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FORMULATION AND EVALUATION OF MICRO ENCAPSULATED SUSPENSION OF OFLOXACIN

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ABSTRACT

The goal in designing sustained release drug delivery system is to reduce the frequency of the dosing, reducing the dose and providing uniform drug delivery. So, Sustained release dosage form is a dosage form that releases one or more drugs continuously in predetermined pattern for a fixed period of time, either systemically or locally to specified target organ. For the treatment of infections, various conventional oral dosage forms like tablets, capsules, suspensions, syrups etc., are available in market. The difficulty experienced in frequent medication and unpleasant taste. For this reason microencapsulated suspensions have attracted great deal of attention. This microencapsulated suspension achieved long half-life to the formulation with masked taste. The Aim of the study is related to the formulation and evaluation of Ofloxacin 25ml of microencapsulated suspension by solvent evaporation method. From the experimental data obtained, it can be concluded that, Ofloxacin + HPMC (30mg) formulation suitable for formulation of microencapsulated suspension of Ofloxacin.

KEYWORDS

Ofloxacin, Micro encapsulation, HPMC, Suspension and Evaporation.

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INTRODUCTION

Development of novel drug delivery system has been one of the that areas of pharmaceutical research. Sustained release dosage forms were designed to release a drug at a predetermined rate by maintaining a constant drug level for specific period of time with minimum side effects. Over the Past 30 years, as the expense and complications involved in marketing new drug entities have increased, with concomitant recognition of the therapeutic advantages of Sustained drug delivery,

greater attention is being paid on development of oral sustained release drug delivery systems[1].

Sustained release dosage forms provide better control of plasma drug levels, less dosage frequency, less side effect, increased efficacy and constant delivery. Undesirable taste is one of several important formulation problems that are encountered with certain drugs The problem of bitter and obnoxious taste of is a challenge to the pharmacist in the present scenario[2,3].

Oral route has been the commonly adopted and most convenient and preferred route for the drug delivery. Oral route of administration has been received more attention in the pharmaceutical field, because of the more flexibility in the designing of dosage form than drug delivery design for other routes[4,5]. The oral drug delivery depends on various factors such as,

Type of delivery system,
The disease being treated,
Patient condition,
Length of the therapy and
Properties of the drug.

METHODOLOGY

Preparation of drug –resin complex (resinate)[6]

Resinates were prepared by batch process. An accurately weighed amount of drug (100mg) was dissolved in 100ml of distilled water. Then ion exchange resin (100mg) was added and stirred on a magnetic stirrer. Resinate thus formed was filtered and washed with copious amount of deionised water to remove any uncomplexed drug. It was then dried at 50°C and the drug content was determined spectrophotometrically at 293.8nm.

Preparation of suspension using resinates

Praparation of Bulk A[7,8]

In a beaker, 6 ml water was heated up to 80°C. Sucrose (10gm) was added under continuous stirring. The temperature was monitored in such a way so that it should not fall below 70°C, till the sucrose was completely dissolved. The prepared syrup was cooled properly at room temperature and kept overnight. Syrup was filtered using 120 mesh nylon cloth.

Praparation of Bulk B[9,10]

Five millilitre of Ultra pure water was taken in a beaker to which 1.8ml of sorbitol solution and 0.2ml glycerin were added. The mixture was stirred properly. To this solution, pluronic F 68(5%), soya lecithin (1%) and HPMC / C934 (5%) in w/w of drug were added with continuous stirring.

Preparation of mucoadhesive suspension and ultrasonication[11,12]

Five millilitre of water was taken in another beaker to which 200mg of Ofloxacin – indion 204 complex (resonates) was added. To the resinate suspension, the bulk B and bulk A were added with continuous stirring. Xanthan gum is used as suspending agent. Methyl paraben sodium (0.015%w/v) and Propyl paraben sodium (0.08%w/v) were added as preservatives.

RESULTS AND DISCUSSION

Ofloxacin was subjected to the following evaluation tests and has passed all the tests.

Evaluation of ofloxacin-indion 204 resin complex

Ofloxacin was loaded on ion exchange resin by batch process. Complexation is essentially a process of diffusion of ions between the resin and surrounding drug solution. As reaction is equilibrium phenomenon, maximum efficacy is best achieved in batch process. The equilibrium ion exchange in solution occurs stoichiometrically and hence is affected by stirring time. Table No.4 Shows Percent drug complexation is more with Indion-204 and hence Indion-204 is selected for further study. The percentage drug loading (wt/wt) with a stirring time of 5, 15, 30, 60, 120 minutes and 24 Hrs was found to be 71.93± 1.04%, 94.32± 1.52%, 92.51± 2.27 % and 94.18±1.92%, 92.48±2.28%, 93.89±2.11% respectively. Hence, 60 minutes mixing time was optimized[13-17].

