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# DEVELOPMENT AND EVALUATION OF TASTE MASKED ORODISPERSIBLE TABLET OF OFLOXACIN

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**Keywords:**
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**ABSTRACT:** Ofloxacin is an antibacterial agent used to treat infections. It is extremely bitter in taste and taste should be masked to formulate it in a palatable form. The purpose of present research work was to formulate tasteless complexes of ofloxacin with indion 204 ion exchange resin. The drug loading onto ion-exchange resin was optimized for mixing time, activation, effect of pH, mode of mixing, ratio of drug: resin and temperature. The resinate was evaluated for taste masking and in vitro drug release. DSC analysis study supported complex formation. ofloxacin-indion 204 complex of ratio 1:1.5 was developed into orodispersible tablet using different superdisintegrants with varying concentration and was evaluated for weight variation, hardness, friability, wetting time, water absorption ratio, content uniformity, disintegration time and dissolution and was found superior over conventional formulation. The F5 batch with disintegration time 19.33 Sec ±3.78 and dissolution within 45 minutes 89.642±2.20 was selected as optimized formulation. By an appropriate selection and combination of excipients, it was possible to obtain orodispersible and taste masked tablets. Batch F5 Contains, Ofloxacin: Indion-204 complex (1:1.5 Ratio, Sodium starch Glycolate, Crosspovidone, Crosscarmellose sodium, $NaHCO_3$, Citric acid, Mannitol, Talc.

**INTRODUCTION:** Orodispersible tablets that are intended to dissolve and/or disintegrate rapidly in the mouth. and are useful in patients such as paediatric, geriatric, bedridden or developmentally disabled, who may face difficulty in swallowing conventional tablets leading to ineffective therapy. Their characteristic terms of self- administration, compactness and ease in advantages such as administration without water, anywhere, anytime lead to their suitability to geriatric and pediatric patients [1-2]. In more recent years, increasing attention has been paid to patient compliance, rapid onset of action, increased fast dissolving and/or bioavailability, and good stability make these tablets popular as a dosage form of choice in the current market hence, it is beneficial to administer such drugs as ODTs. Ofloxacin is a synthetic antibacterial agent used for treatment of a variety of bacterial infections, but therapy suffers from low patients compliance due to its unpleasant taste.

This study was aimed to develop taste masked complex of ofloxacin using ion exchange resin and to prepare orodispersible tablets using different super-disintegrant. Ion exchange resins have been used as drug carriers in polymers carrying ionizable functional groups [3]. Drugs can be loaded into an ion exchange resin by an exchanging reaction, and hence a drug–resin complex is formed.

The orodispersible tablets were evaluated for parametric tests (Hardness, wetting time, water absorption ratio, disintegration time, *in-vitro* release study). Thus in the present study, an attempt has been made to mask the taste of Ofloxacin Solid drug: resin and to formulate ODTs with good mouth feel so as to prepare a "patient-friendly dosage form" [4].

**MATERIALS AND METHODS:**

**Materials** Ofloxacin was a gift from Holden medical laboratories (Nasik, India), Ion Exchange Resins: Indion-214, Indion-204 gift from (ION Exchange India Ltd., Mumbai, India) and Tulsion-343 from Thermax Ltd. Pune, (Sodium Starch Glycolate, Microcrystalline Cellulose, crosscarmellose sodium were provided as gift samples by Maple Biotech Pvt. Ltd, (Pune, India). All other chemicals used in the study were of analytical grade.

**Methodology:**

**Preparation of Drug Resin Complex (Resinate):** The IER is selected on the basis of drug nature and requirements of the formulation. The study was carried out among three different resins viz. Indion-214, Indion-204, and Tulsion-343 in order to screen most suitable resin for complexation with ofloxacin. Resinates were prepared using batch method. In each case, 100 mg ofloxacin in deionised water was stirred with 100 mg of resin using magnetic stirrer at 500 rpm. The amount of drug loaded at the end of 1 hour was determined indirectly by estimating the amount remaining to be loaded in solution Spectrophotometrically at 293.8nm.

