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# FORMULATION AND CHARACTERIZATION OF STOMACH SPECIFIC DRUG DELIVERY SYSTEM OF NIZATIDINE

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## ABSTRACT
Floating drug delivery systems (FDDS) or hydro-dynamically balanced systems have a bulk density lower than gastric fluids and thus remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. While the system is floating on the gastric contents, the drug is released slowly at a desired rate from the stomach. After the release of the drug, the residual system is emptied from the stomach.

**KEYWORDS:** Floating drug delivery systems, Effervescent systems, Matrix Tablets, In vitro Drug Release, nizatidine.

## INTRODUCTION
During the last decade, many studies have been performed concerning the sustained release dosage forms of drug, which have aimed at the prolongation of gastric emptying time (GET). The GET has been reported to be from 2 to 6 hours in humans in the fed state. Accordingly, when a sustained release dosage form is administered orally, sufficient bio-availability and prolongation of the effective plasma level obtained. Retention of drug delivery systems in the stomach prolongs overall gastro intestinal transit time, thereby resulting in improved bioavailability.[1,2]

Floating drug delivery systems (FDDS) or hydro-dynamically balanced systems have a bulk density lower than gastric fluids and thus remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. While the system is floating on the gastric contents, the drug is released slowly at a desired rate from the stomach. After the release of the drug, the residual system is emptied from the stomach.[3,4]

Effervescent systems are matrix type of systems prepared with the help of swellable polymers such as Methylcellulose and chitosan and various effervescent compounds, e.g. sodium bicarbonate, tartaric acid and citric acid. They are formulated in such a way that when in contact with the gastric contents, $CO_2$ is liberated and gets entrapped in swollen hydrocolloids, which provides buoyancy to the dosage forms.[5,6]

## METHODOLOGY
### Formulation of nizatidine gastro-retentive tablets of different systems
### i) Effervescent floating technique
The formulations were fabricated by direct compression method using 12 mm flat faced punch of 10 station Rimek compression machine employing different polymers like carboxy methyl ethyl cellulose(CMEC), carbopol 971G and swelstar MX-1. For the manufacturing of floating tablets, the active pharmaceutical agent i.e. nizatidine was passed through sieve no 20 and thoroughly mixed with polymer(s), diluents (lactose mono hydrate) and gas forming agent (sodium bicarbonate and citric acid) using a mortar and pestle for 10 min, which was passed through sieve no. 60, and then colloidal silicon dioxide (passed through sieve no. 60) was added as flow promotor and mixed for 5 minutes, to the above blend magnesium stearate(passed through sieve no. 60) was added as lubricant and mixed for 2 minutes. The percentage of polymer used was 20-40% of total tablet weight irrespective of the type of polymer used.[7,8]

**Table 1: Formulation table for Nizatidine tablets of effervescent system.**

| Ingredients | Qantities in mg | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | EF1 | EF2 | EF3 | EF4 | EF5 | EF6 | EF7 | EF8 | EF9 |
| Nizatidine | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 |
| Lactose | 114 | 84 | 54 | 114 | 84 | 54 | 114 | 84 | 54 |
| CMEC | 60 | 90 | 120 | -- | -- | -- | -- | -- | -- |
| Carbopol 971G | -- | -- | -- | 60 | 90 | 120 | -- | -- | -- |
| Swelstar MX-1 | -- | -- | -- | -- | -- | -- | 60 | 90 | 120 |
| Sodium bicarbonate | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| Citric acid | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 0 |
| Colloidal $SiO_2$ | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Mag.stearate | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| **Total weight** | **300** | **300** | **300** | **300** | **300** | **300** | **300** | **300** | **300** |

**ii)Non - Effervescent floating technique**

The formulations were fabricated by direct compression method using 12 mm flat faced punch of 10 station rimek compression machine employing different polymers like carboxy methyl ethyl cellulose, carbopol 971G and swelstar MX-1. For the manufacturing of floating tablets, the active pharmaceutical agent i.e. drug was passed through sieve no 20 and thoroughly mixed with polymer(s), diluents (lactose mono hydrate) and floating agent (polypropylene foam powder) using a mortar and pestle for 10 min, which was passed through sieve no. 60, and then colloidal silicon dioxide(passed through sieve no. 60) was added as flow promotor and mixed for 5 minutes, to the above blend magnesium stearate(passed through sieve no. 60) was added as lubricant and mixed for 2 minutes. In all the formulations, the amount of drug was kept constant. The percentage of polymer and floating agent used was 50-54% of total tablet weight irrespective of the type and combination of polymers used.[9,10]