Maximum drug loading on the resin occurs at pH 4; a maximum of 95.16 % ± 4.49 for 1:1.5 of drug with Indion 204. As pH increases above 4 percentage of drug loading decreases. This may be due to fact that the fraction of ofloxacin protonation decreases as the pH increases and reduces the interaction with the resin. The pHof the solution

affects both solubility[18] and the degree of ionization of drug and resin. The results can be attributed to the fact that cationic drug is ionized at lower pH value and hence demonstrate high binding capacity while at higher pH protonated fraction of cationic drug decreases and interaction with resin also decreases[19-21].

Evidence of complex formation

Differential scanning calorimetry of the plain drug showed a sharp endothermic peak at 261.5^{o}C, whereas the solid: drug resin complex of ofloxacin with indion 204 ion exchange resins did not show any peak in the DSC graph indicating the complete complexation of the drug with indion 204, as shown in Figure No.2.

Table No.1: Formulation of microencapsulated suspension of Ofloxacin

S.No	Ingredients	Quantity of Ingredients (mg)					
		F-1	F-2	F-3	F-4	F-5	F-6
1	Ofloxacin-Indion 204 (1:16) (resonates)	200	200	200	200	200	200
2	Carbopol 934 (5%)	20	25	30	---	---	---
3	HPMC	---	---	---	20	25	30
4	Sucrose	15	15	15	15	15	15
5	Xanthan gum (%w/v)	0.6	0.6	0.6	0.6	0.6	0.6
6	Sorbitol sol. (70%)(ml)	1.8	1.8	1.8	1.8	1.8	1.8
7	Glycerin (ml)	0.2	0.2	0.2	0.2	0.2	0.2
8	Pluronic F68 (5%)	5	5	5	5	5	5
9	Soyalecithin (1%)	1	1	1	1	1	1
10	Peppermintoil, sunset yellow (ml)	0.2	0.2	0.2	0.2	0.2	0.2
11	Methylparaben and propyl paraben	0.02	0.02	0.02	0.02	0.02	0.02

Table No.2: Physical characterization of ofloxacin

S.No	Test	Limits As Per Monograph	Observation
1	Description	Off white to yellow crystals	Complies with U.S.P.
2	Solubility	Slightly soluble in water, alcohol, dichloromethane and methyl alcohol; sparingly soluble in chloroform.	Complies with U.S.P.
3	Melting point	270 - 275°C	272-275
4	Identification	UV absorption spectroscopy	Complies with U.S.P.
5	Assay	98.0 - 101.0%	99.79%

Table No.3: Linearity table of ofloxacin IN 0.1N HCL solution

S.No	Concentration (µg/ml)	Absorbance
1	2	0.252
2	4	0.482
3	6	0.741
4	8	0.947
5	10	1.172
6	12	1.419
7	14	1.670
8	16	1.952
9	18	2.165

Table No.4: Evaluation of % drug complexation

S.No	Time	% Drug Complexation
1	5	71.93±1.04
2	15	94.32±1.52
3	30	92.51±2.27
4	60	94.18±1.92
5	120	92.48±2.28
6	240	91.47±2.27
7	24hrs	93.89±2.11

Table No.5: Evaluation of drug loading

S.No	PH	Drug loading (%wt/wt)	Drug loading after shaking (%wt/wt)
1	3	52.48±2.13	50.79±1.26
2	3.5	58.93±0.15	52.38±0.38
3	4	60.39±1.39	56.93±1.36
4	4.5	59.57±2.18	56.42±1.78
5	5	58.15±4.43	54.32±3.41
6	5.5	57.13±1.85	53.27±0.87
7	6	56.85±0.57	52.13±0.15