**Optimization of Selected Resin:** Effect of Batch and Column process.

**Batch process:** In this process, 100 mg of Ofloxacin drug solution in distilled water was prepared & added in a beaker containing 150 mg of activated resin slurry and stirred for one hour on magnetic stirrer. Drug content was estimated at 293.8 nm using UV-Spectrophotometer (**Table 1**).

**Column process:** In this process, a glass column (1.4-cm inner diameter, 20-cm length) plugged with cotton was packed with activated resin 150 mg by gently tapping. The 50 ml of distilled water maintained in the column was drained after 30 minutes. Aqueous drug solution (50 ml as per ratio), added in small portions on top of column by using separating funnel. Column was left to equilibrate for 120 minutes. The solution was drained, and drug: resin complex was washed with distilled water. Percent complexation of drug with resin was estimated at 293.8 nm.

**Effect of Drug: Resin ratio:** The Indion-204 which showed highest amount of drug loading for ratio 1:1.5 was optimized for various drug: resin ratios. In each case, 100 mg of ofloxacin was stirred with varying amount of resin in deionised water using magnetic stirrer at 500 rpm. The amount of drug loaded at 60 mins. was determined indirectly by estimating the amount remaining to be loaded in solution spectrophotometrically at 293.8 nm.

**Effect of pH on Drug Loading:** The study was carried out at five pH values 1-7. The pH was adjusted to desired value using 0.1N HCl. Solution of 100 mg ofloxacin drug was stirred with 150mg of resin using magnetic stirrer at 500 rpm. The amount of drug loaded at 60 mins. was determined indirectly by estimating the amount remaining to be loaded in solution spectrophotometrically at 293.8 nm.

**Effect of Temperature on Drug Loading:** The study was carried out at four temperature conditions 30°C, 40°C, 60°C and 80°C. In each case, 100 mg of ofloxacin was stirred with 150 mg of resin in deionised water using magnetic stirrer at 500 rpm. The amount of drug loaded at 60 mins. was determined indirectly by estimating the amount remaining to be loaded in solution spectrophotometrically at 293.8 nm.

**Effect of Drug concentration on Drug Loading**: The study was carried out at three different concentrations 0.5 mg/ml, 1 mg/ml, 1.5 mg/ml, 1.7 mg/ml, 2 mg/ml. In each case, solution equivalent to 100 mg drug was stirred with 150 mg resin in deionised water using magnetic stirrer at 500 rpm. The amount of drug loaded at 60 mins. was determined indirectly by estimating the amount remaining to be loaded in solution spectrophotometrically at 293.8 nm.

**TABLE 1: EFFECT OF RESIN AND TIME OF COMPLEXATIONON PERCENT DRUG COMPLEXATION**

| S. No. | Time (Min) | % Drug complexation | | |
|---|---|---|---|---|
| | | Tulsion-343 | Indion-204 | Indion-214 |
| | | 1:1.5 | 1:1.5 | 1:1.5 |
| 1 | **5** | 81.61±2.19 | 71.93±1.04 | 86.26±1.02 |
| 2 | **15** | 88.33±2.38 | 94.32±1.52 | 92.12±1.03 |
| 3 | **30** | 88.11±2.80 | 92.51±2.27 | 92.01±2.27 |
| 4 | **60** | 91.43±2.89 | 94.18±1.92 | 94.36±2.05 |
| 5 | **120** | 90.49±3.40 | 92.48±2.28 | 94.25±1.91 |
| 6 | **240** | 91.94±4.62 | 91.47±2.27 | 93.34±2.26 |
| 7 | **24hrs** | 90.27±2.79 | 93.89±2.11 | 92.68±2.06 |

**Studies on Drug - Complexes:**

**Drug release from DRC**: Drug release from DRC was determined using United States Pharmacopoeia (USP) type II dissolution apparatus. DRC equivalent to 100 mg of drug of resinate was weighed accurately and added to 900 ml of 0.1 N hydrochloric acid and maintained at 37°C. Drug release was performed at 50 rpm for 120 min. Aliquots of the medium were withdrawn at regular intervals, filtered and the absorbance determined on spectrophotometer. From absorbance values, percent drug dissolved at various time intervals was determined.