**Table 2: Formulation table for floating tablets of non-effervescent system.**

| Ingredients | Quantities in mg | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | NEF1 | NEF2 | NEF3 | NEF4 | NEF5 | NEF6 | NEF7 | NEF8 | NEF9 |
| Nizatidine | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 |
| Lactose | 84 | 78 | 72 | 84 | 78 | 72 | 84 | 78 | 72 |
| CMEC | 90 | 90 | 90 | -- | -- | -- | -- | -- | -- |
| Carbopol 971G | -- | -- | -- | 90 | 90 | 90 | -- | -- | -- |
| SwelstarMX1 | -- | -- | -- | -- | -- | -- | 90 | 90 | 90 |
| Poly propylene foam powder | 60 | 66 | 72 | 60 | 66 | 72 | 60 | 66 | 72 |
| silicon dioxide | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Mag. stearate | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| **Total weight** | **300** | **300** | **300** | **300** | **300** | **300** | **300** | **300** | **300** |

**Evaluation of nizatidine floating tablets**

**Pre-compression parameters**

Prior to the compression, the formulations of powder blends were evaluated for their bulk and tapped densities, respectively, and from these values, compressibility indices and Hausner's ratio were calculated. While the flow properties of the powder blend were determined by calculating the angle of repose.[11]

**Post compression parameters**

**i) Thickness:** Thickness of prepared tablets was tested using vernier calipers. The test was done in triplicates and average was determined.[12]

**ii) Hardness:** The hardness of prepared tablets was determined by using Monsanto hardness tester and measured in terms of kg/cm2. Test was done in triplicate.[13]

**iii) Weight variation:** Twenty tablets were selected randomly from the lot and weighed individually to check for weight variation. IP limit for weight variation in case of tablets weighing 130-324 mg is ± 7.5% and more than 324 mg is ± 5%.[14]

**iv) Friability:** Friability of the tablets was determined using Roche friabilator. This device subjects 10 tablets to the combined effect of abrasions and shock in a plastic chamber revolving at 25 rpm and dropping the tablets at a height of 6 inches in each revolution. Pre-weighed sample of tablets was placed in the friabilator and were subjected to 100 revolutions. Tablets were dedusted using a soft muslin cloth and reweighed.[15]

**v) Buoyancy lag time determination and total floating time:** The in vitro buoyancy was determined by the buoyancy lag time. The tablets were placed in a 250-ml beaker containing 0.1N hydrochloric acid. The time required for the tablet to rise to the surface for floating was determined as the buoyancy lag time and further floating duration of all tablets was determined by visual observation.[16]

**vi) In Vitro Dissolution Studies:** The release rate of drug from floating tablets was determined using United States Pharmacopeia (USP) Dissolution Testing Apparatus 2 (paddle method). The dissolution test was performed using

900 ml of 0.01N HCl in 0.5 % SLS solution at 37 ± 0.5oC and 50 rpm. A sample (5 ml) of the solution was withdrawn from the dissolution apparatus hourly and the samples were replaced with fresh dissolution medium. Absorbance of these solutions was measured using a UV/Visible spectrophotometer. The percentage drug release was plotted against time to determine the release profile.[17,18]

**vii) Drug Content:** The drug content was carried out by weighing 10 tablets from each batch and calculated the average weight. Then the tablets were triturated to get a fine powder. From the resulting triturate, powder was weighed accurately which is equivalent to 100 mg of drug and dissolved in a 100-ml volumetric flask containing 50 ml of dissolution medium and volume was made upto 100 ml with same solvent. The volumetric flask was shaken for 15 mins and after suitable dilution with same medium, the drug content was determined using UV-Visible Spectrophotometer.[19,20]

