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FORMULATION AND EVALUATION OF OFLOXACIN DENTAL FILMS

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ABSTRACT

In this study dental films were formulated with ofloxacin which are used in treatment of periodontits. Hydroxy Propyl Methyl Cellulose (HPMC) of grade k100 is used as a polymer. Polyvinyl alcohol is used as an excipient. Ofloxacin dental films are formulated by solvent casting method. Various evaluation tests like weight variation, moisture content, thickness, folding endurance, drug content and in-vitro drug release were performed for formulations. Formulation F2 shows good release of 97.2%. The dental films are kept in intrapocket region that is region between tooth and gum where the infection is at peak levels. The release of drug reduces the inflammation, pain due to infection.

KEYWORDS

Ofloxaci, Hydroxy Propyl Methyl Cellulose, Inflammation and Formulation.

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INTRODUCTION[1]

In this research paper, dental films are formulated by using ofloxacin as drug for treatment of periodontitis which is an inflammatory response in which the structural support of the tooth is destroyed. In periodontitis, resorption of the alveolar bone, detachment of the ligament supporting the tooth and formation of lesions between teeth and junctional epithelium is observed. The tissues around a tooth that support the tooth are called periodontium which are affected during periodontits. The alveolar bone which acts as a support to the tooth gets progressively lost and the multiplication of microorganisms that grows at the junction of gums

and teeth causes inflammation leading to the loss of teeth and if left untreated leading to chances of stroke and other health problems. Periodontitis arise in sulcus and cervice region between gum and tooth.

In this study, objective is to formulate intrapocket dental films, which could be easily placed into the periodontal pocket, and be capable of delivering therapeutic concentrations of ofloxacin for prolonged period of time at a much lower dose, hence obviating untoward side effects. The pathogens that cause periodontits infection some of them are staphylococcus subspecies responsible for juvenile periodontitis and aureus species responsible for adult periodontitis in Figure No.1[6].

As periodontitis is caused by various species of bacteria and microorganisms, anti-bacterial drugs are used in the treatment of periodontitis. Ofloxacin is used as a drug of choice in formulation of periodontal dental films. Ofloxacin is a broad spectrum antibiotic has bactericidal nature that blocks DNA replication of bacteria by binding to DNA gyrase enzyme. It has more affinity to bacterial DNA gyrase. When dental film is placed in intrapocket, the drug reduces the infection caused by the bacteria and gradually decreases the inflammation [5].

MATERIAL AND METHODS

All materials that used in the project work are used in minimum quantity. Ofloxacin is used as a drug in the formulation. HPMC of K100 grade and PVP is used as polymers in Table No.1 and 2.

Characterization

Drug and excipients are characterized by IR studies. Individual drug and formulations are characterized by IR studies to know the purity and interactions among the excipients and drug.

Standard Curve of Ofloxacin in Phosphate Buffer 6.8pH

10mg of ofloxacin dissolved in 100ml mixture of phosphate buffer to obtain concentrations ranging 2,4,6,8 and 10µg/ml. The absorbance of solution was measured at 293 nm using UV Visible Spectrophotometer. The readings obtained are tabulated in table and the graph is obtained in Table No.3, 4 and Figure No.2.

Method of Preparation[2]

Periodontal dental films are prepared by solvent casting method.

- Weighed quantity of HPMC (k100) polymer was taken dissolved thoroughly in sufficient quantity of distilled water.
- After homogeneous mixture obtained add PVA solution (previously dissolved in hot water) mixed using magnetic stirrer.
- Required quantities of drug were weighed and dissolve in small quantity of water and pour into polymer solution mix thoroughly.
- Kept aside for 10 min for saturation of solution of dental film.
- This solution poured into petriplate that was applied lubricant glycerol.
- Keep the petriplate at room temperature to evaporate solvent from the solution.
- The formed dental films are removed from petriplate and kept in desiccators.

RESULTS AND DISCUSSION[3]

Weight variation

10 patches were weighed and they were cut into different pieces. The individual weights were determined by using the electronic balance and the average weight was calculated.

Folding endurance

Folding endurance of the film was determined by repeatedly folding the film at the same place up to 300 times till it broke or folded, which is considered satisfactory to reveal good film properties. This test was carried out on all the films

Moisture content

The percentage moisture loss was carried out to check integrity of the film at dry conditions. Films were weighed and kept in a desiccator containing anhydrous calcium chloride. After 3 days, the films were taken out and reweighed and the percentage moisture loss was calculated using the formula.

