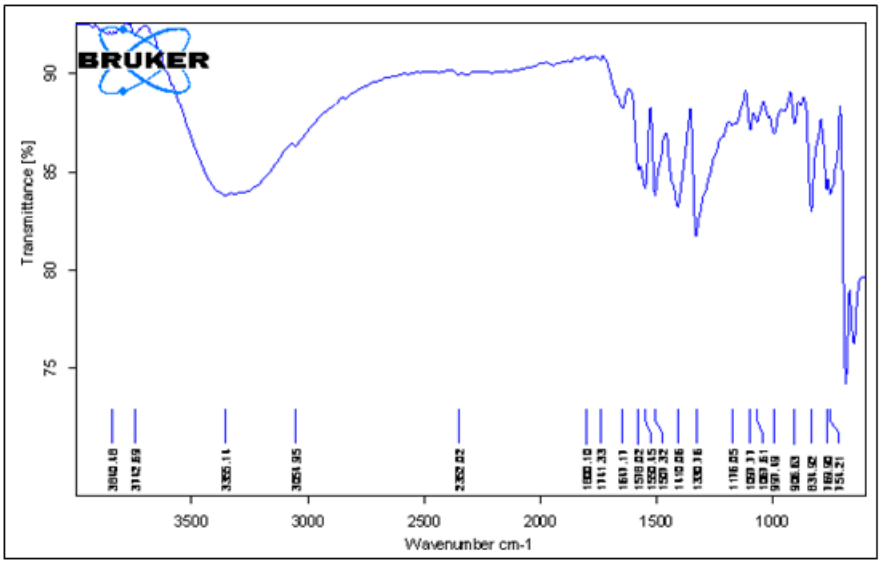

Figure 2: FT-IR Spectrum of Levofloxacin (Sample).

D) Determination of moisture content

Principle: The titrimetric determination of water is based upon the quantitative reaction of water with an anhydrous solution of sulphur dioxide and iodine in the presence of a buffer that reacts with hydrogen ions. In the original titrimetric solution, known as Karl Fisher Reagents, the sulfur dioxide and iodine was dissolved in pyridine and methanol. The test specimen may be titrated with the reagent directly, or the analysis may be carried out by a residual titration procedure. The stoichiometry of the reaction is not exact, and the reproducibility of a determination depends upon such factors as the relative concentration of the reagent ingredients, the nature of the inert solvent used to dissolve the test specimen, and the technique used in the particular determination. Therefore, an empirically standardized technique is used in order to

achieve the desired accuracy. Precision in the method is governed largely by the extent to which atmospheric moisture is excluded from the system.

Table 4: Determination of moisture content.

E) Determination of λ max of Levofloxacin

The λmax of Levofloxacin was determined by analyzing the drug solution in double beam ultraviolet spectrophotometer. Accurately weighed 10 mg of drug was dissolved in 10 ml of 0.1 N HCl solution in 10 ml of volumetric flask. The resulted solution was 1000µg/ml of strength and from this solution 1 ml solution was pipette out and transfer into 10 ml capacity of volumetric flask and volume was made upto 10 mL with 0.1 N HCl solution. This solution was scan at wavelength 400-200 nm on UV spectrophotometer. The higher absorption peak was obtained at 294 nm which was the λmax of drug.

Preparation of calibration curve of Levofloxacin

Previously prepared stock solution (1000 µg/mL of strength) of Levofloxacin was use to prepare suitable dilution into concentration range of 2-10 µg/ml. 0.2, 0.4, 0.6,0.8 and 1.0 mL of solution was taken in different volumetric flask having 10 mL of capacity and dilute upto 10 mL with 0.1 N HCl to obtained 2, 4, 6, 8 and 10 µg/mL of solution. The absorbance of these solutions was taken at 294nm using UV- spectrophotometer (Labindia-3000 Plus). Graph between absorbance and concentration was plotted folloed linearly regressed on Microsoft excel.

Table 5: Calibration curve of Levofloxacin in 0.1 N HCl.

S. No.	Concentration (µg/mL)	Absorbance
1	0	0
2	2	0.137
3	4	0.258
4	6	0.372
5	8	0.479
6	10	0.597

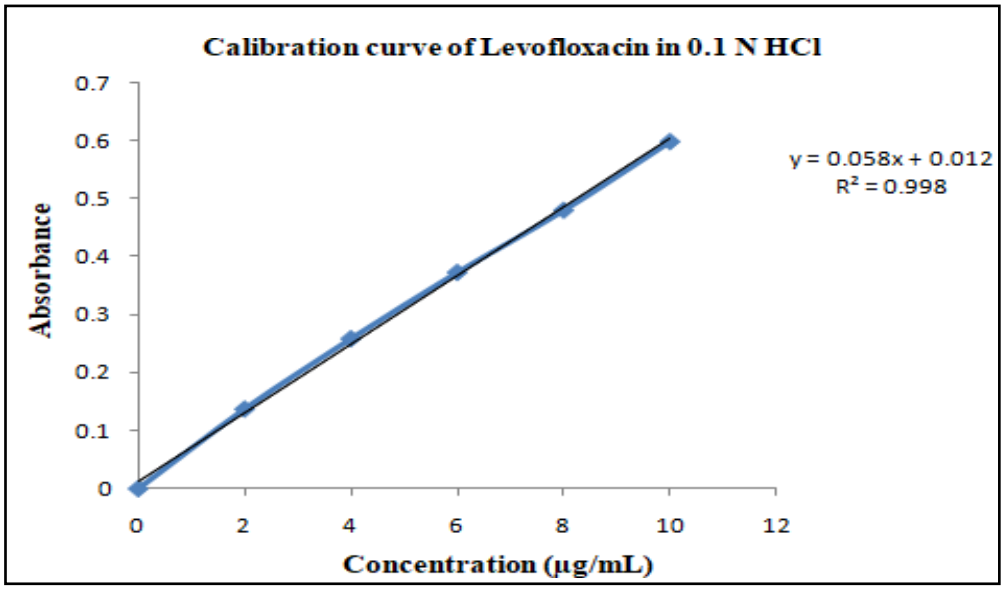

Figure 4: Calibration curve of Levofloxacin in 0.1 N HCl at 294nm.

SUMMARY AND CONCLUSION

Matrix tablets of Levofloxacin using HPMC (K4M, K15M, and K100M) and CMC prepared by direct compression method were found to be good without chipping, capping and sticking. The drug content was uniform in all the formulations of tablets prepared. Low values of standard deviations indicate uniform distribution of drugs within the matrices. The drug polymer ration influenced the release of drug from the formulations. An increase in polymer decreased the drug release. Formulation F4 with drug polymer (HPMC K4 and carbopol) has shown promising results as per USP test I requirements. Swelling restricted matrix tablets of Levofloxacin were prepared using HPMC K and carbopol to achieve desired release rates over a period of 12 hours, which can help to reduce the dose and its frequency.

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