## RESULT

**i) Characterization of nizatidine effervescent floating tablets.**

**Table 3: Characterization of nizatidine floating tablets.**

| Formulation code | Hardness Kg/cm$^2$ | Thickness (mm) | Avg. wt. (mg) | Friability (%) | Assay (%) | Floating lag time | Total floating time |
|---|---|---|---|---|---|---|---|
| EF1 | 6.30±0.28 | 4.20±0.20 | 300.20±5.61 | 0.42±0.03 | 98.98±1.26 | 39 sec | >8 h |
| EF2 | 6.50±0.36 | 4.10±0.34 | 298.12±2.05 | 0.24±0.02 | 98.86±0.05 | 37 sec | >12 h |
| EF3 | 6.30±0.52 | 4.30±0.24 | 300.01±1.92 | 0.15±0.01 | 99.92±1.08 | 35 sec | >12 h |
| EF4 | 6.50±0.08 | 4.70±0.18 | 301.20±0.92 | 0.41±0.03 | 98.58±0.94 | 19 min | >8 h |
| EF5 | 7.00±0.62 | 4.60±0.05 | 297.30±2.94 | 0.32±0.02 | 99.12±1.95 | 17 min | >12 h |
| EF6 | 7.20±0.59 | 4.20±0.23 | 299.60±1.05 | 0.19±0.01 | 99.65±2.84 | 14 min | >12 h |
| EF7 | 6.60±0.01 | 4.10±0.34 | 301.20±5.46 | 0.25±0.02 | 99.78±4.93 | -- | -- |
| EF8 | 6.80±0.08 | 4.20±0.10 | 300.14±0.08 | 0.29±0.01 | 97.41±2.09 | -- | -- |
| EF9 | 7.30±0.06 | 4.70±0.03 | 298.12±0.94 | 0.22±0.02 | 98.96±1.58 | -- | -- |

**ii) In vitro dissolution studies of Effervescent formulations**

**Table 4: In vitro dissolution studies of floating tablets (Effervescent formulations).**

| Time (h) | Cumulative % drug released (Mean ± S.D) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | EF1 | EF2 | EF3 | EF4 | EF5 | EF6 | EF7 | EF8 | EF9 |
| 1 | 35.62±0.82 | 29.56±0.39 | 29.72±0.72 | 23.69±1.02 | 10.08±0.06 | 15.58±0.17 | 37.11±0.83 | 15.14±0.58 | 10.67±0.84 |
| 2 | 42.19±0.46 | 33.61±0.85 | 31.06±0.63 | 39.64±0.92 | 28.56±0.64 | 24.17±0.26 | 45.56±0.85 | 24.53±0.93 | 21.5±0.54 |
| 4 | 57.19±0.72 | 42.78±o.64 | 39.64±0.06 | 54.78±0.22 | 37.39±0.38 | 28.03±0.86 | 54.44±0.73 | 41.67±0.62 | 44.56±64 |
| 6 | 73.97±0.36 | 54.00±0.58 | 54.42±0.54 | 68.69±1.26 | 66.75±0.44 | 41.17±1.82 | 67.42±0.09 | 43.08±1.06 | 54.89±0.53 |
| 8 | 96.47±0.92 | 69.14±0.86 | 75.92±0.80 | 77.11±0.74 | 74.36±1 | 59.86±0.72 | 88.17±0.76 | 60.36±0.72 | 67.50±0.83 |
| 10 | 100.00±0.67 | 82.72±0.08 | 78.72±0.32 | 99.97±0.39 | 99.44±0.8 | 85.94±0.37 | 99.90±0.08 | 82.56±0.35 | 79.40±0.95 |
| 12 | - | 99.97±0.18 | 85.5± 0.88 | - | - | 99.90±0.08 | - | 84.53±0.04 | 94.08±0.48 |
| 16 | - | - | 85.6±0.04 | - | - | - | - | 98.06±0.72 | 99.19±0.57 |