% moisture content = initial weight-final weight/initial weight

Thickness of the film

The thickness of each film was measured using screw gauge at different positions of the film and the average thickness was calculated.

Drug content uniformity

Films containing ofloxacin was dissolved in 100 ml of distilled water and kept aside for overnight. Then the solution was filtered with the whatmann filter paper. From the filtrate 5 ml was taken and diluted with distilled water in 100 ml standard flask. The absorbance of the solution was measured at 278 nm using a UV spectrometer.

In vitro drug release[4]

Film of known weight and dimensions were taken separately into small test tubes containing 10 ml of pH 7.4 phosphate buffer. The test tubes were sealed with the aluminum foil and kept at room temperature. The sample was withdrawn and replaced with fresh 1 ml of pH 7.4 for every 1 hour up to 6 hours. The concentration of drug in the buffer was measured at 278 nm by using a UV-spectrophotometer in Table No.5.

IR Spectroscopy

Infra-red spectroscopic study of ofloxacin

In IR analysis, the spectrum of pure ofloxacin showed an intense and well-defined bands characteristic to ofloxacin at 3038 1/cm (=C-H stretching(alkene), 2785 1/cm (O-H stretching(acid), 1708 1/cm (C=O stretching(carbonyl) 1454(C=C stretching (aromatic) 1241(C-N stretching (amine), 1052 (C-O stretching (ether), this IR analysis shows that ofloxacin is pure.

Infra-red spectroscopic study of formulation F1

In IR analysis, the spectrum of pure drug and polymer showed an intense and well-defined bands characteristic to drug and polymer at 2924 1/cm (C-H stretching (alkane), 1708 1/cm (C=O stretching (carbonyl), 1454(C=C stretching (aromatic)), 1049(=C stretching (aromatic), 802 (=C-H bending (alkene), this IR analysis shows that drug and polymer is pure.

Infra-red spectroscopic study of Formulation F2

In IR analysis, the spectrum of F2 showed an intense and well-defined bands characteristic to F2 at 2924 1/cm (C-H stretching (alkanes), 1708 1/cm (C=O stretching (carbonyl) 1454(C-H bending (alkanes) 1049 (C-N stretching (aliphatic amine) 802 (C-C_l stretching (alkyl halide), this IR analysis shows that F2 is pure. Interpretation of IR spectra of F2 in Figure No.3 to 6.

Table No.1: Materials Used For the Study

S.No	MATERIALS	MANUFACTURER
1	OFLOXACIN	HI MEDIA LABORATORY
2	HPMC	HI MEDIA LABORATORY
3	PVA	HI MEDIA LABORATORY
4	GLYCERINE	HI MEDIA LABORATORY

Table No.2: Equipments Used For the Study

S.No	EQUIPMENT	MANUFACTURER	MODEL NO.
1	U.V-visible Spectrophotometer	SHIMADZU	UV-1700
2	Magnetic stirrer	REMI	IMLH

Table No.3: Standard curve of Ofloxacin

S.No	Concentration(µg/ml)	Absorbance
1	0	0.000
2	2	0.300
3	4	0.483
4	6	0.699
5	8	0.839
6	10	1.060

Table No.4: Physiochemical characteristics of Dental films containing Ofloxacin

Formulations	Thickness (mm)	Weight Variation (mg)	Folding endurance	Moisture Content (%)	Drug content
F1	0.21 (±0.01)	2.22 (±0.01)	50.87 (±0.23)	10.23 (±0.13)	93.35 (±0.21)
F2	0.31 (±0.05)	2.12 (±0.05)	113.56 (±0.27)	10.13 (±0.17)	92.17 (±0.36)
F3	0.20 (±0.01)	2.12 (±0.02)	108.75 (±0.26)	10.32 (±0.12)	90.66 (±0.18)
F4	0.14 (±0.01)	2.11 (±0.01)	103.39 (±0.25)	10.51 (±0.14)	95.89 (±0.19)

Table No.5: *In-vitro* drug release

TIME (hrs)	% DRUG RELEASE			
	F1	**F2**	**F3**	**F4**
0	0	0	0	0
1	68.2	54	35.6	50
2	72.5	67.9	65.3	36.2
3	78.7	74.4	73.3	53
4	85.3	86.3	82.6	72.6
5	92.3	97.2	87.2	84