**Panel evaluation of taste:** Panel of 9 members using sensory evaluation method determined the threshold bitterness value. Taste evaluation in volunteers confirmed that the taste of drug was masked by complexing with Indion 204 resin. The majority of the volunteers found the drug resin complex to be tasteless and agreeable as shown in **Table 3**.

***In vitro* evaluation of Drug Content at pH 6.8:** Drug release from the DRC was also performed in 10 ml of pH 6.8 solution by adding drug complex equivalent to 10 mg of Ofloxacin to a test tube. The mixtures were filtered after shaking for 60 s. The filtrates were assayed for drug. Drug resinates are insoluble hence, even resinate of bitter drugs have virtually no taste. With the correct selection of ion exchange resin, the drug is not released in the mouth so that the patient does not taste the drug when it is swallowed.

**Differential Scanning Calorimetery (DSC) studies:** A Mettler Toledo differential scanning calorimeter (DSC Q100v9.4Build287) (Mettler Toledo, Greifensee, Switzerland) was used to analyze the thermal behavior of Ofloxacin and drug: resin complex of Ofloxacin: Indion-204. Indium standard was used to calibrate the DSC temperature. Nitrogen was purged at 50 ml/min and 100 ml/min through cooling unit. The thermal behavior of hermetically sealed samples (5-10 mg) was heated at 20°C/min.

**FT-IR Spectroscopy:** FT-IR spectrum of the drug, Indion-204, Ofloxacin: Indion-204 (1:1.5) was recorded on Jasco Dispersive Type FT-IR Spectrophotometer using the KBr disc technique & the spectra were recorded over the wave number 4000 to 500 $cm^{-1}$.

**Selection of Superdisintegrant and Formulation of ODTs:** Before formulation of tablets, the best superdisintegrant among Sodium starch glycolate, Croscarmellose sodium, Crospovidone and combination of citric acid & sodium bicaronate was screened out (**Table 2**).

The best superdisintegrant screened was used for the final formulation of tablets. Tablets were prepared in various batches containing a blend of mannitol as a diluents and superdisintegrant in various concentrations. Tablets were prepared by direct compression using flat-faced punches.

**Physical Properties of the Tablet Blend** [5]: Physical properties such as bulk density, tapped density, compressibility index, and the angle of repose of blend were determined (**Table 4**). Percent compressibility was calculated using Equations 1.

Percent compressibility =

$$\{( D t - D b ) / D t \} \times 100 \ldots\ldots\ldots\ldots (1)$$

Where, Dt and Db are tapped and bulk densities.

**Evaluation of Tablet:** The prepared orodispersible tablets were evaluated for hardness, weight variation, thickness, friability and drug content (**Table 5**) [6, 7]. Hardness of the tablets was tested using a Strong-Cobb hardness tester (Tabmachine,Mumbai, India). Friability of the tablets was determined in a Roche friabilator (Campbell Electronics, Mumbai, India). The thickness of the tablets was measured by vernier calliper. Weight variation test was performed according to the official method.

**TABLE 2: DIFFERENT FORMULATION COMPOSITION**

| S. No. | Ingredients | Tablet Ingredients (mg) | | | | |
|---|---|---|---|---|---|---|
| | | Formulations | | | | |
| | | F1 | F2 | F3 | F4 | F5 |
| 1 | Ofloxacin: Indion-204 complex (1:1.5 Ratio) | Equivalent to 100 mg (259) | Equivalent to 100 mg (259) | Equivalent to 100 mg (259) | Equivalent to 100 mg (259) | Equivalent to 100 mg (259) |
| 2 | Sodium starch Glycolate | 30mg | ---- | --- | 10mg | 10mg |
| 3 | Crospovidone | ---- | 30mg | --- | 10mg | 10mg |
| 4 | Crosscarmellose Sodium | --- | --- | 30mg | 10mg | 10mg |
| 5 | $NaHCO_3$ | ---- | ---- | --- | --- | 12mg |
| 6 | Citric acid | ---- | ---- | ---- | --- | 10mg |
| 7 | Mannitol | 3.75mg | 3.75mg | 3.75mg | 3.75mg | 3.75mg |
| 8 | Talc | 1.25mg | 1.25mg | 1.25mg | 1.25mg | 1.25mg |
| 9 | Flavor | q.s. | q.s. | q.s. | q.s. | q.s. |