**iii) Characterization of floating tablets (Non-Effervescent formulations)**

**Table 5: Characterization of floating tablets (Non-Effervescent formulations).**

| Formulation code | Hardness (Kg/cm$^2$) | Thickness (mm) | Avg wt (mg) | Friability (%) | Assay (%) | Floating lag time | Total floating time |
|---|---|---|---|---|---|---|---|
| NEF1 | 6.30±1.08 | 4.10±0.26 | 298.60±1.8 | 0.38±0.02 | 99.16±4.20 | 55 sec | >8 h |
| NEF2 | 7.00±0.82 | 4.00±0.31 | 298.50±3.8 | 0.46±0.03 | 98.68±2.26 | 52 sec | >12 h |
| NEF3 | 6.40±0.92 | 4.50±0.38 | 300.60±5.1 | 0.21±0.02 | 99.56±2.89 | 49 sec | >12 h |
| NEF4 | 5.90±0.72 | 4.60±0.08 | 298.80±8.9 | 0.36±0.01 | 97.99±6.41 | 23 min | >8 h |
| NEF5 | 6.20±0.27 | 4.20±0.29 | 297.80±4.2 | 0.29±0.02 | 98.85±5.21 | 34 min | >12 h |
| NEF6 | 7.20±0.35 | 4.00±0.34 | 302.90±9.2 | 0.33±0.03 | 98.52±6.54 | 35 min | >12 h |
| NEF7 | 6.80±0.75 | 4.30±0.40 | 297.40±10.6 | 0.12±0.01 | 98.79±7.26 | -- | -- |
| NEF8 | 6.50±0.56 | 4.30±034 | 299.40±9.1 | 0.21±0.01 | 97.98±5.91 | -- | -- |
| NEF9 | 7.00±0.01 | 4.80±0.08 | 303.20±6.4 | 0.11±0.01 | 97.2±0.83 | -- | -- |

**iv) In vitro Dissolution Studies**

**Table 6: *In vitro* Dissolution Studies for floating tablets (non-effervescent systems)**

| Time (h) | Cumulative % drug released (Mean ± S.D) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | NEF1 | NEF2 | NEF3 | NEF4 | NEF5 | NEF6 | NEF7 | NEF8 | NEF9 |
| 1 | 37.03±1.02 | 28.17±0.9 | 28.19±0.35 | 28.14±1.30 | 15.64±0.5 | 14.33±0.82 | 45.44±0.75 | 21.53±0.72 | 8.72±0.86 |
| 2 | 43.25±0.92 | 30.83±1.2 | 31.33±0.94 | 42.69±0.38 | 29.11±0.2 | 28.19±38 | 51.72±0.75 | 28.2±0.75 | 18.56±0.43 |
| 4 | 63.31±0.85 | 43.61±0.8 | 42.69±0.62 | 57.56±0.84 | 39.5±0.5 | 30.81±0.9 | 65.31±0.85 | 42.4±0.45 | 41.5±0.56 |
| 6 | 76.5±0.212 | 57.28±0.4 | 53.36±0.75 | 71.75±0.53 | 64.81±0.8 | 42.28±0.8 | 70.47±0.22 | 45.86±0.47 | 52.11±0.65 |
| 8 | 99.25±1.16 | 70.53±0.5 | 75.36±0.58 | 80.06±0.48 | 72.19±0.5 | 45.08±0.5 | 91.22±0.81 | 63.14±0.46 | 54.81±0.54 |
| 10 | 100.03±0.68 | 85.56±0.7 | 83.72±0.92 | 98.92±0.82 | 92.11±0.7 | 56.78±0.2 | 98.00±0.56 | 95.33±0.76 | 63.25±0.13 |
| 12 | - | 99.72±0.3 | 84.11±0.86 | 100.0±1.09 | 94.94±0.8 | 61.81±0.7 | 100.00±1.82 | 90.08±0.43 | 86.86±0.85 |
| 16 | - | - | 85.79±1.36 | - | 95.75±0.5 | 78.92±0.5 | - | 99.94±0.45 | 99.97±0.05 |

## CONCLUSION

The tablets in the dissolution medium, interaction happens between sodium bicarbonate and citric acid. This results in generation of $CO_2$ which gets entrapped in the polymeric gel matrix. As the gas tries to escape from the matrix, buoyancy is provided and floating happens. Flotation of the dosage form is determined by the resulting weight, which is the difference between the buoyancy force when entirely submerged and the weight of the dosage form. The tablet will float if this difference, or resulting weight, is positive. Drug release occurred in a slow and gradual manner over a prolonged period of more than 12 hours from formulations. The nature of the polymer (Molecular weight, hydrophilicity, Wettability, cross linking, swellability) has an influence on the drug release profile of the system. Thus, each polymer is showing a different effect. Out of all different formulation the EF3 and NEF3 are the best optimized formulations which provide sustain release of drug and better floating time as compared to others.

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