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# Formulation development and comparative evaluation of multiple and single unit tablets of omeprazole magnesium

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**Abstract :** The aim of the present study was to develop multiple unit particulate system and single unit tablets of omeprazole magnesium as a delayed release dosage form and study the in-vitro release pattern of test product by comparing with the marketed reference product. The work was carried out to delay the release of omeprazole magnesium by using enteric polymer methacrylic acid copolymer type-C. The optimized formula of omeprazole magnesium delayed release tablets were prepared using wet granulation technique for single unit tablets and pellet technology for multiple unit particulate system. The multiple unit pellets and single unit tablets were found to be satisfactory with respect to physical as well as chemical characteristics. The dissolution profiles of these were compared with that of the reference product - Prilosec® and the comparisons of the drug release profiles were found to be satisfactory. Single unit tablet process would be an effective, low cost and simple alternative approach compared with the use of more expensive process like fluidization process and adjuvant in the formulation of oral dosage tablets.
**Key-words :** Omeprazole magnesium; Delayed release pellets and tablets, Enteric polymer; Fluidization process.

## Introduction

Omeprazole magnesium (OPM) is a proton pump inhibitor (PPI) which blocks the $H^+/K^+$- adenosine tri-phosphate system and inhibits the final common step in gastric acid secretion.After oral administration the absorption of OPM is very rapid, and it is unstable at low pH and hence leads to therapeutic inefficacy.



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Therefore, it is very necessary for OPM drug to bypass the acidic pH of stomach which can be achieved by formulating enteric release or delayed release dosage forms (single unit or multiple units) by using various enteric coating polymers. By using delayed release systems, the drug is released in the intestine and is absorbed[1].

The main objective of using delayed release products is to protect the drug from gastric fluids, and to reduce gastric distress of the drugs particularly irritatingin the stomach or to ease gastrointestinal passage for drugs that are better absorbed from the intestine. Delayed release dosage forms which are meant to be targeted to colon are typically enteric coated. Enteric coating polymers are mainly insoluble substances as they do not dissolve in the acidicfluids of the stomach but dissolve when they reach the higher pH of the small intestine. The most commonly used polymers are polyvinyl acetate phthalate (PVAP), hydroxyl propyl methyl cellulose phthalate (HPMCP), cellulose acetate phthalate (CAP) and Methacrylic acid copolymers[2].

The oral drug delivery systems are broadly classified into single unit dosage forms (Ex. Capsules, tablets) and multiple unit dosage forms (Ex. pellets, mini-tablets). Even though similar drug release profiles can be obtained with both single unit and multiple unit dosage forms, pellets offer several other added therapeuticbenefits. The OPM delayed release single unit tablets (20mg) were prepared by using wet granulation technique with the help of rapid mixer granulator and multiparticulate system by using pellet technology with the help of fluidized bed processor equipment. Solution/Suspension layering technology is used to develop enteric coated pellets for enhancing the stability in acidic media, due to the presence of polymer film formation on the pellets surface. Whereas, enteric coating causes immediate release of drug in alkali media at the site of action[3].

## Material and Methods

### Materials

Omeprazole magnesium was obtained as a gift sample from Hetero Drugs, Hyderabad. Instacoat EN super II was procured from Ideal cures Pvt ltd, Mumbai.Sugar Spheres (# 40 – 60, Werer, USA), HPMC (Hypromellose E5LV, Colorcon, USA), Mannitol (Roquette, USA), SLS (Stepan, Newyork), HPC (Klucel EXF), SFS (Rank organics), Talc (Luzenac, Italy), Magnesium Stearate (Ferro, Cleveland),Iron oxide red (Roha dry chem. Pvt ltd), MCC (Avicel 101, FMC Biopolymer, USA), MCC (Avicel 200, FMC Biopolymer, USA), Sodium starch glycolate(JRS Pharma LP, USA), Opadry 13G84576 pink (Colorcon , USA) were procured from Hetero Drugs, Hyderabad. All other chemicals and solvents used were of analytical and pharmaceutical grade.

