**J Young Pharm, 2020; 12(2) Suppl: s39-s44**
A multifaceted peer reviewed journal in the field of Pharmacy
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*Original Article*

# Formulation and Evaluation of Extended Release Matrix Tablets of Tenatoprazole Sodium using Synthetic Polymers

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## ABSTRACT

Extended release formulations are designed to release their medication in a controlled manner at a predetermined rate, duration and location to achieve and maintain optimum therapeutic blood levels of a drug. The present investigation is aimed to formulate the extended release matrix tablets of Tenatoprazole sodium with various grades of different polymers like Carbopol, HPMC and Eudragit grades. The tablets were prepared by wet granulation technique. The prepared ER Matrix tablets were evaluated for various physico chemical parameters. All the formulations resulted in acceptable Pharmacopoeia limits. *In-vitro* drug release studies (USP dissolution rate test apparatus II, 75 rpm, 37°C ±0.5°C) using 0.1N hydrochloric acid (1.2 PH ) for first 2 hrs and phosphate buffer (PH 6.8) as a dissolution medium (900ml) for the next 12 hrs. Among all the formulation F-5(drug: Carbopol-974P-NF in ratio of 1:1.5) shows better result upto 12 hours of the drug release was found to be 99.47±0.22 so it's an Optimized formulation.

**Key words:** Carbopol, ER Matrix, Eudragit, Methocel, Tenatoprazole sodium, Wet granulation.

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**DOI:** 10.5530/jyp.2020.12s.44

## INTRODUCTION

Proton pump inhibitors (PPIs) are very effective in the treatment of symptoms and healing of erosive and ulcerative disease in the spectrum of acid-related disorders. PPIs produce significantly more effective and prolonged acid suppression than H2-receptor antagonists (H2-RAs) and currently available PPIs, at higher daily doses or administration frequencies, can maintain a pH >4 for up to 16–18 h / day. It has been shown that healing in acid-related disorders is directly related to the degree and duration of acid suppression and the length of treatment. However, a significant number of patients with acid-related disorders do not adequately respond to once or even twice daily PPI therapy.[1] A suboptimal symptomatic response to PPI therapy commonly leads the physician to double the PPI dose. The pharmacokinetic properties of the currently available PPIs limit their ability to produce prolonged acid suppression, leading to markedly reduced efficacy during the nocturnal period (Figure 1 and 2).[2] PPIs produce greater acid suppression if taken before food, because the maximum number of acid pumps is inserted into the canalicular membrane and they require an acidic intra-canalicular environment with active acid secretion in the gastric parietal cell to permit conversion to the active sulphenamide and covalent binding of the sulphenamide to effect inhibition of acid secretion. As current PPIs all have similar plasma half-lives between 1 and 2 h, any proton pumps synthesized or activated after the plasma level of the PPI falls below threshold will not be blocked from secreting acid, with the possible exception of sulphenamide derivatives, trapped at high concentration in the secretory canaliculi.[3]

Tenatoprazole is a new PPI that has a prolonged plasma half-life of around 9 h which is 5–7 fold longer than the currently available PPIs. In contrast to current PPIs, characterized by pyridine and benzimidazole moieties, tenatoprazole has an imidazopyridine ring in place of the benzimidazole moiety. The results of several studies indicate that racemic tenatoprazole produces more prolonged suppression of intragastric acidity than esomeprazole, an S-enantiomer of omeprazole that is more effective than its parent racemic compound. STU-Na is the S-enantiomer of tenatoprazole and, preliminary pharmacological studies indicate that it too may be more effective than its parent racemic compound.[4,5]

## MATERIALS AND METHODS

Materials: Tenatoprazole sodium was received as a gift sample from LARA DRUGS PVT LTD, Hyderabad. Carbopol-941P, Carbopol-974P-NF, Methocel K4M, Methocel K100 LV, Eudragit-S 100, L-100, RS100, RL-100 was supplied by Yarrow Chem Products, Mumbai. PVP-K 30, IPA, Aerosil, Magnesium Stearate and Microcrystalline Cellulose was supplied by Signet Chem Mumbai.

