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Formulation and Evaluation of Sustained Release Tablet of Ibuprofen

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Abstract : In this study of Ibuprofen it is an (NSAIDs) non steroidal anti- inflammatory drug and used as analgesic & anti –inflammatory drug. It can be also used in the treatment of rheumatoid arthritis, osteoarthritis, and primary dysmenorrheal. Ibuprofen is absorbed rapidly, bound avidly to protein, but it has low aqueous solubility so it also lowers the dissolution profile of drug. To overcome this problem, various techniques are used, like solid dispersion, complexation, co-solvency, hydro trophy. nano-technology approach. The main aim of proposed work was to develop Ibuprofen tablets, sustained release dosage form, for the treatment inflammation and pain in the body. Ibuprofen is used to reduce fever and treat pain or inflammation caused by many conditions such as headache, toothache, back pain, arthritis, menstrual cramps, or minor injury. Sustained release formulation is the drug delivery system that designed to achieve a prolonged therapeutic effect by continuously releasing medication over an extended period of time after administration of single dose. The tablets were prepared by direct compression method using hydroxypropylmethylcellulose (HPMC K4M), Avicel pH 102, magnesium stearate and talc. In the formulation HPMC K4M and magnesium stearate used in varying ratios. Tablets blends were evaluated for loose bulk density, tapped density, compressibility index and angle of repose shows satisfactory results. The compressed tablets were then evaluated for various physical tests like diameter, thickness, uniformity of weight, hardness, friability and drug content. The results of all these tests were found to be satisfactory. The in vitro dissolution study was carried out for 12 hours using paddle method in phosphate buffer (pH6.8) as dissolution media. Formulation F3 shows – of drug release at the end of 12 hours.

Keywords : Ibuprofen, ,Sustained Release, Dissolution Rate

Introduction

Oral route of drug delivery is the most preferred route of the various drug molecules among, all other routes of drug delivery because of ease of administration, patient compliance and flexible design of dosage

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form.[1] Sustained release formulation maintains a uniform blood level of drug with better patient compliance as well as increased efficacy of drug. Sustained release tablets are generally taken once or twice a day during a course of treatment whereas in conventional dosage forms there is need to take 3-4 times dosage in a day to achieve the same therapeutic action.[1,2]

Propranolol hydrochloride, a non-selective beta –adrenergic blocker, has been widely used in the treatment of hypertension, angina pectoris, and pheochromocytoma and cardiac arrhythmias.[3] Because of its relatively short plasma half-life, patients are routinely asked to take propranolol hydrochloride in divided daily dose, once every 6-8 hr. such frequent drug administration may reduce patient compliance and therapeutic efficacy.[4] In recent years, slow or sustained release formulation of propranolol hydrochloride have become available with claims that these formulation maintain beta adrenoreceptor blockade throughout a 24 h period and enable the drug to be given once daily.[5] The half-life of Ibuprofen is 3to 5 h. the daily dose of propranolol is 40 mg daily given in divided dose. Ibuprofen is used to reduce fever and treatpain or inflammation caused by many conditions such as headache, toothache, back pain, arthritis, menstrual cramps, or minor injury Therefore, to improve patient compliance and to decrease the incidence of adverse effects and side effects, propranolol is formulated as a sustained release table using hydroxypropymethylcellulose. Then the prepared tablets were evaluated for appearance, weight variation, diameter, thickness, hardness, friability, drug content and in vitro drug release.



Fig. 1: Structure of Sustained Release Tablet.

Materials and Method

Materials

Ibuprofen was obtained from Alembic Pvt. Ltd; Vadodara.HPMC, Avicel, CarbopolLoba Chemic Mumbai. All other chemicals and ingredients were used for study are of Analytical grade.

Methods

Orodispersible tablets containing 100 mg of Ibuprofen were prepared by direct compression method and the different formulae employed in the study are shown in table no 15.The drug and excipients were passed through 60 mesh sieve to ensure better mixing. Avicel PH 102 was used as directly compressible diluents. The directly compressible mixture was compressed using KBr press machine. Before compression, the surface of die and punch were lubricated with Talc.[6]

Table No 1: Composition Of Sustained Release Tablet.

| Ingredients (mg) | F1 | F2 | F3 |
|------------------|-----|-----|-----|
| Ibuprofen | 200 | 200 | 200 |
| HPMC | 10 | 15 | 20 |
| Carboopol | 15 | 20 | 10 |
| Avicel | 20 | 10 | 15 |
| Lactose | 18 | 18 | 18 |
| Mg Sterate | 14 | 14 | 14 |
| Talc | 12 | 12 | 12 |
| Falvour | 6 | 6 | 6 |

Evaluation Parameters

Preformulating studies of Ibuprofen:

Characterization of Ibuprofen: Description

Ibuprofen was found to be colour, odour, nature & taste.