**TABLE 3: VOLUNTEERS 0PINION TEST FOR OFLOXACIN BEFORE AND AFTER TASTE MASKING**

| Formulation | Average bitterness value |
|---|---|
| Pure drug | 5 |
| Formulation F5 | 1.33±0.57 |
| Marketed tablet | 2.33±0.57 |

**TABLE 4: EVALUATION OF MIXED BLEND OF DRUG AND EXCIPIENTS**

| | | Formulations | | | | |
|---|---|---|---|---|---|---|
| Sr. No. | Property | F1 | F2 | F3 | F4 | F5 |
| 1 | Angle of repose | 25.56±0.70 | 25.13±0.78 | 26.25± 0.81 | 26.88± 1.77 | 26.61±0.44 |
| 2 | Bulk density gm/$cm^3$ | 0.56±0.011 | 0.56±0.018 | 0.57± 0.008 | 0.57±0.024 | 0.57±0.016 |
| 3 | Tapped density gm/$cm^3$ | 0.65±0.008 | 0.66±0.024 | 0.67± 0.014 | 0.67±0.008 | 0.67±0.016 |
| 4 | % compressibility | 13.86±1.42 | 13.7± 1.13 | 14.49± 0.63 | 13.96±2.08 | 13.93±0.77 |
| 5 | Flowability | Good | Good | Good | Good | Good |

**TABLE 5: EVALUATION STUDY OF FORMULATION CONTAINING SOLID DRUG: RESIN COMPLEX**

| S. No. | Parameters | F1 | F2 | F3 | F4 | F5 |
|---|---|---|---|---|---|---|
| 1 | Weight variation | Passes | Passes | Passes | Passes | Passes |
| 2 | Hardness kg/sqcm | 2.833±0.25 | 3±0.547 | 2.833±0.51 | 2.583±0.58 | 3±0.316 |
| 3 | Friability | 0.79± 0.012 | 0.76±0.045 0. | 0.77± 0.021 0 | 0.72±0.024 | 0.73 ±0.059 |
| 4 | Content uniformity | 98.28±0.31 | 98.03± 0.05 | 98.89± 0.13 | 98.14±0.22 | 0598.89±0.13 |
| 5 | Disintegration time | 156.6±9.073 | 165.3±5.89 | 171.6±2.309 | 141±3.605 | 19.33±3.78 |
| 6 | Wetting time | 10.66±2.0816 | 12.33±2.516 | 15.66±1.527 | 11.66±2.516 | 8.66±1.154 |
| 7 | % Water absorption ratio | 91.64± 0.32 | 95.64±0.19 | 103.75±0.20 | 101.50±0.32 | 115.43±0.60 |

**Wetting Time and Water absorption ratio** [8]: A piece of tissue paper folded twice was placed in a small Petri dish (internal diameter of 5.5 cm) containing 6 ml of water. A tablet was placed on the paper and the time required for complete wetting was measured. The wetted tablet was then weighed.

Water absorption ratio 'R' was determined using the equation =

100 (Wa-Wb) / Wb ……..(2)

Where, Wb is weight of tablet before water absorption Wa is weight of tablet after water absorption.

***In-vitro* Disintegration Time:** *In vitro* disintegration time for orodispersible was determined using USP and modified disintegration apparatus with SSF (pH 6.2) as the disintegrating medium. During this study we made an attempt to develop a more suitable apparatus for orodispersible tablet because many reports [9-10] indicated the unsuitability of the conventional disintegration test apparatus for ODT. Briefly, the apparatus consisted of a glass beaker of 1000-ml capacity with the wire basket positioned in the beaker with the help of a support in a way that when the beaker contained 900 ml of disintegrating medium, the basket had only 6 ml of it. A magnetic bead was placed at the bottom of the beaker maintained at 37±2°C. Disintegration time was determined at 25 and 50 rpm.