## METHODS

### Preformulation Studies

### Standardization of Tenatoprazole sodium by UV-Visible Spectrophotometry

**a) In 0.1 N Hcl Solution**

**i) Preparation of stock solution:** Stock solution 100µg/ml Tenatoprazole sodium was prepared in 0.1N Hcl solution. This solution was approximately diluted with 0.1N Hcl to obtain a concentration of 10µg/ml. The resultant solution was scanned in range of 200- 400nm using UV double beam spectrophotometer (Lab India UV-3000+).

**ii) Standard calibration of Tenatoprazole sodium in 0.1N Hcl:** 100mg of Tenatoprazole sodium was accurately weighed and dissolved in 100ml of 0.1N Hcl to obtain a concentration of 1000µg/ml. From the above 10ml was withdrawn and diluted to 100ml to obtain a concentration of 100µg/ml. From this stock solution aliquots of 0.5ml, 1ml, 1.5ml, 2ml

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and 2.5ml were diluted in 10ml volumetric flask with phosphate buffer to give concentrations in range of 5µg/ml to 25µg/ml respectively, absorbance was measured at 236nm.

**b) In pH 6.8 phosphate Buffer (Table 4)**

**i) Preparation of stock solution:** Stock solution 100µg/ml of Tenatoprazole sodium was prepared in phosphate buffer of pH 6.8. This solution was approximately diluted with phosphate buffer of pH 6.8 to obtain a concentration of 10µg/ml. The resultant solution was scanned in range of 200- 400nm using UV double beam spectrophotometer (Lab India UV-3000+).

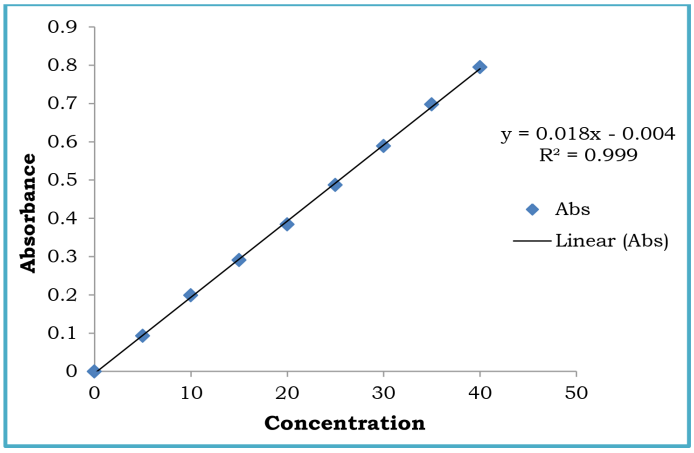


**Figure 1:** Standard graph of Tenatoprazole sodium pH 6.8 phosphate buffer.

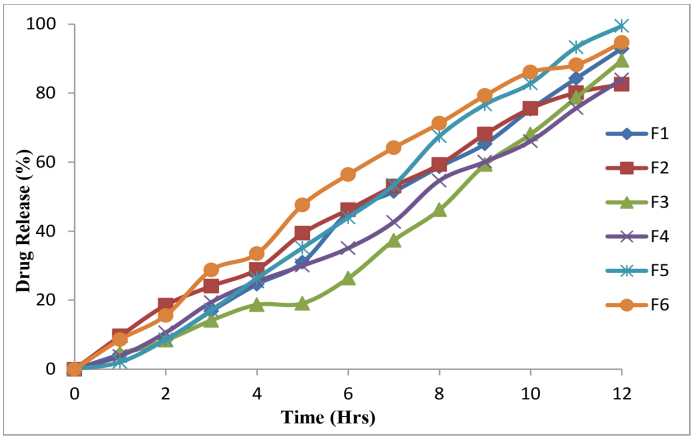


**Figure 2:** Dissolution profiles of Formulations F1-F6.

**ii) Standard calibration of Tenatoprazole sodium in phosphate buffer of pH 6.8:** 100mg of Tenatoprazole sodium was accurately weighed and dissolved in100ml of pH 6.8 phosphate buffer to obtain a concentration of 1000µg/ml. From the above 10ml was withdrawn and diluted to 100ml to obtain a concentration of 100µg/ml. From this stock solution aliquots of 0.5ml, 1ml, 1.5ml, 2ml and 2.5ml were diluted in 10ml volumetric flask with phosphate buffer to give concentrations in range of 5µg/ml to 25µg/ml respectively, absorbance was measured at 238nm.[6]