Melting point of drug

The melting point of Ibuprofen was carried out

Standard curve of Ibuprofen:

Standard curve of ibuprofen in phosphate buffer pH 7.2 at 221 nm was plotted using various concentrations against the absorbance values found at respective concentrations. The standard curve of ibuprofen was found to be linear in the range of 5-30 µg/ml, which means that present drug sample was obeying Beers- Lamberts range (5-30 µg/ml) and coefficient of correlation was found to be 0.999. The observations of calibration curve are shown in table 6, the plot of calibration curve is shown in figure 4 and the parameters from the calibration curve are mentioned in the table no. 7.

Fourier Transform Infrared Spectroscopy[7]

The fourier transform infra-red analysis was conducted for the structure characterization FTIR spectra of the pure drug Nimesulide. Approximately 5mg of samples were mixed with 50mg of spectroscopic grade KBr, samples were scanned in the IR ranges found 500 to 2000 cm⁻¹, with a resolution of 4 cm⁻¹.

Evaluation of Sustained Release Tablet[8]

7.9 Evaluation of tablets:

1) Diameter and Thickness-

The thickness of the tablet is mostly related to the tablet hardness can be used as initial control parameter. Ten tablets were randomly selected and tablet thickness was determined using vernier caliper and the reading was recorded in millimeters.

2) Hardness-

Hardness or Tablet crushing strength (TCS) is the force required to break the tablet or ability of a tablet to withstand mechanical shocks while handling. The Hardness of tablet was determined by Hardness testing apparatus (Monsanto hardness tester). It was expressed in terms of kg/cm².

3) Friability-

Friability of tablet was by using Roche friabilator. Twenty tablets were weighed and placed in friabilator and rotate at 25 rpm for 4 min. The tablet were taken out, dedusted and reweighed. The weight loss should not be more than 1%. The percentage friability of the tablets was calculated by the formula:

Percentage friability= (Initial weight of tablet-Final weight of tablet)/ Final weight of tablet x100

4) Wetting Time-

A piece of tissue paper (10.75×12mm) folded twice was placed in a culture dish (d=6.5 cm) containing 6 ml of water. A tablet was carefully placed on the surface of tissue paper and the time required for the tablet was noted as the wetting time.

5) Water Absorption Ratio-

Test was done with the same procedure as that of wetting time .In this test initial weight of tablet was taken before placing on Petri dish. After complete wetting the wetted tablet was then weighed .Water absorption ratio, R was determined using the equation.

$$R=100(W_b-W_a)/W_b$$

Where, W_a is weight of tablet before water absorption

W_b is weight of tablet after absorption

6) Weight variation –

The weight of the tablet being made was routinely determined to ensure that a tablet contains the proper amount of drug. Twenty tablets selected randomly were weighed individually, calculating the average weight and comparing the individual weights to the average.

7) In Vitro Disintegration-

Six tablets of each formulation were used to determine disintegration time. Phosphate buffer (pH 6.8) was used as a disintegration medium and temperature was maintained 37 ± 0.5 °C. Average disintegration time of six tablets was determined. Media volume 900ml.[11,12]

Results And Discussion

1) **Appearance** –Ibuprofen was found to be White, Amorphous powder having bitter test.

2) **Melting Point-** The melting point of Ibuprofen was found to be 72°C.

3) **Calibration curve:** Drug Ibuprofen

Table No 2: Standard Curve of Ibuprofen Drug.

| Concentration | Absorbance |
|---------------|------------|
| 0.2 | 0.091 |
| 0.4 | 0.131 |
| 0.6 | 0.214 |
| 0.8 | 0.266 |
| 0.10 | 0.327 |
| Slope | 0.3204 |
| Intercept | 0.0112 |
| R^2 | 0.9960 |