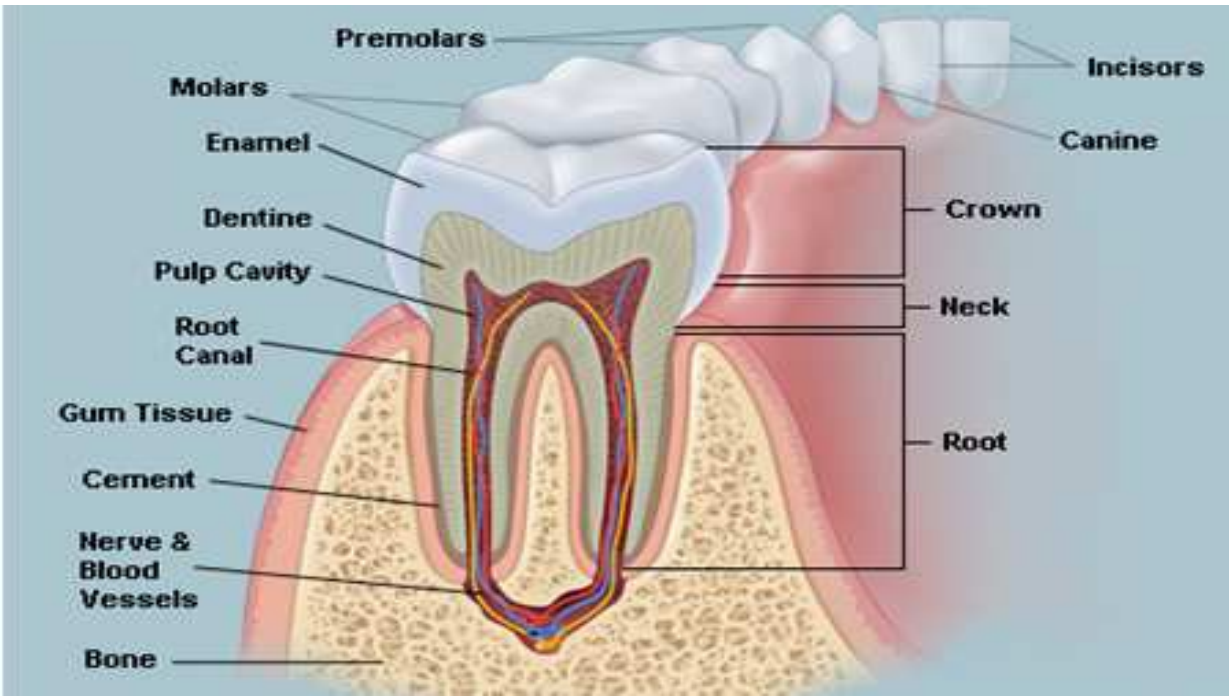

Figure No.1: Parts of teeth

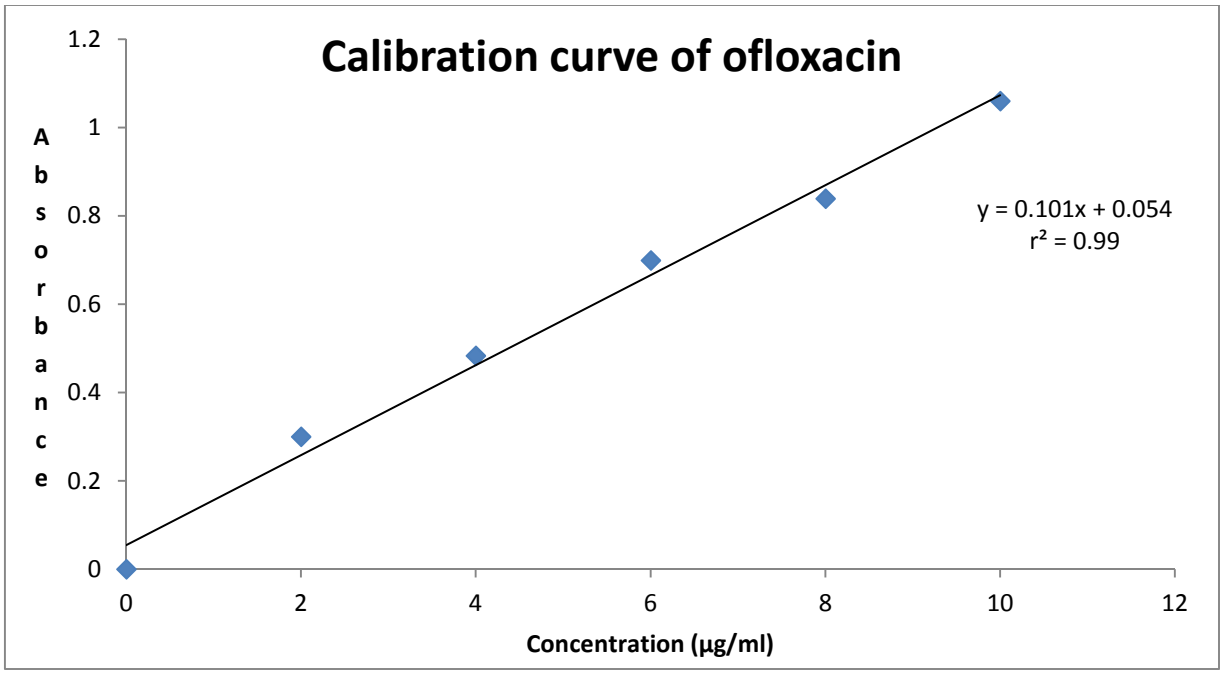

Figure No.2: Standard curve of ofloxacin in phosphate buffer 6.8pH

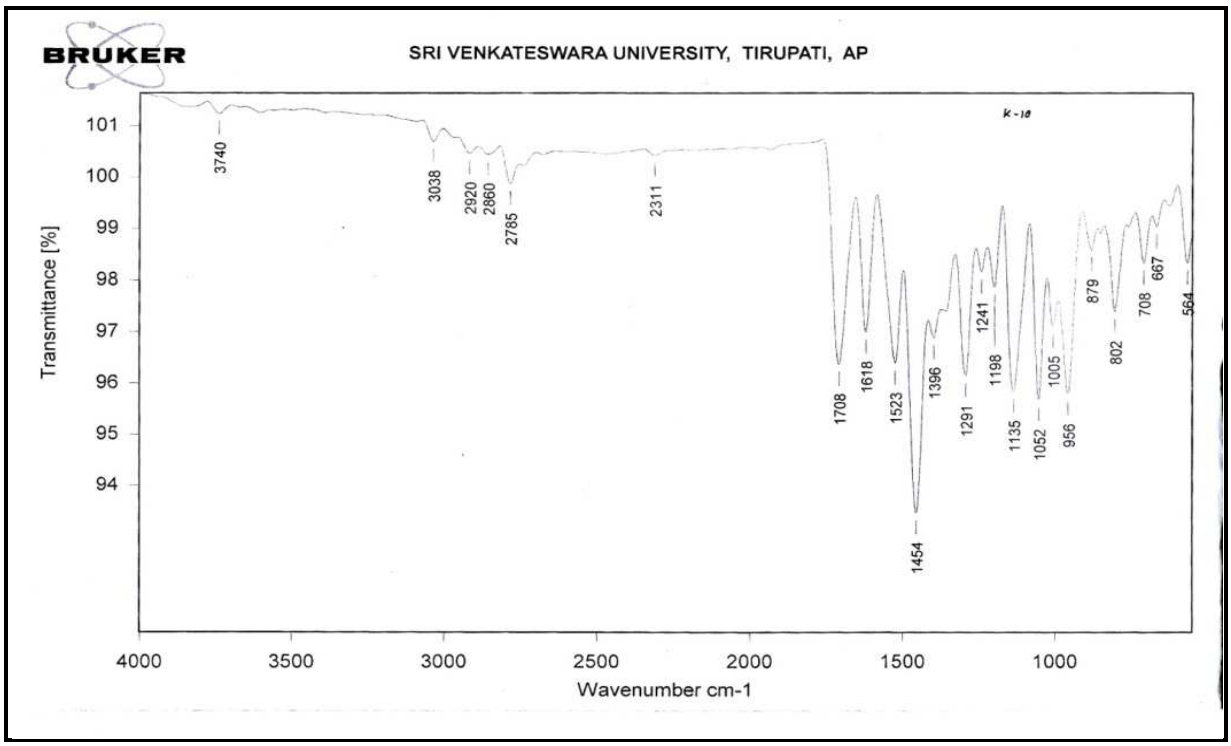

Figure No.3: IR spectroscopy of pure drug Ofloxacin

