

## DEVELOPMENT AND CHARACTERIZATION OF SINGLE LAYER OSMOTIC CONTROLLED RELEASE TABLET FOR LOW SOLUBLE DRUG NORFLOXACIN

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### ABSTRACT

The aim of the present research work were to develop and characterize single layer osmotic controlled release tablet for low soluble drug Norfloxacin by using direct compression, coating and drilling technique by using various different concentration of excipients. Now a days, the drug delivery system are becoming more difficult day by day, as pharmaceutical researchers dealing with new techniques for the better understanding of biochemical and physicochemical properties to make their performance better. As we know, the Novel Drug Delivery System is a great approach in the field of Pharmaceutical preparation, the Osmotic Drug Delivery System provides more easy ways for the patient compliance. There are various methods which are used for the preparation of different types of osmotic pump tablets, the drug which is taken here is Norfloxacin by applying direct compression methods associated with coating and drilling process. In this research work, we had prepared single layer osmotic pump tablet of norfloxacin to fulfil it's low solubility profile and better patient compliance. There are total six types of formulations was prepared with different concentrations of excipients by using direct compression method, and coating of tablets and drilling of tablets were performed for better release of drugs due to osmosis process. The granules of tablets and prepared tablets were

evaluated for different parameters. From all the result and readings, it can be concluded that, the single layer osmotic pump tablet is found to be better option for the drugs having poor solubility.

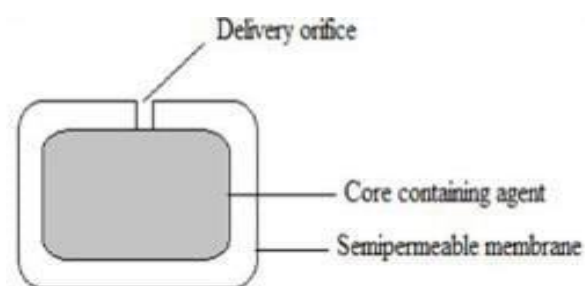
**KEYWORDS:** Osmosis, Osmotic Drug Delivery System, NDDS, Elementary osmotic drug tablet, etc.

## INTRODUCTION

As we know, the Novel Drug Delivery System is a great approach in the field of Pharmaceutical preparation, the Osmotic Drug Delivery System provides more easy ways for the patient compliance.

### Single Core Osmotic Pump (SCOP)

In starting osmotic that delivery system doesn't know about the single core osmotic pump devices. The single core osmotic pump devices are formulated and introduced first in 1970 to deliver a drug at 0 order rate for prolonged action and it is having minimum dependency on the environmental factor such as motility and pH. In the single core osmotic pump devices which can be formulated in the form of tablets consist of a core in which drug is enclosed and which is surrounded by a semi permeable membrane and drilled with laser and formation of an orifice. When this osmotic pump delivery system of single core which is in the form of tablet mostly injected in the body then Water is absorbed in its surrounding such as GIT fluid dissolve the drug present in the single Core and due to the formation of osmotic pressure over here the drug start dissolving and pushing it outside from the core and releasing in the system.<sup>[1,2]</sup>



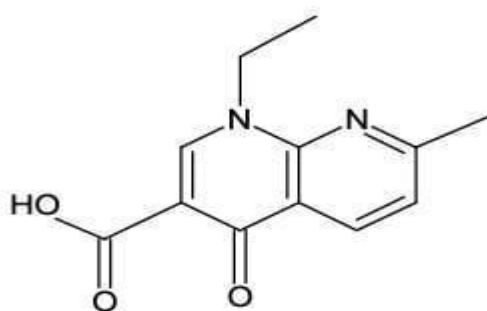
**Fig. 1.1: Single Core osmotic pump.**

### Norfloxacin

For the treatment of various types of diseases the fluoroquinolones which are derivatives of quinolones and having a broad spectrum antibiotic nature are used. In the recent 10 years