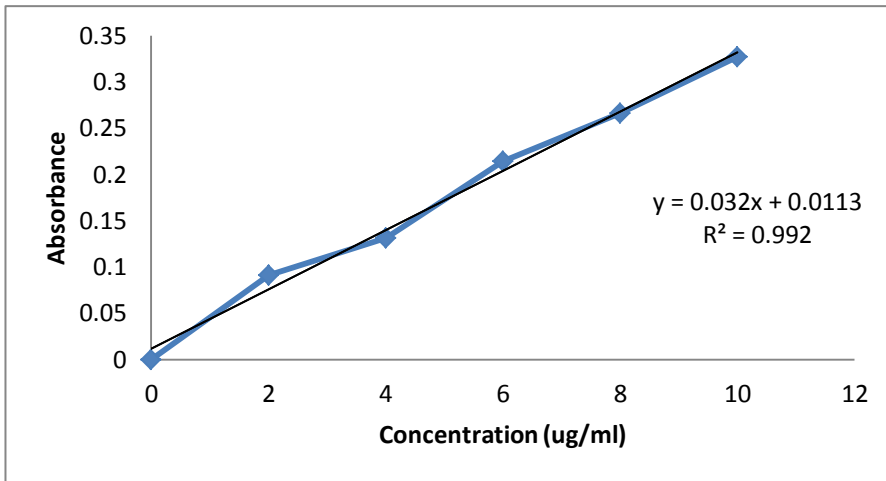


Fig. 2: Standard Curve of Ibuprofen

IR-Spectroscopy of Pure Drug

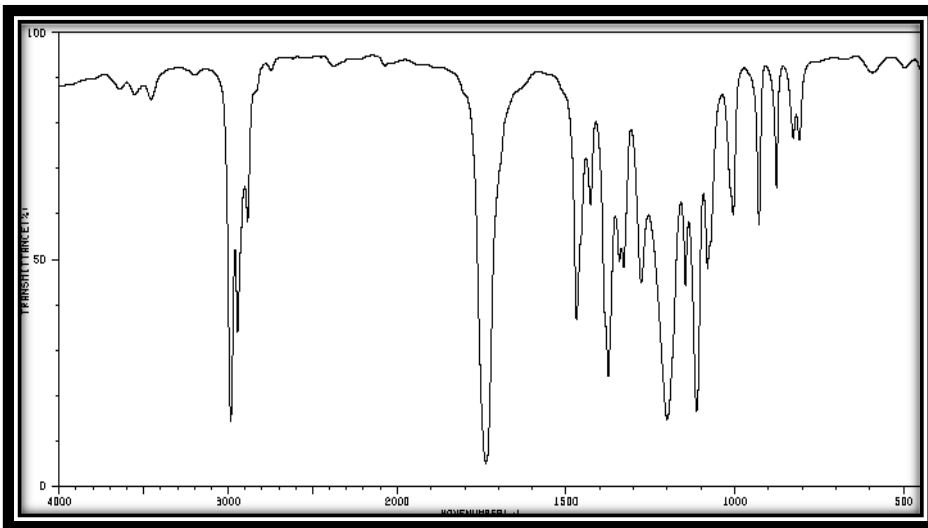


Fig. 6: IR Interpretation value of Ibuprofen

Table No 3: IR Interpretation value of Ibuprofen.

| Functional Group. | Standard Wavenumber Rang. (Cm-1) | Observed Wavenumber (Cm-1) |
|-------------------------|----------------------------------|----------------------------|
| Aromatic C-H (stretch) | 3000-3100 | 3010 |
| Aromatic C=C (stretch) | 1400-1600 | 1464.22 |
| Acid | | |
| i)C=O (stretch) | 1700-1725 | 1703.35 |
| ii)O-H (stretch) | 2500-3300 | 2876.20, |
| iii)C-O (stretch) | 960-1310 | 1234.45 |
| Alkane i) C-H (stretch) | 2850-3000 | 2876.20 |
| Ether i)C-O (stretch) | 1000-1300(1070- | 1106.23 |

4) Physical Characteristics of Oral Sustained Tablet-

Physical characteristics of oral Sustained Release powder were examined Angle of Repose, Bulk Density, Tapped Density, Carr’s Index(CI), Hausner’s Ratio and values for which reported in table no According to survey ranges of properties.

Table No 4: Physicochemical evaluation Granules.

| Properties | F1 | F2 | F3 |
|-----------------|--------------------|--------------------|--------------------|
| Bulk Density | 0.4761 | 0.4347 | 0.6666 |
| Tapped Density | 0.6250 | 0.5555 | 0.8333 |
| Hausner's Ratio | 1.3127 | 1.2718 | 1.2500 |
| % Carr's Index | 23.8240 | 21.7461 | 20.0048 |
| Angle Of Repose | 27.68 ⁰ | 25.59 ⁰ | 28.30 ⁰ |

From the above value of bulk density and tapped density the value for Carr's index and Hausner's Ratio were calculated. The value of angle of repose was found to be less than 25⁰. Carr's index was found to be 5-15 range. The value of Hausner's ratio was found to be less than 1.27. All these value indicates excellent flow properties for oral Sustained Release tablet.