***In-vitro* Dissolution studies:** The *In-vitro* dissolution studies were carried out using USP apparatus type II (paddle) at 50 rpm. The dissolution medium used was pH 1.2 (900ml) maintained at 37±0.5$^{o}$C. Aliquots of dissolution media were withdrawn at different intervals and content of ofloxacin was measured by determining absorbance at 293.8 nm. The dissolution experiments were conducted in triplicate. Graphs are shown in **figure 5**.

**Comparison of Optimized Formulation with Conventional Marketed Tablet** *In vitro* Dissolution studies for optimized formulation and uncoated conventional tablet were also carried out (**Figure 5**).

**RESULT AND DISCUSSION:**

**Optimization of ofloxacin-Indion 204 resin complexation:** 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 an 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 1** 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.

Highest drug binding on resin was achieved when activated with 1N HCl. The percentage drug loading with inactivated resin, treated with acid and alkali, was found to be 41.73 ± 0.45 %, 52.34±0.37%wt/wt and 48.21% ± 0.12%wt/wt, respectively. After activation with acid treatment, the exchangeable ion on the resin is H+.Relative selectivity of H+ is least than other ionic form and therefore it increases percent complexation. Therefore acid activated resin is used for preparation of complex. 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 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.

Hence, ofloxacin as a cationic drug will have maximum solubility and complete ionization in this range. Complexation was found to be optimum in case of stirring, a maximum of 94.33±0.58% for 1:1.5 of drug with indion 204 and in case of shaking 92.23±0.82% of drug with indion 204. This finding may indicate the significant involvement of van der waals forces taking place along with drug exchange during complexation. As already known equilibration time for complex formation is longer, but some kind of energy is required for complexation processes which can be supplied in the form of stirring and shaking.

Energy supplied by all the modes may vary and hence there is significant effect of modes of mixing on percent drug complexation. The drug-loading efficiency for a drug-resin ratio 1:1, 1:1.5 and 1:2 of batch process was 84.01±2.37 94.33±2.61% wt/wt, 97.212± 1.7 %w/w for indion 204. It is due to the fact that, increase in the amount of resin increases the amount of drug adsorbed from the solution. A 13% wt/wt increase of loading efficiency was observed in batch process, when drug-resin ratio was changed from 1:1 to 1:2.

Hence, the drug loading performed at intermediate drug-resin ratio for indion 204. Temperature does not show significant effect on percentage drug loading.