comma these drugs shows a promising effect in various types of bacterial problems and gain its clinical attention in this years. In comparison of different types of Beta lactom antibiotics this drug is found to be more promising as it has the property of oral absorption and synthetically derived agents with special requirements. In 1962 Nalidixic acid was the first anti microbial agent that had been synthesized. After that so many chemical agents has been synthesized and introduced in therapy of anti microbial activity. Dissolved drugs having abroad spectrum of antibacterial activity that includes gentamicin resistance and gentamicin susceptible streams of pseudomonas arroginosa. Norfloxacin is a very important component of this antibacterial broad spectrum family and it is the first choice of patience for the diagnosis and treatment of infections caused by bacteria in the binary infection urinary infection and respiratory tract infection. The norfloxacin was the first agent of fluoroquinolones to be used as therapeutic agent. The patent was applied in 1978 for norfloxacin to become first agent of fluoroquinolones and approved by us FDA in 1984. Norfloxacin inhibits the amino glycoside resistant pseudomonas Arrow genosa and beta lectomys producing microorganism full stop there are multiple derivative of this family associated with this drug play a vital role for the treatment and having high demand in clinical practice.

From nlidixic acid all other floroquinolones derivatives are synthesized. If we observe the chemistry of Norfloxacin is 1- ethyl-6-fluoro 1,4- dihydro-4-oxo-7-(1-piperazinyl) -3-quinolone carboxylic acid. The chemical structure of Norfloxacin is  $C_{16}H_{18}FN_3O_3$ . If we observe it's physical properties, then it's melting point is  $221^{\circ}C$ , it's molecular weight is 319.331 dalton and it's color is white to pale yellow and in texture, it is crystalline powder. In taste it is very bitter and having no sense of odor. Now, coming towards it's solubility, it is very slightly soluble in water, ethanol and methanol and freely soluble in glacial acetic acid. It's distribution coefficient is 0.46 in octanol- water system.<sup>[3,5]</sup>



**Fig. 1.2: Chemical structure of Nalidixic Acid.**



**Fig 1.3: Chemical structure of Norfloxacin.**

## **MATERIALS AND METHODS**

### **Chemical Required**

All the ingredients used in this study were of standard pharmaceutical ranking. Norfloxacin were obtained from the Sigma Aldrich, Merck India. Natrosol Polyox WSR Coagulant, Methocel, Cellulose acetate, Klucel, Xanthan Gum, Neosorb P 30/60, Xylitol, Citric Acid, Polyethylene glycol 4000, Sodium lauryl sulphate were obtained from SHEAT College of Pharmacy and of analytical reagent ranking.

### **Apparatus Required**

The apparatus which are needed for making single core osmotic pump tablet are- Weighing Balance, Spatula, Butter Paper, Measuring Cylinder, Beaker, Glass rod, Sieve #22, Tablet punching machine, Mortar and pestle, Hot air oven, Funnel, Burette stand, Digital vernier caliper, Monsanto Hardness tester, Friability test apparatus, Scanning electron microscope, etc.

### **Procedure for formulation of Single Core osmotic pump tablet of Norfloxacin<sup>[6,8]</sup>**

- The direct compression method is applied for the formulation of core tablets.
- The polyox coagulant, Xanthum gum, Methocel K4M, klucel HF and Natrosol 250 HX were used in core 10% w/w to prepare the formulations and to select a water swellable polymer.
- Then the release profile of these polymers were analysed for estimating the effects of these polymers.
- The Norfloxacin were added with swellable polymer and stirred for 10 minutes.
- Then by using a 40- mesh screen, the above mixture were sieved and a binder and osmotic agent were added in it for geometric dilution.

- After adding in geometric dilution, it is again mixed for 10 minutes.
- Then SLS and acryflow- 1 which are the wetting agent and lubricant were added in the mixture and again stirred for the 5 minutes.
- By using Rotatory tablet machine, and weighing the powder for an average weight that is,  $695 \pm 10$  mg and directly compacted as a tablet. The rotatory tablet machine consist of 13 mm diameter round, smooth, and standard concave tooling.
- **Coating and Drilling**
  - By the use of a traditional laboratory coating pan, the single core tablets were processed for coating.
  - By using the polymers such as PEG-4000 and cellulose acetate 398-10, the coating solution were prepared. In this coating solution, 356 grams of acetone and 20 grams of water added.
  - The tablet were heated for a specific temperature that is,  $40 \pm 5^\circ\text{C}$  for 10 minutes and then the coating process of tablet were started.
  - The coating solution was sprayed continuously on the tablets by the constant rate of 4-5 ml/min.
  - The coating method was applied on a 100 tablet batch.
  - The 20 rpm speed was maintained in the rotational pan and the temperature of the hot air input was maintained at  $40 \pm 5^\circ\text{C}$ .
  - By the use of mechanical micro drills the osmotic coated tablet was drilled and perforated by one side. The 850  $\mu\text{m}$  diameter orifice were created for the release of drug.