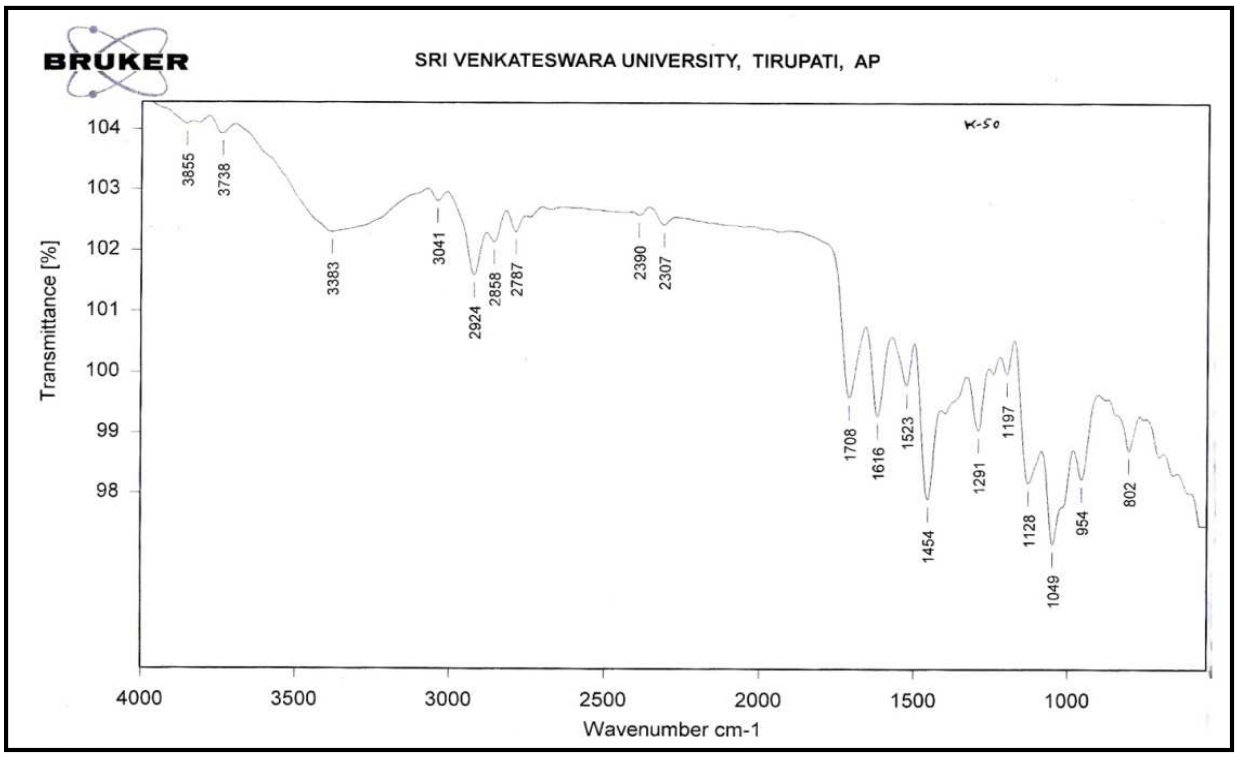

Figure No.4: Infrared spectroscopy of Formulation F1

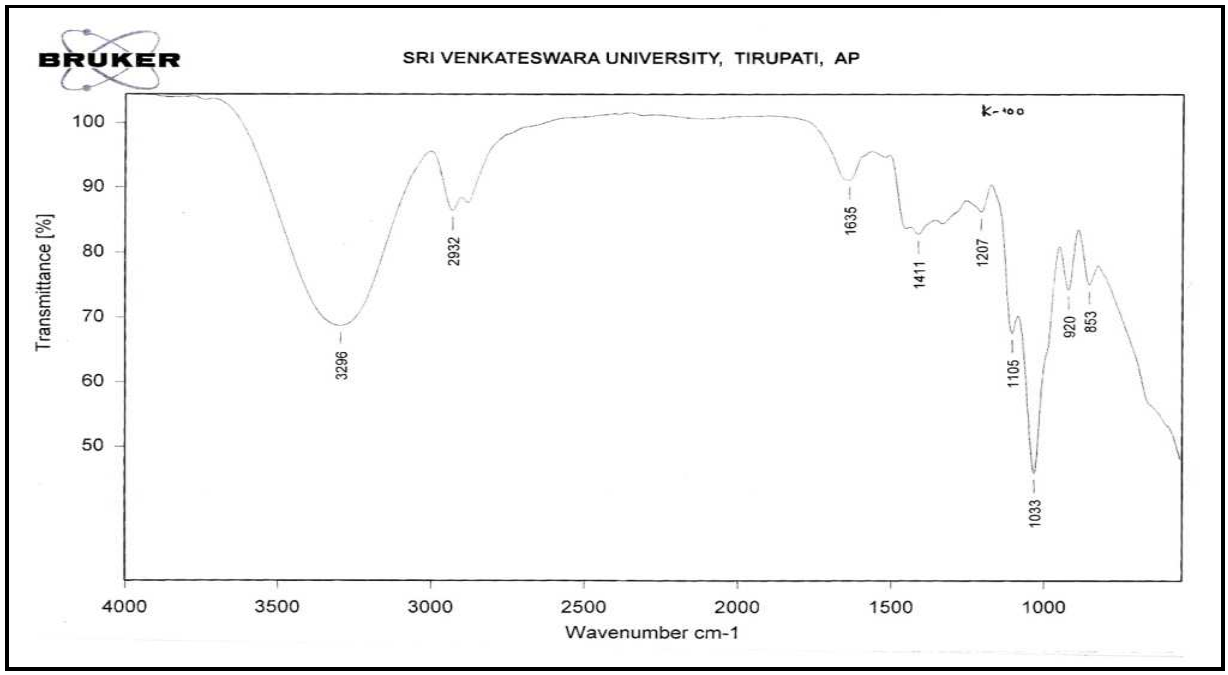

Figure No.5: Infrared spectroscopy of formulation F2

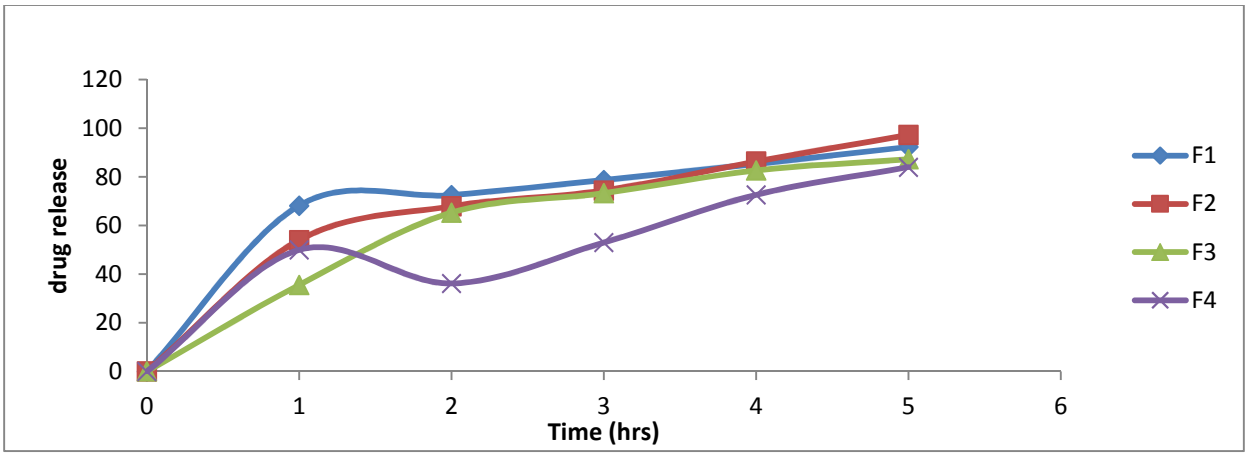

Figure No.6: *In vitro* drug release profile of formulations

CONCLUSION

Dental films are formulated by using ofloxacin as a drug. The dental films are formulated by using HPMC is used as a polymer. The formulated dental films are evaluated by some evaluation tests. Among the four formulations formulation F2 showed good drug release of 97.2%. Dental films are used in the treatment of periodontits. The prepared dental films are kept in intra pocket region where there is presence of more infection.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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