## FORMULATION DEVELOPMENT OF TABLETS

### Preparation of Tablets

**Wet granulation method:** All the powders were passed through 80 mesh. Required quantities of Tenatoprazole sodium, polymer, binder (PVPK30), Sodium bicarbonate were mixed thoroughly and a sufficient volume of granulating agent (Isopropyl alcohol) was added slowly. After enough cohesiveness was obtained, the mass was sieved through 22/44 mesh. The granules were dried at 40°C for 12hrs. Once, dry the granules retained on 44 mesh were mixed with 10% of fine granules that passed through 44 mesh (Figure 3, 4). Aerosil and magnesium stearate were added as glidant and lubricant. Finally MCC is added to make up 250mg. In all formulations, the amount of the active ingredient is equivalent to 40 mg of Tenatoprazole sodium (Table 1, 2)

### Evaluation of Tenatoprazole sodium ER matrix tablets

### Evaluation of granules

### Angle of repose

The angle of repose of granules was determined by the funnel method. The granules were allowed to flow through the funnel freely onto the surface. The diameter of the powder cone was measured and angle of repose was calculated using the following equation.

$$\text{Tan } \theta = h/r$$

Where h and r are the height and radius of the powder cone.

### Bulk Density

Both loose bulk density and tapped bulk density were determined and calculated by using the following formulas.

**Table 1: Composition of extended release matrix tablets of Tenatoprazole sodium using synthetic polymers.**

| INGREDIENTS | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
|---|---|---|---|---|---|---|---|---|---|
| Tenatoprazole sodium | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 |
| Carbopol-941P | 40 | 60 | 80 | --- | --- | --- | --- | --- | --- |
| Carbopol-974P-NF | --- | --- | --- | 40 | 60 | 80 | --- | --- | --- |
| Methocel K4M | --- | --- | --- | --- | --- | --- | 40 | 60 | --- |
| Methocel K100LV | --- | --- | --- | --- | --- | --- | --- | --- | 40 |
| PVP-K 30 | 12.5 | 12.5 | 12.5 | 12.5 | 12.5 | 12.5 | 12.5 | 12.5 | 12.5 |
| Sodium bicarbonate | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| IPA | QS | QS | QS | QS | QS | QS | QS | QS | QS |
| Aerosil | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Mg.Stearate | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| MCC | 137.5 | 117.5 | 97.5 | 137.5 | 117.5 | 97.5 | 137.5 | 117.5 | 137.5 |
| Total Weight(mg) | 250 | 250 | 250 | 250 | 250 | 250 | 250 | 250 | 250 |

**Table 2: Composition of extended release matrix tablets of Tenatoprazole sodium using synthetic polymers.**

| INGREDIENTS | F10 | F11 | F12 | F13 | F14 | F15 | F16 | F17 | F18 |
|---|---|---|---|---|---|---|---|---|---|
| Tenatoprazole sodium | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 |
| Eudragit-S 100 | --- | 40 | 60 | --- | --- | --- | --- | --- | --- |
| Eudragit-L 100 | --- | --- | --- | 40 | 60 | --- | ---- | --- | --- |
| Eudragit-RS 100 | --- | --- | --- | | | 40 | 60 | --- | --- |
| Eudragit-RL 100 | 60 | --- | --- | --- | --- | --- | --- | 40 | 60 |
| Sodium bicarbonate | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| PVP-K 30 | 12.5 | 12.5 | 12.5 | 12.5 | 12.5 | 12.5 | 12.5 | 12.5 | 12.5 |
| IPA | QS | QS | QS | QS | QS | QS | QS | QS | QS |
| Aerosil | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Mg.Stearate | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| MCC | 117.5 | 137.5 | 117.5 | 137.5 | 117.5 | 137.5 | 117.5 | 137.5 | 117.5 |
| Total Weight(mg) | 250 | 250 | 250 | 250 | 250 | 250 | 250 | 250 | 250 |