**Table 1.1- Formulation of Single Core osmotic pump tablet of Norfloxacin.**

Ingredients (mg)	N1	N2	N3	N4	N5	N6
Norfloxacin	200	200	200	200	200	200
Polyox Coagulant	-	50	-	-	-	-
HPMC K4M	-	-	50	-	-	-
Natrosol 250 HX	-	-	-	50	-	-
Xanthan Gum	-	-	-	-	50	-
Klucel HF	-	-	-	-	-	50
Neosorb P30/60DC	336	276	276	276	276	276
Klucel EXF	40	40	40	40	40	40
Citric acid	115	115	115	115	115	115
SLS	17	17	17	17	17	17
Acryflow-L	7	7	7	7	7	7

**Table 1.2: Coating membrane composition for Single core osmotic pump tablet of Norfloxacin.**

Batch No.	CA: PEG	%Weight Gain	Orifice Diameter	No. of Orifice
N31	6.5:3.5	10	840	1
				2
				4
N32	7.0:3.0	10	840	1
N33	7.5:2.5	10	840	1
N34	8.0:2.0	10	840	1
N35	6.5:3.5	10	340	1
N36	6.5:3.5	10	540	1
N37	6.5:3.5	10	640	1
N38	6.5:3.5	8	8401	1



**Fig-1.4: The Norfloxacin drug (API).**

### Preformulation studies<sup>[9,10]</sup>

#### Organoleptic properties of Drug

The colour, odour, taste and texture were the important features that were tested in the organoleptic study of the active pharmaceutical ingredient or are of the selected drug.

#### Identification of drug

In the sector of pharmaceutical research, environment, food, agricultural for the quality control of many products, the most authenticated method were used over the last 10 years and known as Infrared Spectroscopy for the identification of drug. The Fourier transform infrared spectroscopy were one of the authenticated method used for identification of a compound. For the pharmaceutical analysis, the FTIR (Fourier-transform infrared

spectroscopy) were proved as brilliant procedure which claims many merits meanwhile the time it is in use, it is easy, selective, green, fast, sensitive and help to guaranteed regulations conformity via the protocols of validation.

### **Solubility of Drug**

The Solubility is defined as the liquification of a specific amount of molecular in a particular portion of fluid at an optimum decided temperature, and as the solubility rate will enhanced, the bioavailability of the compound were also increased.

There were different solvents such as ethanol, methanol and water were used for the evaluation of a specific molecule solubility. In a test tube take 5 ml of various solvents and add the tweak of a drug molecule, and shake it properly for 5 to 10 minutes. By this process, the solubility of a drug compound can be determined.

### **Molecular weight of drug**

The molecular weight of the drug were estimated by using the weight of each atom used for the composition of the drug.

### **Partition Coefficient of drug**

The volume of a medication to cross the cell membrane and its volume of lipophilicity is recognized as its Partition coefficient. The n-octanol, phosphate buffer were used to estimate the partition coefficient of Norfloxacin. A separating funnel were taken and 50 mg of drug were added in 50 ml of n-octanol phosphate buffer. Until the equilibrium were gained, till then, the solvent moisture were shaken. The Whatman filter paper no. 41 is used to filter the phosphate buffer and the stages of the solvent moisture were detached by using separating funnel.

### **Melting point of drug**

The capillary fusion technique in the most mutual method used for determining the melting point. A capillary tube is used to take the model and the heat will be provided to the sample, until its start melting and ranges to its melting point. Hence, the melting point can be stated.

### **Infrared spectroscopy**

To examine the functional group of a compound, The Infrared spectroscopy is done such as – CN, -OH, -CH, -NH<sub>2</sub>, -CO. Reliant upon the concentration of part, the solid drug examples were assorted in pellet of KBr or polyethylene The vessel is occupied with KBr pellet and 50



mg of medication samples and the Infrared rays were approved through it. On the Spectrography (a graph), the outcome will be experimental with the proportion of transmittance on Y-axis and wavenumber on X axis the amount of transmittance was noted on the graph.

The FTIR positions for fourier transform infrared spectroscopy. The FTIR is a novel adding in Genetic and taxonomic technique, and it is used to recognize the microorganism.