**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 2**.

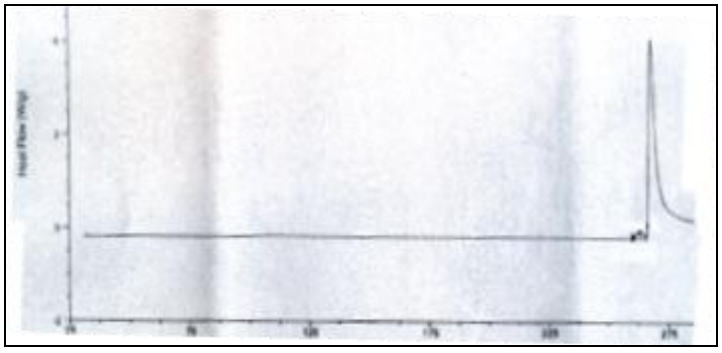

**FIG. 1. DSC THERMOGRAM OF OFLOXACIN**

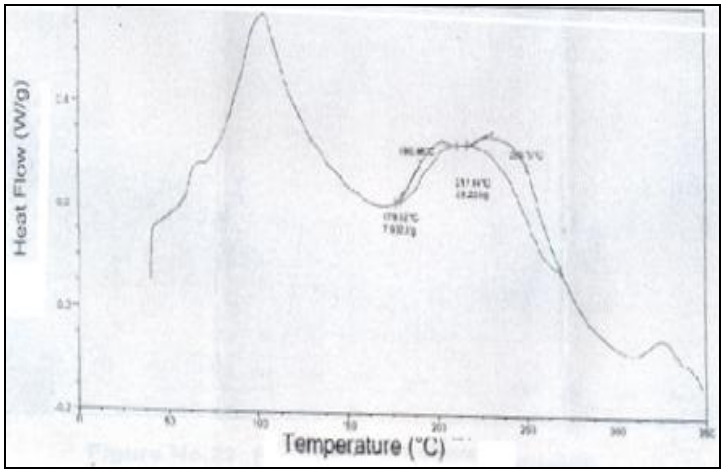


**FIG. 2. DSC THERMOGRAM OF OFLOXACIN: INDION-204 (1:1.5)**

Ofloxacin release from drug–resin adsorbate was observed using United States Pharmacopoeia USP 24 type II dissolution apparatus and drug release was 90.64±1.88 within 45 min. *In vitro* drug release in average salivary pH of 6.7 was less than 1.0% within 2 min. The presence of exchangeable ions of ionisable electrolytes in simulated salivary fluid may be responsible for this release. The amount released is insufficient to impart bitter taste while the formulation passes through the mouth to further parts of gastrointestinal tract.

A drug–resin complex is made from the bitter drug and ion exchange resins,saliva are not able to break the drug–resin complex but it is weak enough to be broken down by the hydrochloric acid present in the stomach, thus the drug–resin complex is absolutely tasteless and stable, with no aftertaste. The complexation of ofloxacin and Indion-204 produces amorphous tasteless drug resinate. Taste evaluation in volunteers found the DRC to be tasteless and agreeable with maximum acceptability. FTIR spectra of pure drug, pure resin and resinate confirms the complexation between drug and resin as shown in **fig. 3, 4, 5**.