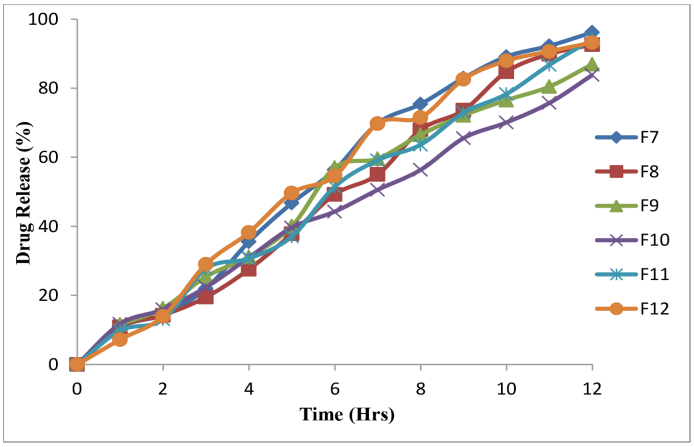


**Figure 3:** Dissolution profiles of Formulations F7-F12.

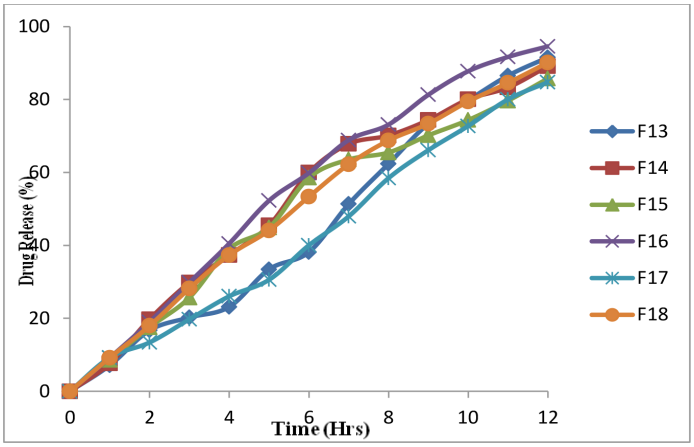


**Figure 4:** Dissolution profiles of Formulations F13-F18.

**Table 3: Observations for graph of Tenatoprazole sodium in 0.1N HCl (236nm).**

| S.No | Concentration(µg/ml) | Absorbance(nm) |
|---|---|---|
| 1 | 0 | 0 |
| 2 | 5 | 0.111 |
| 3 | 10 | 0.216 |
| 4 | 15 | 0.303 |
| 5 | 20 | 0.406 |
| 6 | 25 | 0.511 |

**Table 4: Observations for graph of Tenatoprazole sodium in pH 6.8 phosphate buffer (238nm).**

| S.No | Concentration(µg/ml) | Absorbance(nm) |
|---|---|---|
| 1 | 0 | 0 |
| 2 | 5 | 0.092 |
| 3 | 10 | 0.200 |
| 4 | 15 | 0.289 |
| 5 | 20 | 0.385 |
| 6 | 25 | 0.486 |

LBD = weight of the powder / volume of the packing

TBD = weight of the powder / tapped volume of the packing

**Compressibility Index:** The compressibility index of the granules was determined by Carr's compressibility index.

$$\text{Carr's index (\%)} = [\text{TBD-LBD}] \times 100/\text{TBD}$$

**Hausner's ratio:** The Hausner's ratio is a number that is correlated to the flowability of a powder or granular material. The ratio of tapped density to bulk density of the powders is called the Hausner's ratio. It is calculated by the following equation.[7]

$$H = \text{Tapped density / Bulk density}$$

## Evaluation of tablets

**Average weight:** To study weight variation, 20 tablets of each formulation were weighed using an electronic balance (Sartorius India, limited) and the test was carried according to the Indian Pharmacopoeia.[8]

**Drug Content:** Five tablets were weighed individually and the drug was extracted in pH 6.8 phosphate buffer. The drug content was determined according to the IP.