### **Drug excipients Interaction**

We cannot describe the real process used for gaining the interaction between medication and excipients. In numerous literature, there are many systems are given for this, If we associate, then in evaluation of excipient and excipient interaction, the medicine- excipient interaction happens more. The medication excipient interface can be triggered due to numerous details, on this basis, it can be categorized into two sorts as follows

- Physical interactions
- Chemical Interactions

- **Physical interactions**

The physical interaction is very mutual now a days, but then also the procedure to perceive it is difficult. At the time of manufacturing numerous dosage forms, such as, a drug dissolution modification, a physical interaction can happen. Due to this, the act of the product can differ.

- **Chemical Interactions**

At the time of development of numerous molecules, the response can be occur between the medications and remains/froths current in the excipients or the chemical reaction between the medications and excipients. The chemical interaction can reason the ruin of the pharmaceutical product. The ruin of the creation is defined in ICHQ3B (ICH guideline ICHQ3B 2008).

For determining the drug excipient interface trainings in our investigation work, we had perform the Fourier Transform Infrared Spectroscopy (FTIR).

### **Standard curve for the quantitative estimation of drug**

A 10 ml of solution was prepared in which 10mg drug was mixed with 0.1 N hcl with slightly shaking. 1 ml of this mixture was withdrawn and used for the formulation of stock solution. From this stock solution different concentration was taken and diluted as different samples



and absorbance was estimated at 278 nm. The calibration curve was plotted according to the concentration and absorbance value. The regression value and correlation coefficient was calculated.

### **Evaluation and Characterization<sup>[11,13]</sup>**

- **Evaluation of granules**

The granules were evaluated for estimation of better flow properties of particles. There are various parameters for this purpose are as follows-

#### **Angle of Repose**

First of all, the granule sample were poured in the funnel which is associated with a burette stand at a particular height. This step is responsible for making a pile on a graph paper. Now take a scale and measure the height of the pile and draw a circle with the help of pencil around the circumference of granules.

Therefore,

Where,  $\theta$  is the angle of repose.

#### **Bulk density**

$$\tan \theta = h/r \text{ or } \theta = \tan^{-1} (h/r)$$

The granule sample were transferred in a measuring cylinder and by the scale of cylinder the bulk volume of sample were noted and granules sample weight should be taken. The formula is

$$D_b = M/V_b$$

Where, M is the mass of powder

and  $V_b$  = bulk volume of the powder.

#### **Tapped density**

The granule was weighted and transferred in a measuring cylinder. The measuring cylinder tapped for at least 20 minutes duration about 100 times and tapped volume were observed

$$D_t = M/V_t$$

Where,

M = mass of powder

$V_t$  = tapped volume of the powder.

**Compressibility Index**

The granules sample compression property can be calculated if we have the exact value of tapped density and bulk density

Therefore,

$$\text{Compressibility index} = (D - D / D) \times 100$$

Where, D = the tapped density D = bulk density.

**Hausner's Ratio**

It is the ratio of bulk volume and tapped volume difference associated with its weight of granule sample.

$$\text{Hausner's Ratio} = \text{Tapped Density} / \text{Bulk Density}$$

- **Evaluation of Pre-coated tablet**

The characteristic like hardness thickness, fragile nature of tablet, drug percentage present in the tablet and distribution of drug uniformly was evaluated before coating of tablet are as follows

**Hardness of Pre-coated Tablet**

The tablet were placed at the right angle between the jaws of the hardness tester. After that screw gauge fitted tightly and pressure developed over there is measured for testing the hardness of tablet.

**Thickness**

Before coating of the tablets the tablet wall thickness was evaluated by using Vernier caliper.

**Weight variation test of Pre-coated Tablet**

There are total 6 types of formulation which were weight separately and a mean value were calculated. Then weight of each tablet was compared by mean weight of the tablets.

**Friability of Pre-coated Tablet**

For testing the property of tablets to withstand scrape in packing, conveying and handling the friability test were used. The average friability percentage for all the preparations were found within the boundaries as per the standard.

**Drug content uniformity of Pre-coated Tablet**

The random 25 tablets were weighed separately and transferred in a mortar, and triturated in the powder form. 15 gram of sample powder were taken and mixed with phosphate buffer 6.8 to make a 100 ml solution. The solution were filtered by using filter media and its absorbance was estimated on double beam UV Spectrophotometer.