Table No.6: Evaluation of formulations

S.No	Evaluation parameter	F-1	F-2	F-3	F-4	F-5	F-6
1	PH	7.2	7.2	7.2	7.2	7.2	7.2
2	Density	1.184	1.189	1.188	1.246	1.241	1.244
3	Sedimentation volume	1.30	1.29	1.28	0.99	0.99	1.00
4	potency	101%	101%	98%	99%	99%	99%
5	Redispersibility	+++	+++	+++	+++	+++	+++
6	shear thinning	1.38	1.38	1.37	1.42	1.43	1.42
7	thixotropic index	1.38	1.39	1.38	1.48	1.48	1.49
8	Taste	Sweet, palatable	Sweet, palatable	Sweet, palatable	Sweet, palatable	Sweet, palatable	Sweet, palatable
9	Particle size (µm)	2.02	1.86	1.78	2.09	2.14	2.25

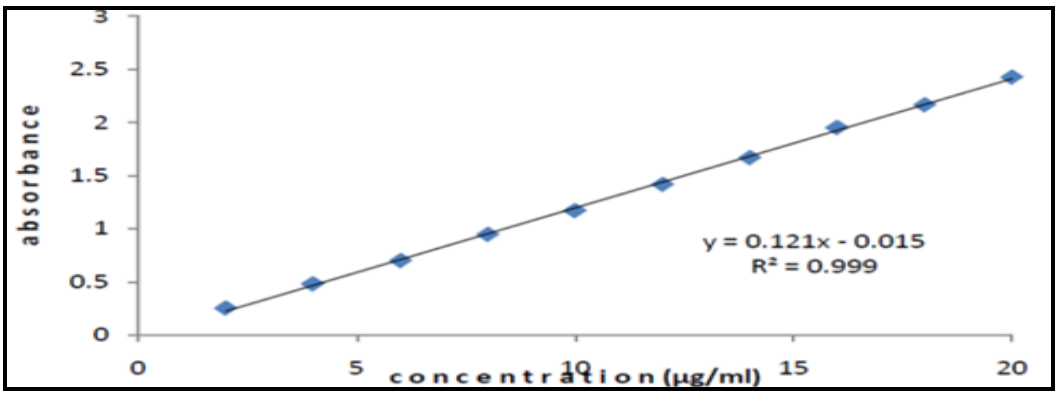

Figure No.1: Calibration curve of ofloxacin at 293nm

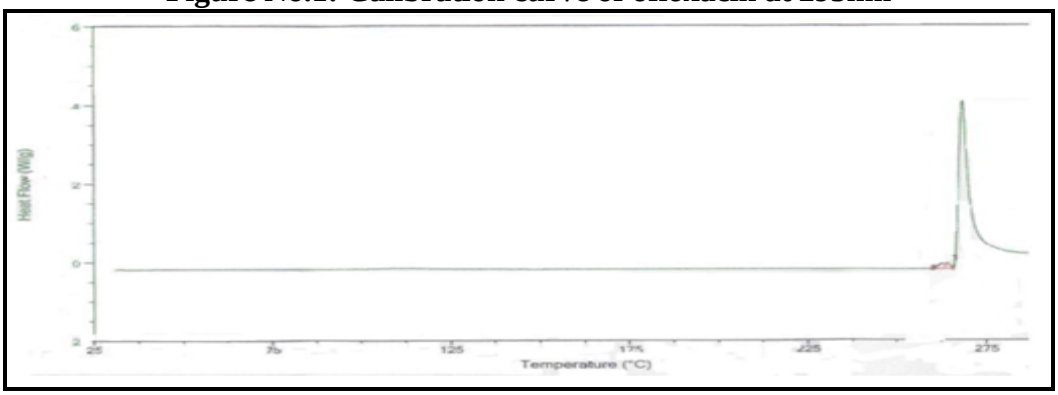

Figure No.2: DSC thermogram of Ofloxacin

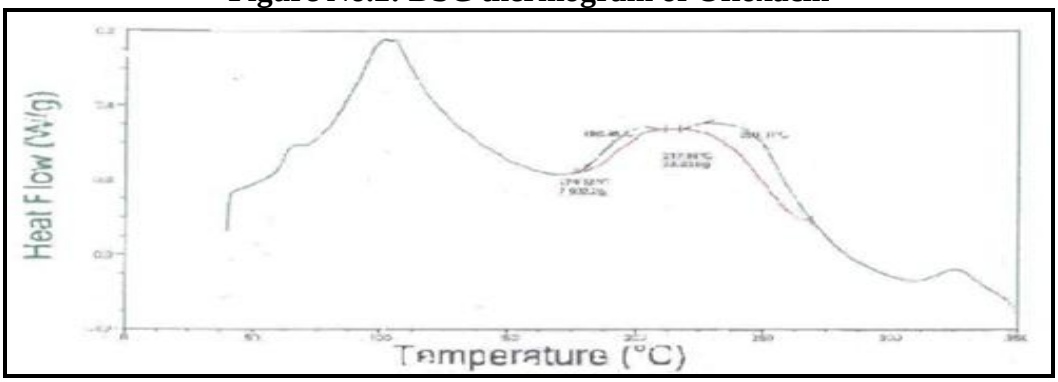

Figure No.3: DSC thermogram of ofloxacin: Indion-204 (1:1.5)