**Hardness and Friability:** The hardness and friability were determined using the Monsanto hardness tester (Cadmach, Ahmedabad, India) and the friability testing apparatus (Indian equipments, Mumbai, India), respectively.[9]

**Table 5: PRE Compression Parameters.**

| F.Code | Bulk density (g/ml) | Tapped density (g/ml) | Hausner's ratio | Carr's Compressibility Index (%) | Angle of repose (θ) |
|---|---|---|---|---|---|
| F1 | 0.426±0.28 | 0.524±0.39 | 1.230±0.32 | 18.70±0.37 | 24.12±0.24 |
| F2 | 0.431±0.36 | 0.537±0.17 | 1.245±0.09 | 23.20±0.13 | 24.65±0.18 |
| F3 | 0.412±0.09 | 0.479±0.15 | 1.162±0.17 | 13.98±0.05 | 25.77±0.27 |
| F4 | 0.467±0.37 | 0.558±0.14 | 1.371±0.16 | 16.51±0.68 | 26.09±0.34 |
| F5 | 0.574±0.33 | 0.602±0.16 | 1.048±0.58 | 12.98±0.36 | 27.18±0.06 |
| F6 | 0.471±0.15 | 0.588±0.17 | 1.248±0.05 | 19.89±0.24 | 25.08±0.17 |
| F7 | 0.543±0.28 | 0.646±0.15 | 1.189±0.11 | 15.94±0.47 | 23.33±0.26 |
| F8 | 0.481±0.32 | 0.542±0.16 | 1.126±0.08 | 19.06±0.14 | 25.11±0.25 |
| F9 | 0.452±0.11 | 0.629±0.23 | 1.391±0.23 | 21.67±0.03 | 24.72±0.43 |
| F10 | 0.536±0.34 | 0.650±0.26 | 1.212±0.17 | 17.46±0.48 | 26.67±0.28 |
| F11 | 0.564±0.22 | 0.602±0.19 | 1.067±0.14 | 20.59±0.43 | 26.13±0.43 |
| F12 | 0.581±0.37 | 0.599±0.15 | 1.031±0.08 | 17.29±0.28 | 24.52±0.44 |
| F13 | 0.431±0.07 | 0.497±0.17 | 1.153±0.17 | 19.83±0.16 | 22.06±0.13 |
| F14 | 0.544±0.19 | 0.602±0.04 | 1.106±0.99 | 21.05±0.25 | 26.64±0.08 |
| F15 | 0.490±0.19 | 0.552±0.27 | 1.126±0.12 | 18.49±0.06 | 25.89±0.15 |
| F16 | 0.436±0.18 | 0.586±0.22 | 1.344±0.16 | 17.14±0.06 | 27.13±0.17 |
| F17 | 0.412±0.07 | 0.477±0.13 | 1.157±0.08 | 20.14±0.03 | 22.27±0.18 |
| F18 | 0.503±0.13 | 0.598±0.29 | 1.1899±0.04 | 19.61±0.11 | 23.43±0.05 |

The data are presented as mean value ± S.D. (n = 3)

**Table 6: Evaluation of sustained release matrix tablet.**

| F.Code | Weight variation(mg) * | Thickness (mm) ¥ | Hardness (kg/cm²) Ӿ | Friability (%) ψ | % Drug Content € |
|---|---|---|---|---|---|
| F1 | 250±0.41 | 3.66±0.23 | 4.98±0.56 | 0.78±0.04 | 98.19±0.53 |
| F2 | 249±0.72 | 3.99±0.19 | 4.79±1.18 | 0.65±0.03 | 99.51±0.98 |
| F3 | 250±0.98 | 4.13±1.44 | 5.04±0.35 | 0.52±0.02 | 97.14±0.79 |
| F4 | 248±1.16 | 3.57±0.19 | 4.35±0.42 | 0.56±0.27 | 100.48±0.07 |
| F5 | 250±0.09 | 3.78±0.36 | 4.69±0.29 | 0.57±0.25 | 99.98±0.23 |
| F6 | 250±1.79 | 3.89±0.14 | 5.14±0.35 | 0.55±0.04 | 97.54±1.16 |
| F7 | 248±2.04 | 4.07±0.17 | 4.38±0.05 | 0.77±0.18 | 96.74±1.72 |
| F8 | 250±0.21 | 3.69±0.24 | 4.35±0.18 | 0.55±0.19 | 98.14±0.98 |
| F9 | 249±1.17 | 4.15±1.13 | 5.06±0.07 | 0.43±0.11 | 98.88±0.59 |
| F10 | 250±0.28 | 3.06±0.99 | 4.58±0.16 | 0.89±0.07 | 101.26±0.15 |
| F11 | 249±1.26 | 3.67±0.34 | 4.44±0.62 | 0.52±0.13 | 99.14±0.09 |
| F12 | 250±0.89 | 3.15±0.18 | 4.47±0.31 | 0.68±0.24 | 99.22±0.08 |
| F13 | 249±1.31 | 3.98±0.44 | 4.99±0.15 | 0.67±0.05 | 98.69±0.22 |
| F14 | 248±1.87 | 3.33±0.27 | 5.11±0.13 | 0.44±0.22 | 101.04±0.98 |
| F15 | 250±0.26 | 3.59±0.63 | 4.15±0.94 | 0.54±0.03 | 98.96±0.66 |
| F16 | 250±0.94 | 3.99±0.74 | 4.14±1.26 | 0.57±0.12 | 99.16±0.03 |
| F17 | 249±1.44 | 3.89±0.19 | 4.55±0.27 | 0.75±0.54 | 99.25±0.95 |
| F18 | 250±0.88 | 3.44±0.06 | 4.96±0.24 | 0.57±0.16 | 98.86±0.24 |