- **Evaluation of coated tablet- The thickness of tablet**

After coating of the tablets the tablet coated wall thickness was evaluated by using Vernier caliper.

**Thickness of film**

When the thickness of pre-coated tablet was detected from the coated tablet thickness, the value which is found is considered as thickness of film.

$$\text{Thickness of coat} = \frac{\text{Thickness of coated tablet} - \text{Thickness of uncoated tablet}}{2}$$

**Weight variation test**

There are total 6 types of formulation which were weight separately and a mean value were calculated. Then weight of each tablet was compared by mean weight of the tablets.

**In vitro release studies**

Type-2 dissolution apparatus used for estimation for drug release from the single core osmotic pump tablet and the speed was set at 50 rpm at a constant temperature. time to time upto 24 hours the sample +dissolution medium at each hours was withdrawn upto 5 ml.

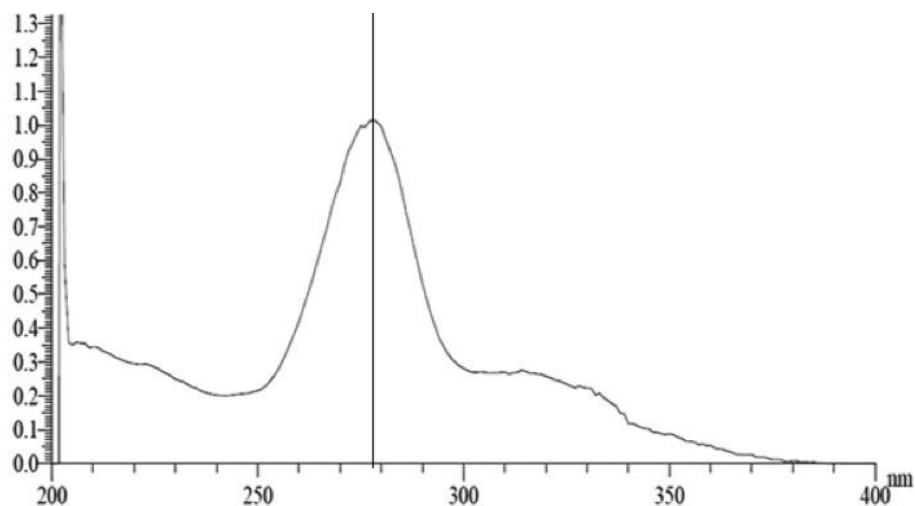
**RESULT AND DISCUSSION****RESULT****Preformulation studies****Organoleptic Evaluation of Norfloxacin**

The organoleptic evaluation of Norfloxacin were estimated as

S.No	Colour	Odour	Taste	Texture
1	White to pale yellow	Odourless	Bitter	Hygroscopic, Photo sensitive crystalline powder

### Identification of Norfloxacin

The U.V Spectroscopy and FTIR were performed for the identification of Norfloxacin. The U.V absorbance maxima of Norfloxacin was shown at 278 nm.



**Fig 1.5: UV Spectra of Norfloxacin.**

### Solubility of Norfloxacin

The solubility of Norfloxacin was evaluated and the following results were found.

S.NO.	Solvent	Solubility in mg/ml
1	Methanol	2.43
2	Acetone	2.6
3	Water	0.45

### Partition Coefficient

Partition coefficient of Norfloxacin was observed by taking its three readings to get an average value.

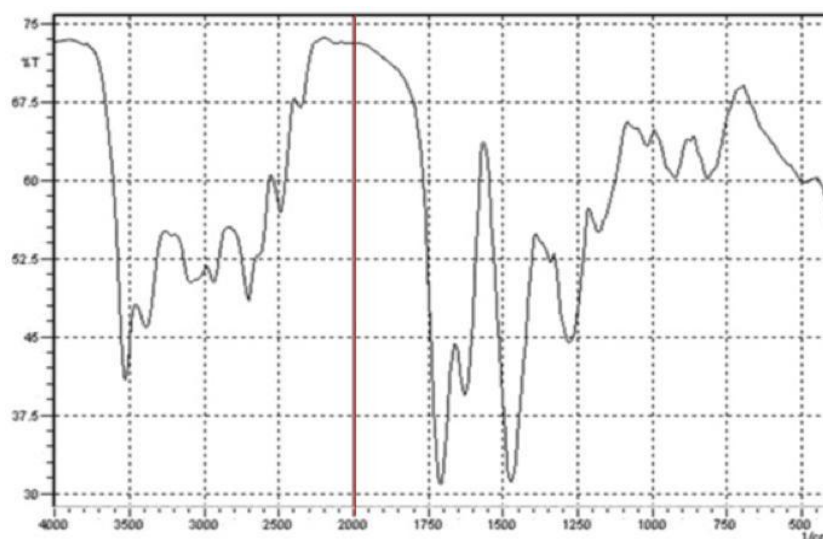
S. No.	Drug	Partition coefficients (log p)
1	Norfloxacin (I reading)	0.50
2	Norfloxacin (II reading)	0.48
3	Norfloxacin (III reading)	0.46