### Pre-formulation studies:

The preformulation studies are useful in developing a stable formulation. Further, Preformulation parameters increases the chances in formulating an safe, efficacious, stable and acceptable product. The pure drug and developed formulations was evaluated for flow properties. Different tests were carried out such asAngle of repose,bulk density (BD), tapped density (TD), compressibility index (CI) and Hausner's ratio.

### Particle size analysis:

The API omeprazole magnesium is fluffy in nature. Hence, the particle size analysis was done using Malvern technique.Laser diffraction apparatus uses the scattering behaviour of light by dispersed particles. The average particle size(i.e. average equivalent diameter) is defined as the diameter where 50% mass of the powder have a larger equivalent diameter, and the remaining 50% mass have a smaller equivalent diameter.

### Preparation of pellets incorporated tablet

### Drug loading stage

The required amount of sugar spheres were weighed and transferred into a fluidized bed processor and the specifiedquantity of OPM was dissolved in water. The ingredients HPMC-E5 and SLS were dispersed in the drug solution with continuous stirring and this suspension was sprayed onto sugar spheres at 3-12rpm by bottom spray technique. After coating, these pellets were dried at low temperature for 30mins in fluidized bed processor. The composition of ingredients for drug loading stage is shown in **Table 1.**

**Table 1:Composition of the drug loading optimization trials**

| Tablet core | Weights of excipients (mg/tablet) | | | |
|---|---|---|---|---|
| | **D1** | **D2** | **D3** | **D4** |
| Omeprazole magnesium | 20.6 | 20.6 | 20.6 | 20.6 |
| Sugar Sphere (# 40 - 60) | 40 | 37 | 42 | 39 |
| HPMC (Hypromellose E5LV) | **3** | **6** | **1** | **3** |
| SLS | **1** | **1** | **1** | **2** |
| Purified water | q.s. | q.s. | q.s. | q.s. |
| total(drug coated pellets) | 64.6 | 64.6 | 64.6 | 64.6 |

*D = Drug coating

**Sub coating stage**

The coating solution was prepared by adding HPC, magnesium stearate, Talc in water and was used to coat the drug loaded pellets in fluidized bed processor at a speed of 3-12 rpm and dried at 50°C for 30mins. The composition of ingredients for sub coating stage is shown in as shown in **Table 2.**

**Table 2:Composition of the Sub coating optimization trials**

| Sub - coating layer | Weights of excipients (mg/tablet) | | |
|---|---|---|---|
| | **B1** | **B2** | **B3** |
| **Core material (D1)** | 64.6 | 64.6 | 64.6 |
| HPC (Klucel EXF) | **2** | **4** | **6** |
| Talc | 6.8 | 6.8 | 6.8 |
| Magnesium Stearate | 0.6 | 0.6 | 0.6 |
| Purified water | q.s. | q.s. | q.s. |
| total( barrier layer pellets) | 74 | 76 | 78 |

*B = Barrier coating

**Enteric coating stage**

Enteric coating solution was prepared by mixingInstacoatEN super II and iron oxide red in water and then sprayed on the sub-coated pellets in fluidized bed processor and dried for 2 hrsat 45°C as shown in **Table 3**.[4]

**Table 3: Composition of the enteric coating optimization trials**

| Enteric coating layer | Weights of excipients (mg/tablet) | | | | |
|---|---|---|---|---|---|
| | **EM1 (14%)** | **EM2 (30%)** | **EM3 (50%)** | **EM4 (70%)** | **EM5 (60%)** |
| **Sub coated pellets (B2)** | 76 | 76 | 76 | 76 | 76 |
| Instacoat EN super II | 10.6 | 22.8 | 38 | 53.2 | 45.6 |
| Iron oxide red | 0.106 | 0.106 | 0.106 | 0.106 | 0.106 |
| Purified water | q.s. | q.s. | q.s. | q.s. | q.s. |
| Total | 86.71 | 98.906 | 114.106 | 129.306 | 121.706 |

*EM = Multiple unit enteric coating

**Compression of pellets to tablets**

For preparing tablets, first MCC 200, MCC 101and SSG were passed through sieve no 40 and blended with the required quantity of enteric coated pelletsin octagonal blender for a period of 10mins. This blend was lubricated with magnesium stearate in octagonal blender for a period of 5mins. The final blendwas compressed into tablets[5].