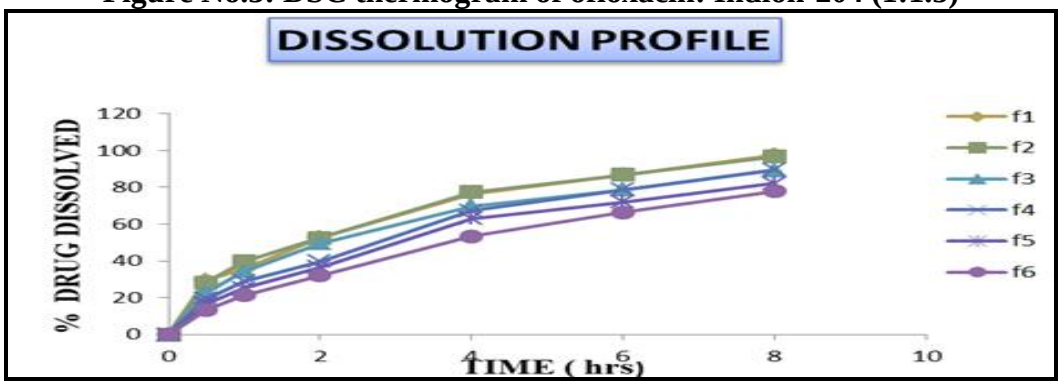

Figure No.4: Dissolution profile of microencapsulated formulations

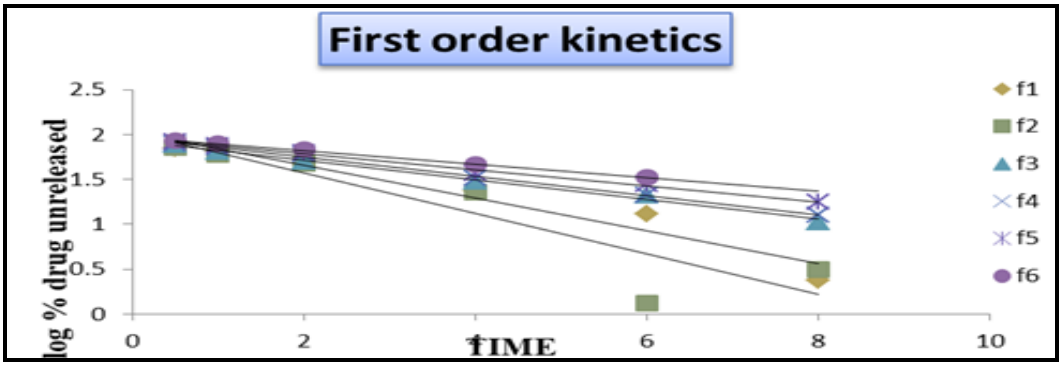

Figure No.5: First order kinetics of microencapsulated formulations

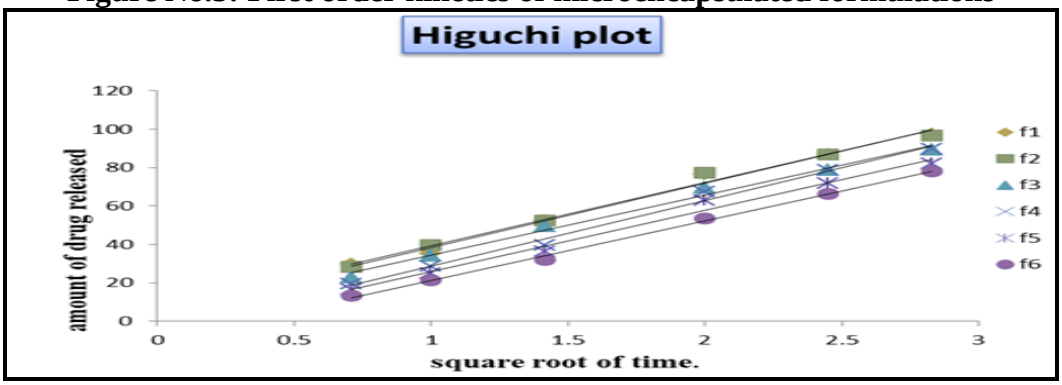

Figure No.6: Higuchi plot of microencapsulated formulations

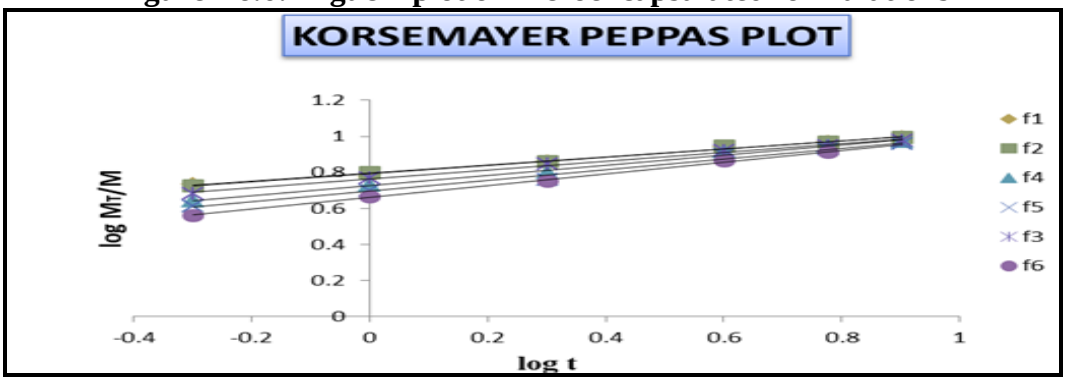

Figure No.7: Korsemayer peppas plot of microencapsulated formulations

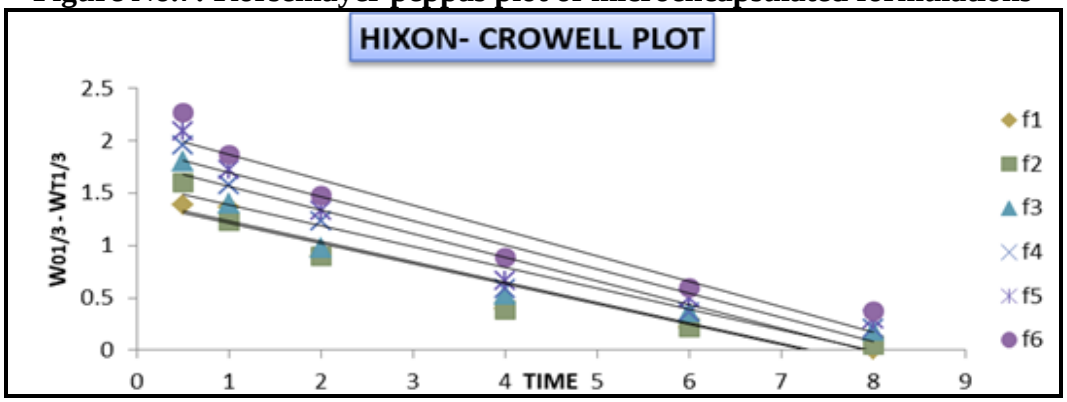

Figure No.8: Hixon crowell plot of microencapsulated formulations

CONCLUSION

The results have shown that the dissolution rate of the drug increases with increase in concentration of HPMC. The dissolution rate increase in following order.

Ofloxacin marketed suspension < Ofloxacin + C 934 < Ofloxacin + HPMC and

Ofloxacin + HPMC (20mg) < Ofloxacin + HPMC (25mg) < Ofloxacin + HPMC (30mg).

The evaluation studies show all formulations passes the test.

FTIR studies have proven that there is no interactions between drug and excipients.

Formulations F-3, F-6 gave better sustained release and antibacterial activity.

Comparitive study of F-3, F-6 with marketed product reveal the F-3 is best fitted formulation for preparation of microencapsulated suspension.

The release pattern of the above formulations was best fitted to Korsmeyer-Peppas model, Higuchi and zero-order model.

From the experimental data obtained, it can be concluded that, Ofloxacin + HPMC (30mg) formulation suitable for formulation of microencapsulated suspension of Ofloxacin.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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