### Melting point of Norfloxacin

The capillary fusion method was used to evaluate the melting point of Norfloxacin and the observation was as follows.

S. No.	Method Used	Experimental values
1	Capillary Fusion Method (I reading)	219°C- 221°C
2	Capillary Fusion Method (II reading)	220°C- 222°C
3	Capillary Fusion Method (III reading)	221°C- 223°C

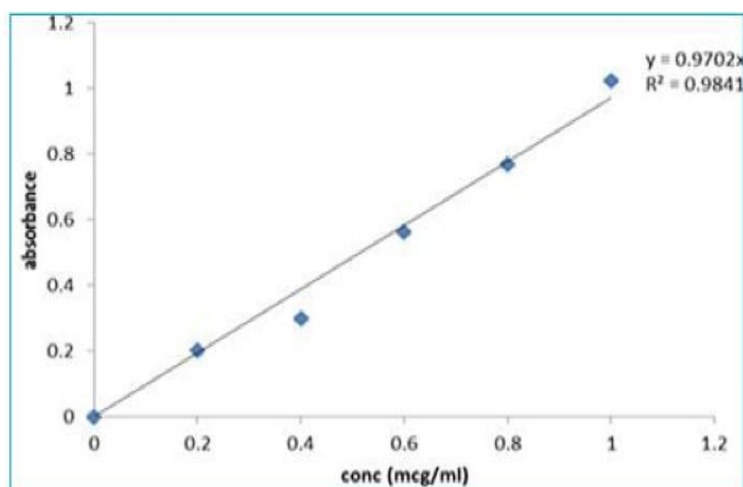
### FTIR of Norfloxacin



**Fig 1.6: FTIR Spectra of Norfloxacin.**

Functional Group	Observed IR Range of Norfloxacin
Hydroxyl group	3550–3500
Imino-moiety of piperazinyl groups	3500–3300
Aromatic, cyclic enes	3000–2950
Ethyl group	2750–2700
Acid group	2500
Carbonyl of acids	1700
Quinolones	1650–1600
O–C–O group of acid	1500–1450
Hydroxyl group	1300–1250
C–F groups	1050–1000
Amines	950–900
Aromatic <i>m</i> -distribution	800

### Standard curve of Norfloxacin



**Fig 1.7: Standard curve of Norfloxacin.**

Concentration ( $\mu\text{g/ml}$ )	Absorbances (nm)
0	0
0.2	0.205
0.4	0.295
0.6	0.552
0.8	0.758
1	1.023

- Evaluation of Granules of Norfloxacin**

**Table 1.3-Angle of Repose Norfloxacin granules.**

Formulations	Angle of repose( $\theta$ )
N1	26.62 $\pm$ 0.43
N2	27.88 $\pm$ 0.73
N3	28.12 $\pm$ 0.35
N4	27.71 $\pm$ 0.05
N5	28.63 $\pm$ 0.32
N6	28.70 $\pm$ 0.06

mean  $\pm$  SD (n=3).