* = n= 20, ¥ = n =10, Ӿ=n=5, ψ=n=10, €=n=5

## *In-vitro* release studies

### Dissolution Conditions

1) Dissolution Medium and time

a) Gastric Resistance: 0.1N HCl for 2 hours.

b) Dissolution: phosphate buffer pH 6.8 for 10 hrs.

2) Volume: 900ml

3) Apparatus: Type II (paddles)

4) Rotation Speed: 75 rpm

5) Temperature: 37°C + 0.5°C

USP dissolution apparatus type II (Electrolab TDT-08L, Mumbai, India) was used to determine the *in vitro* release of Tenatoprazole sodium from the prepared formulations. The dissolution medium was 900 ml of acidic buffer 0.1 N HCl for 2 h and phosphate buffer (pH 6.8) for 12 hrs. The tablet was kept in to the basket at 37 ± 0.5°C and 75 rpm. Samples (5 mL) were withdrawn at regular time intervals and the dissolution medium was replaced with equal volume fresh dissolution medium. The samples were measured by UV spectrophotometer at 270 nm against a blank.[10,11]

# RESULTS AND DISCUSSION

## Pre formulation studies

**Development of calibration curve for Tenatoprazole sodium:** The scanning of the drug solution in the UV range showed maximum absorbance at 236 nm and hence, the calibration curve was developed at this wavelength. The values are given in Table 3.

## Physical characteristics of blends and tablets

The blends of different formulations were evaluated for angle of repose, Carr's compressibility index etc., the results of Angle of repose and Carr's compressibility Index (%) ranged from 22.06-27.2 and 12.98-23.2 respectively which showed that blends from all the formulations having good flow property. The hardness and percentage friability ranged from 4.1-5.1 kg/cm² and 0.22-0.55% respectively. (Table 5-10)

## *In-vitro* Dissolution Studies

**Table 7: Dissolution release profiles of Formulations (F1-F5).**

| S. No | Time (hours) | Cumulative % drug release*(%) | | | | |
|---|---|---|---|---|---|---|
| | | F1 | F2 | F3 | F4 | F5 |
| 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 1 | 4.28±0.32 | 9.64±0.33 | 4.65±0.27 | 3.82±0.53 | 2.06±0.56 |
| 3 | 2 | 8.62±0.36 | 18.56±0.46 | 8.39±0.48 | 10.62±0.57 | 8.57±0.24 |
| 4 | 3 | 16.85±0.12 | 24.09±0.27 | 14.16±0.63 | 19.43±0.61 | 17.09±0.11 |
| 5 | 4 | 24.61±0.48 | 28.91±0.28 | 18.67±0.87 | 25.40±0.73 | 26.35±0.61 |
| 6 | 5 | 30.97±0.63 | 39.39±0.81 | 19.08±0.38 | 30.01±0.47 | 35.19±0.73 |
| 7 | 6 | 45.36±0.75 | 46.21±0.53 | 26.36±0.59 | 35.07±0.56 | 43.98±0.46 |
| 8 | 7 | 51.49±0.51 | 53.08±0.32 | 37.33±0.79 | 42.66±0.54 | 53.37±0.67 |
| 9 | 8 | 58.66±0.43 | 59.29±0.47 | 46.17±0.71 | 54.65±0.63 | 67.53±0.61 |
| 10 | 9 | 65.28±0.61 | 68.11±0.63 | 59.29±0.42 | 60.09±0.39 | 76.69±0.13 |
| 11 | 10 | 75.31±0.87 | 75.56±0.69 | 68.12±0.68 | 66.08±0.58 | 82.84±0.59 |
| 12 | 11 | 84.27±0.18 | 80.13±0.57 | 78.71±0.54 | 75.64±0.41 | 93.26±0.35 |
| 13 | 12 | 92.91±0.25 | 82.58±0.46 | 89.45±0.71 | 83.95±0.65 | 99.47±0.22 |