5) Evaluation of Ibuprofen Tablet-

Physicochemical evaluation of Ibuprofen tablet of different formulation were carried out, in that Thickness, Diameter, weight variation, Hardness, Friability, Tensile Strength, In-Vitro Dissolution study of tablet carried out.

Evaluation of post- compression parameters of Ibuprofen tablet

Table No 4: Physicochemical evaluation Sustained Release Tablet.

| COD E | Thickness (mm) | Diameter (mm) | Weight Variation | Hardness (kg/cm) | Friability (%) |
|-------|----------------|---------------|------------------|------------------|----------------|
| F1 | 0.540 | 0.816 | Complies | 2.10 | 0.8974 |
| F2 | 0.520 | 0.813 | Complies | 2.23 | 0.8438 |
| F3 | 0.520 | 0.820 | Complies | 2.26 | 0.7083 |

Table No 6: Physicochemical evaluation Sustained Release Tablet.

| Time in (hr) | Pure Drug | F1 | F2 | F3 |
|--------------|-----------|-----|-----|------|
| 0 | 0 | 0 | 0 | 0 |
| 30 | 8.18 | 2.3 | 2.6 | 2.2 |
| 1 | 12.10 | 4 | 3 | 6 |
| 2 | 25 | 5 | 8 | 7.2 |
| 3 | 36 | 10 | 12 | 11 |
| 4 | 46.2 | 15 | 13 | 13.5 |
| 5 | 53 | 22 | 21 | 23 |
| 6 | 68 | 31 | 32 | 33 |
| 7 | 79 | 38 | 39 | 36 |
| 8 | 89 | 45 | 42 | 44 |
| 9 | 92 | 52 | 53 | 52 |
| 10 | 100 | 65 | 66 | 69 |
| 11 | | 76 | 75 | 77 |
| 12 | | 85 | 87 | 84 |

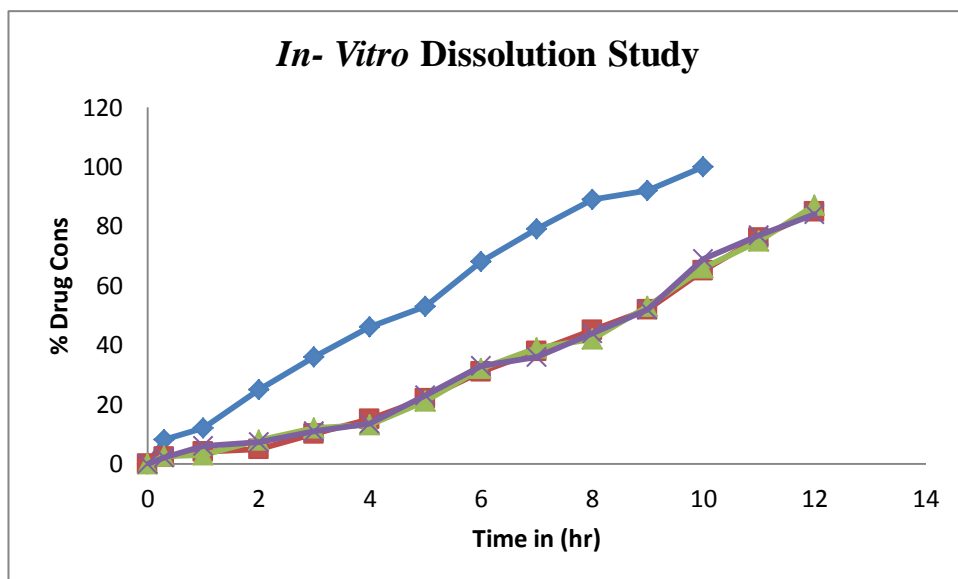


Fig. 4: In-Vitro Dissolution Study of Ibuprofen Sustained Release Tablet.

9. Conclusion:

Ibuprofen is poorly water soluble drug Lower by oral Sustaine of Ibuprofen by direct compression method the dissolution of Ibuprofen Lowered. The result showed that the dissolution rate of drug in oral Sustained tablet was lowered than pure drug. It means oral Sustained tablet form of Ibuprofen strongly Decrease the dissolution of Ibuprofen Direct compression method can be used, because it is an easier, simplified and economical method of manufacturing of tablets. Thus successful development of a novel Ibuprofen tablets fulfils the objective of work.

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