**Table 1.4-Bulk density of Norfloxacin granules.**

Formulation code	Bulk density ( $\text{gm/cm}^3$ )
N1	0.2569 $\pm$ 0.003
N2	0.2591 $\pm$ 0.013
N3	0.2418 $\pm$ 0.002
N4	0.2420 $\pm$ 0.003
N5	0.2522 $\pm$ 0.003
N6	0.2521 $\pm$ 0.004

mean  $\pm$  SD (n=3)

**Table 1.5-Tapped density of Norfloxacin granules.**

Formulations	Tapped density (gm/cm <sup>3</sup> )
N1	0.3104±0.013
N2	0.3113±0.003
N3	0.3279±0.002
N4	0.3112±0.014
N5	0.3188±0.014
N6	0.3526±0.003

mean ± SD (n=3)

**Table 1.6- Compressibility index of Norfloxacin granules.**

Formulations	Compressibility index (%)
N1	12.34±0.19
N2	14.07±0.93
N3	13.84±0.42
N4	13.63±0.58
N5	13.74±0.22
N6	13.51±0.13

mean ± SD (n=3)

**Table 1.7- Hausner's of Norfloxacin granules.**

Formulations	<u>Hausner's ratio</u>
N1	1.12±0.02
N2	1.13±0.01
N3	1.09±0.03
N4	1.16±0.02
N5	1.14±0.04
N6	1.13±0.03

mean ± SD (n=3)



- Evaluation of Pre-coated Norfloxacin Tablet

**Table 1.8- Drug content uniformity of Norfloxacin Single Core osmotic pump pre-coated tablet.**

Formulations	% drug content
N1	96.40± 0.4064
N2	98.03±0.2510
N3	99.25 ± 0.1355
N4	98.20±0.1296
N5	97.29±0.1822
N6	98.83±0.1255

**Table 1.9- Thickness (in mm) of Norfloxacin Single Core osmotic pump pre-coated tablet.**

Formulations	Thickness
<b>N1</b>	3.15±0.1280
<b>N2</b>	3.62±0.0902
<b>N3</b>	3.79±0.0773
<b>N4</b>	3.58±0.2153
<b>N5</b>	3.55±0.1409
<b>N6</b>	3.80±0.1129

**Table 1.10- Weight variation test of Norfloxacin Single Core osmotic pump pre-coated Tablet.**

Formulations code	Average weight (mg) (n=20)
N1	270±0.3964
N2	271±0.1842
N3	273.4±0.3211
N4	275.7±0.2515
N5	279.5±0.2093
N6	276±0.2430

**Table 1.11- Hardness test of Norfloxacin Single Core osmotic pump pre-coated tablet.**

Formulations code	Hardness (kg/cm <sup>2</sup> ) (n=10)
N1	3.43±0.1725
N2	2.75±0.1519
N3	3.70±0.1420
N4	4.05±0.0945
N5	3.62±0.1975
N6	3.50±0.1242

Table 1.12- Friability test of Norfloxacin Single Core osmotic pump pre-coated tablet.

Formulations code	Friability (%) (n=20)
N1	0.40±0.006
N2	0.24±0.02
N3	0.32±0.09
N4	0.38±0.015
N5	0.37±0.009
N6	0.41±0.010

- Evaluation of Coated Norfloxacin Tablet

Table 1.13- Thickness of Norfloxacin Single Core osmotic pump coated tablet.

Formulations code	Thickness of coated tablet (mm) (n=10)
N1	4.55±0.0160
N2	4.58±0.0222
N3	4.59±0.0193
N4	4.63±0.0130
N5	4.66±0.0121
N6	4.60±0.0391

Table 1.14- Weight variation of Norfloxacin Single Core osmotic pump coated tablet.

Formulations code	Average weight (mg) (n=20)
N1	285±0.8760
N2	287±0.9780
N3	287±0.7249
N4	289±0.7992
N5	291±0.3589
N6	280±0.3543

### Scanning Electron Microscopy Of Norfloxacin Single Core Osmotic Pump Coated Tablet

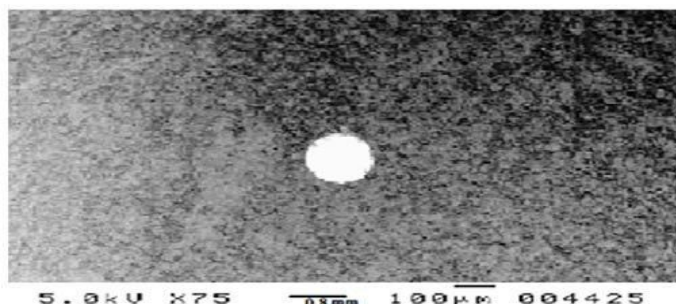
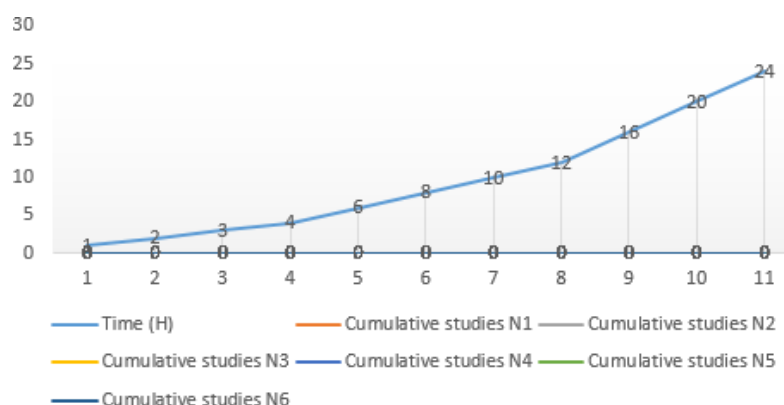