The data are presented as mean value ± S.D. (n = 3)

**Table 8: Dissolution release profiles of Formulations (F6-F10).**

| S. No | Time (hours) | Cumulative % drug release*(%) | | | | |
|---|---|---|---|---|---|---|
| | | F6 | F7 | F8 | F9 | F10 |
| 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 1 | 8.62±0.47 | 10.81±0.35 | 10.88±0.58 | 11.60±0.32 | 11.78±0.47 |
| 3 | 2 | 15.60±0.16 | 14.44±0.41 | 14.29±0.69 | 16.29±0.47 | 15.96±0.59 |
| 4 | 3 | 28.73±0.49 | 21.99±0.36 | 19.51±0.17 | 25.45±0.36 | 22.38±0.52 |
| 5 | 4 | 33.49±0.41 | 35.58±0.59 | 27.57±0.43 | 31.21±0.45 | 30.97±0.48 |
| 6 | 5 | 47.61±0.54 | 46.76±0.33 | 37.85±0.65 | 40.07±0.48 | 39.66±0.36 |
| 7 | 6 | 56.41±0.45 | 56.37±0.64 | 49.26±0.77 | 57.02±0.53 | 44.28±0.55 |
| 8 | 7 | 64.18±0.68 | 69.83±0.38 | 55.03±0.65 | 59.63±0.45 | 50.58±0.64 |
| 9 | 8 | 71.26±0.61 | 75.42±0.52 | 67.95±0.52 | 66.55±0.67 | 56.37±0.13 |
| 10 | 9 | 79.30±0.59 | 82.94±0.37 | 73.63±0.49 | 72.13±0.59 | 65.54±0.29 |
| 11 | 10 | 86.09±0.61 | 89.15±0.64 | 84.77±0.57 | 76.54±0.69 | 70.08±0.33 |
| 12 | 11 | 88.21±0.55 | 92.26±0.46 | 89.86±0.11 | 80.48±0.75 | 75.73±0.14 |
| 13 | 12 | 94.64±0.16 | 96.18±0.38 | 92.59±0.58 | 86.96±0.79 | 83.84±0.15 |

The data are presented as mean value ± S.D. (n = 3)

**Table 9: Dissolution release profiles of Formulations (F11-F14).**

| S. No | Time(hrs) | Cumulative % drug release*(%) | | | |
|---|---|---|---|---|---|
| | | F11 | F12 | F13 | F14 |
| 1 | 0 | 0 | 0 | 0 | 0 |
| 2 | 1 | 9.85±0.34 | 7.23±0.51 | 7.13±0.27 | 7.65±0.41 |
| 3 | 2 | 13.06±0.27 | 13.94±0.43 | 16.71±0.81 | 19.76±0.56 |
| 4 | 3 | 27.75±0.45 | 29.06±0.25 | 20.24±0.72 | 29.82±0.39 |
| 5 | 4 | 30.71±0.14 | 38.25±0.36 | 23.16±0.63 | 37.36±0.53 |
| 6 | 5 | 37.07±0.29 | 49.68±0.58 | 33.44±0.79 | 45.48±0.27 |
| 7 | 6 | 51.52±0.16 | 54.57±0.97 | 38.16±0.51 | 59.94±0.19 |
| 8 | 7 | 59.15±0.37 | 69.77±0.77 | 51.34±0.67 | 67.82±0.22 |
| 9 | 8 | 63.65±0.25 | 71.50±0.65 | 62.36±0.44 | 70.13±0.81 |
| 10 | 9 | 72.89±0.55 | 82.60±0.63 | 73.35±0.52 | 74.36±0.42 |
| 11 | 10 | 78.33±0.64 | 87.94±0.51 | 79.81±0.49 | 80.04±0.36 |
| 12 | 11 | 86.76±0.73 | 90.67±0.72 | 86.54±0.87 | 83.29±0.47 |
| 13 | 12 | 94.16±0.27 | 93.23±0.49 | 91.55±0.23 | 89.13±0.45 |