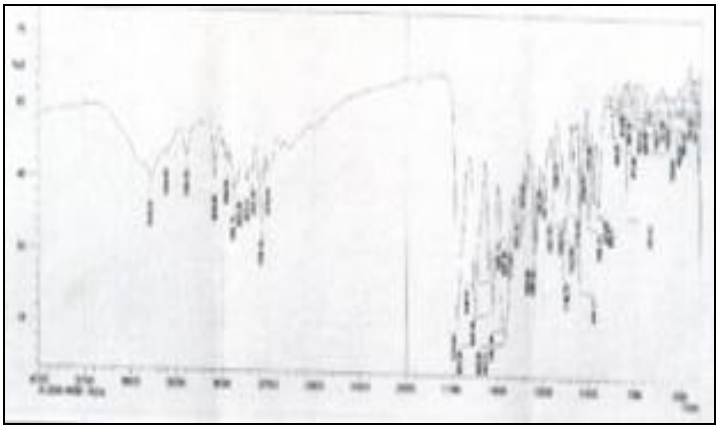

**FIG. 3: FTIR SPECTRA OF OFLOXACIN**

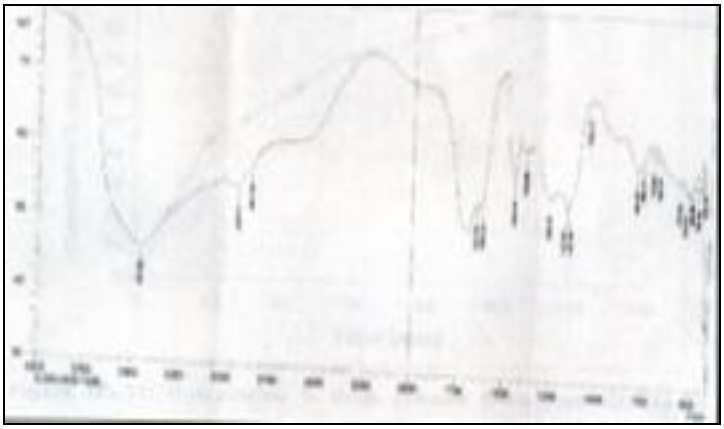

**FIG. 4: FTIR SPECTRA OF INDION-204**

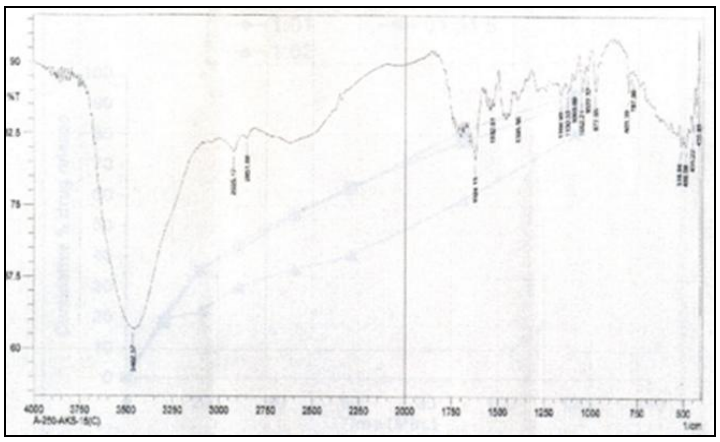

**FIG. 5: FTIR SPECTRA OF OFLOXACIN: INDION-204**

The tablet blend of all the batches were evaluated for different derived properties viz.-angle of repose (between 25 and 27), Bulk density (between 0.55 and 0.57 gm/cm$^3$), Tapped Density (0.65-0.67 gm/cm$^3$), Compressibility index (between 13 and 15, and flowability (good). The results of Angle of repose and compressibility indicated that the flowability of blend is significantly good. Orodispersible tablets were prepared in batches F1–F5 and evaluated for tablet properties like, weight variation, hardness, and friability, wetting time, water absorption ratio, content uniformity, disintegration time and dissolution.

All the tablets passed weight variation test as the percent weight variation was within the pharma-copoeial limits. Hardness were shown in the range of 2 to 3 kg/cm$^2$ in all the formulations which indicated good mechanical strength with an ability to withstand physical and mechanical stress conditions while handling. In all the formulations, the friability value was less than 1% and meets the official limit. The results of disintegration of all the tablets were found to be within prescribed limits and satisfied the criteria of Orodispersible tablet. The values were found to be in the range of 19 to 172 seconds.

The percentage drug content of all the tablets was found to be between 97.92±0.32% and 98.89±0.13% of ofloxacin which was within acceptable limit. All the tablets prepared were subjected for release profile. The tablets prepared from crosspovidone, cross-carmellose sodium, sodium bicarbonate & citric acid i.e., F1-F5 showed a drug release within 45 min 89.64± 2.20. The wetting time and Percent water absorption ratio were also in acceptable limit and it was found to be 8.66± 1.154, 115.43± 0.60 respectively.

Among five Batches, Batch F5 is selected as optimized batch because of its lowest disintegration time and highest drug release. In comparison, formulation F5 was compared with conventional marketed formulation. The drug release of marketed product and F5 formulation was found to be 84.685±1.89 % and 92.65±1.89% within 45 min respectively ( **fig. 6**).

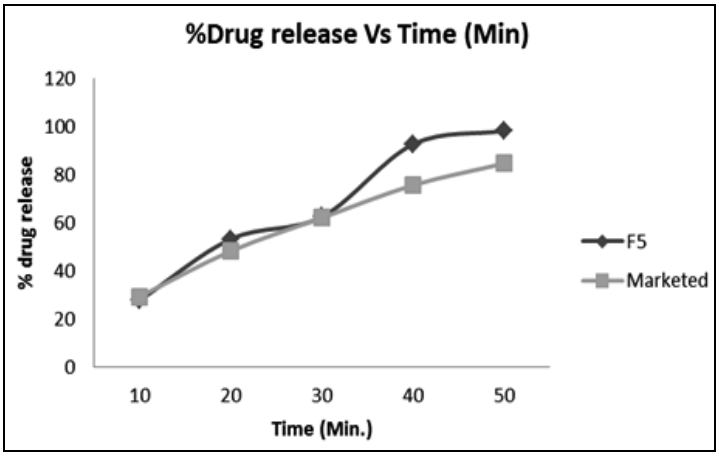


**FIGURE 6: *IN-VITRO* DRUG RELEASE PROFILE OF FORMULATION F5 AND MARKETED FORMULATION**

**CONCLUSION**: In the end, it can be concluded that pharmaceuticals complexed using ion exchange resins have shown improved organoleptic performance of pharmaceuticals and better patient compliance.

This study shows an urgent need for a new dosage form which can improve patient compliance. For better masking effective techniques are being developed constantly in the pharmaceutical industry.

Presently, the use of these techniques depends on the nature of the drug, thus the use of cation exchange resin offers good taste masking of ofloxacin and its formulation into orodispersible tablet offers advantages over conventional tablet.

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