Fig 1.7- Scanning electron microscopy of Norfloxacin Single Core osmotic pump coated table.

**Table 1.15- *In vitro* release studies of Norfloxacin Single Core osmotic pump coated Tablet.**

Time (H)	Cumulative studies					
	N1	N2	N3	N4	N5	N6
1	0.456±0.17	0.875±0.40	0.987±0.30	0.879±0.10	0.949±0.32	0.605±0.62
2	0.845±0.28	1.203±0.95	1.373±0.60	1.003±0.12	1.259±0.65	3.065±0.23
3	2.688±0.62	3.220±0.20	2.142±0.65	1.730±0.29	4.251±0.50	4.241±0.33
4	5.253±0.61	5.060±0.70	4.612±0.49	7.312±0.31	5.268±0.92	5.271±0.43
6	11.82±0.70	11.41±0.01	17.45±0.19	9.231±0.43	11.45±0.75	15.81±0.60
8	21.53±0.60	33.75±0.09	20.73±0.70	22.30±0.25	16.21±0.61	17.95±0.83
10	29.73±0.49	54.90±0.20	32.41±0.25	25.91±0.62	24.91±0.32	30.05±0.45
12	45.84±0.30	76.62±0.51	52.02±0.34	46.21±0.52	40.62±0.13	44.51±0.30
16	73.18±0.69	85.83±0.63	75.73±0.17	60.01±0.90	55.24±0.05	52.79±0.03
20	94.03±0.65	94.40±0.80	93.02±0.24	71.43±0.80	73.02±0.40	65.52±0.70
24	94.56±0.39	94.93±0.43	94.54±0.15	83.70±0.40	78.52±0.32	86.23±0.62



**Fig 1.8- Line graph for *In vitro* release studies of Norfloxacin Single Core osmotic pump coated tablet.**

## DISCUSSION

The organoleptic belongings of Norfloxacin were calculated, it is white to off-white color, crystalline powder, tasteless and odorless in nature. The maximum absorbance of Norfloxacin in UV Spectra were detected at 278 nm. FTIR spectra were achieved for Norfloxacin and the peak were shown in above figure. The calibration curve for Norfloxacin were designed.

Afterward that, six types of formulations of Norfloxacin single core osmotic pump tablet were prepared by using direct compression method and post-evaluation of Norfloxacin single core osmotic pump tablet were done for pre- coated tablets and coated tablets such as drug content uniformity, thickness, weight variation, SEM, hardness, friability, in-vitro drug release studies and the results were revealed in the overhead stated tables.

## CONCLUSION

The goal of the current research work were to developed and symbolise the Norfloxacin single core osmotic pump tablet by applying direct compression methods associated with coating and drilling process. Currently a days, the medicine spreading preparation are becoming additional rough day by day, as beneficial academics dealing with original methods for the enhanced considerate of biological and physico-chemical properties to make their performance better-quality. The Osmotic drug delivery system is more active for the release of high dose of drug in comparision conventional oral system. In this research work, we had prepared single layer osmotic pump tablet of norfloxacin to fulfil it's low solubility profile and better patient compliance.

There are total six types of formulations was prepared with different concentrations of excipients by using direct compression method, and coating of tablets and drilling of tablets were performed for better release of drugs due to osmosis process. The granules of tablets and prepared tablets were evaluated for different parameters. From all the result and readings, it can be concluded that, the single layer osmotic ump tablet is found to be better option for the drugs having poor solubility.

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## Conflict of Interest

There is no Conflict of Interest among the authors.

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