**Film coating stage:**

Coating solution was prepared by adding opadry pink in water and then sprayed on to the compressed tablets in Neocota perforated coating pan[6].

**Preparation of single unit tablets:**

**Core tablet preparation**

Required amounts of omeprazole magnesium, MCC (Avicel 101), SSG were weighed, passed through sieve # 60and mixed with mannitol. The above mixture was loaded into Rapid Mixer Granulator and dry mix was carried out for a period of 15 min with impellor at slow speed and chopper off. The above blend was now granulated using HPMC E5 dissolved in water as a binder solution and kneading as carried out for 2min and the wet granular mass was dried in the drier.The dried granules were sifted through sieve # 30.These sifted granules were blended with mannitol, talc and SSG in octagonal blender for a period of 10mins. These blended granules were lubricated with sodium stearylfumarate in octagonal blender for 5mins.The blend was compressed using 13×6mm size concave shaped punch toolings[7].

**Sub coating stage**: Compressed tablets were coated with sub coating solution of weighed amounts of HPMC E5 and water in NEOCOTA coating pan.

**Enteric coating stage**: Sub-coated tablets were coated with the enteric coated material, Instacoat EN super II and purified water.

**Film coating stage:**Enteric coated tablets were coated in Neocotacoating pan, with the film coating solution containing weighed amount of opadry pink dissolved in purified water under continuous stirring[6].

**Table 4:Formulation trails for optimization of binder and disintegrating agent concentration**

| **Ingredients** | **optimization of binder concentration mg/tablet** | | | | **optimization of disintegrating agent concentration mg/tablet** | | | |
|---|---|---|---|---|---|---|---|---|
| **Core tablet** | **C1** | **C2** | **C3** | **C4** | **C5** | **C6** | **C7** | **C8** |
| OMP | 22.5 | **22.5** | 22.5 | 22.5 | 22.5 | 22.5 | **22.5** | 22.5 |
| Mannitol | 75 | **75** | 75 | 75 | 75 | 75 | **75** | 75 |
| MCC(Avicel 101) | 129.5 | **126.5** | 123.5 | 121 | 123.5 | 128.5 | **125.5** | 125.5 |
| SSG | 6 | **6** | 6 | 6 | **3** | **3** | **6** | **9** |
| HPMC E5 | **0** | **3** | **6** | **9** | 3 | 3 | **3** | 3 |
| p.water | q.s | **q.s** | q.s | q.s | q.s | q.s | **q.s** | q.s |
| Mannitol | 50 | **50** | 50 | 50 | 50 | 50 | **50** | 50 |
| Talc | 6 | **6** | 6 | 6 | 6 | 6 | **6** | 6 |
| SSG | 5 | **5** | 5 | 5 | 3 | 9 | **6** | 3 |
| SSF | 6 | **6** | 6 | 6 | 6 | 6 | **6** | 6 |
| Total | 300 | **300** | 300 | 300 | 300 | 300 | **300** | 300 |

During enteric-coating**(Table 5)**, tablets are coated with 8% (ES1), 11% (ES2), and 14% (ES3) enteric build ups **(Figure 1)**.

**Table 5:Formulation trails for sub coating, enteric and film coating– optimization**

| Sub-coating | mg/tablet | | | | Enteric coating (S3) | mg/tablet | | | Film coating | mg/tablet ST1 |
|---|---|---|---|---|---|---|---|---|---|---|
| | S1 (1%) | S2 (2%) | S3 (3%) | S4 (4%) | | ES1 8% | ES2 11% | ES3 14% | | |
| core tablet (C7) | 300 | 300 | 300 | 300 | Sub-coated tablets(S3) | 309 | 309 | 309 | Enteric coated tablets ( E2) | 343 |
| HPMC E5 | 3 | 6 | 9 | 12 | Instacoat EN super II | 24.72 | 33.99 | 43.26 | Opadry pink | 10.3 (3%) |
| Purified water | q.s | q.s | q.s | q.s | Water | q.s | q.s | q.s | Purified water | q.s |
| TOTAL | 303 | 306 | 309 | 312 | Total | 333.7 | 342.99 | 352.3 | Total | 353.3 |