The data are presented as mean value ± S.D. (n = 3)

## CONCLUSION

The Present Research work was to formulate and evaluate extended release Matrix tablets of Tenatoprazole sodium was prepared by wet granulation technique by using different polymers of Carbopol, HPMC and Eudragit grades. Formulations (F1-F18) fulfill the official limit for Physico Chemical parameters like weight Variation, hardness, friability and drug content uniformity. *In-vitro* dissolution studies showed that Tenatoprazole sodium tablets of in 1:1(Drug: Polymer) proportion, prepared by wet granulation method is the best to increase extended effect due to the polymer concentration. Formulation F5 (drug: Carbopol-974P-NF in ratio of 1:1.5) Shows extended drug release of 99.47±0.22 % in 12 hours so it was selected as the best formulation among all the formulations.

**Table 10: Dissolution release profiles of Formulations (F15-F18).**

| Time (hrs) | Time(hrs) | Cumulative % drug release*(%) | | | |
|---|---|---|---|---|---|
| | | F15 | F16 | F17 | F18 |
| 0 | 0 | 0 | 0 | 0 | 0 |
| 1 | 1 | 8.59±0.72 | 9.21±0.49 | 9.28±0.25 | 9.22±0.51 |
| 2 | 2 | 17.56±0.67 | 18.98±0.25 | 13.40±0.41 | 17.97±0.76 |
| 3 | 3 | 25.70±0.82 | 29.85±0.45 | 19.75±0.29 | 28.22±0.25 |
| 4 | 4 | 39.05±0.46 | 40.51±0.31 | 26.05±0.36 | 37.35±0.36 |
| 5 | 5 | 44.9±0.17 | 52.28±0.42 | 30.58±0.52 | 44.10±0.39 |
| 6 | 6 | 58.54±0.27 | 59.84±0.51 | 40.04±0.55 | 53.34±0.46 |
| 7 | 7 | 63.54±0.63 | 68.87±0.35 | 47.96±0.42 | 62.23±0.62 |
| 8 | 8 | 65.47±0.33 | 73.11±0.68 | 58.45±0.37 | 68.76±0.55 |
| 9 | 9 | 70.17±0.64 | 81.29±0.59 | 66.11±0.36 | 73.38±0.38 |
| 10 | 10 | 74.36±0.67 | 87.74±0.47 | 72.74±0.59 | 79.45±0.72 |
| 11 | 11 | 79.67±0.58 | 91.66±0.35 | 80.04±0.67 | 84.56±0.89 |
| 12 | 12 | 85.75±0.69 | 94.56±0.26 | 84.74±0.83 | 90.12±0.43 |

The data are presented as mean value ± S.D. (n = 3)

## ACKNOWLEDGEMENT

The author would like to give sincere gratitude to the Progenerics Pharma Pvt. Ltd., Hyderabad, for providing all requirements for this Research work. I am also thankful to Brilliant Group of Institutions, R.R Dist, for providing valuable support in doing my Ph.D work.

## CONFLICT OF INTEREST

The authors declared none.

## ABBREVIATIONS

**ER:** Extended Release; **PPI:** Proton Pump Inhibitor; **HPMC:** Hydroxypropyl Methyl cellulose.

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**Article History:** Submission Date : 20-03-2020; Revised Date : 29-04-2020; Acceptance Date : 23-05-2020.
Cite this article: Divya B, Sreekanth J, Satyavati D. Formulation and Evaluation of Extended Release Matrix Tablets of Tenatoprazole Sodium using Synthetic Polymers. J Young Pharm. 2020;12(2)Suppl:s39-s44.