**8% EC Tablet11% EC Tablet14% EC Tablet**

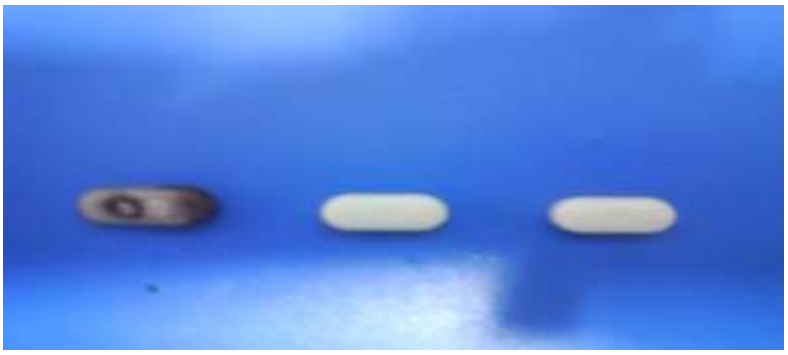

**Figure1**:**Schematic diagram of different builds up of enteric coated tablets**

**Evaluation of delayed release formulations**

Physical evaluation of coated pelletswas done for identification of pinholes, lumps formation and cracking of the film.The coated pelletscompressed tablet and single-unit enteric coated tablet formulations equivalent to 20.60mg of omeprazole magnesium were evaluated[8].

**Post-compression tests**

The prepared tablets were evaluated for post-compression parameters to determine their physicochemical properties.

**Assay procedure**

Accurately weighed quantity of pellets and tablets equivalent to about 20.60mg of omeprazole magnesiumwere transferred into 100ml volumetric flask. About 50ml of diluent was added to the flask and was sonicated for about 15min, make up to the required volume with diluent and then mixed. A portion of the solution was filtered through 0.45 µm filter and filtrate was analyzed by HPLC.

**Acid resistance**

About 500ml of dissolution medium wasplaced in 6 vessels and the medium was allowed to equilibrate to a temperature 37±0.5$^{o}$C. Pellets or tablets equivalent to theoretical net content of one tablet was placed in each of the vessel and the apparatus was operatedat 100 rpm for 2 hours. After 2 hours, the medium containing the pellets were filtered through a sieve with an aperture size of 0.2mm.The pellets were collected on the sieve, rinsed with water using 60ml of sodium borate solution. The pellets were thenquantitatively transferred into a

100ml volumetric flask, and sonicated for about 20 min until the pellets were broken up. About 20ml of 95%ethanol was added to the flask and diluted to volume with 0.01M dibasic tetraborate and mixed. Finally, the solution was filtered through 0.45µm membrane filter.

**Procedure:**Separately inject 20µl of standard and sample preparations (five injections each) into the chromatographic system. The chromatograms were then recorded for measurement of peak responses.

**Dissolution:**

Protocol was conducted as directed for acid resistance stage with a new set of tablets from the same batch. After 2hours, 400ml of 0.235M dibasic sodium phosphate buffer (pH 10.4) was added to 500ml of 0.1 N HCl medium in the vessel. And the pH was adjusted to 6.8±0.05, if necessary with 2N sodium hydroxide or 2 N HCl. Theapparatus was operated at 100 rpm for specified time and 10ml of the sample solution was withdrawn from each vessel. Thesolution was filtered through 0.45µm membrane filter.Thenimmediately,5ml of above filtered solution was transferred into a test tube containing 1 ml of 0.25 N NaOHsolution and mixed.

**Procedure:**Separately inject 20µl of standard and sample preparations (five injections each) into the chromatographic system. The chromatograms were then recorded for measurement of peak responses.

**Fourier transform infrared spectroscopic studies[FT-IR]**

FT-IR has been employed as a useful tool to identify drug excipient interaction.FTIR spectroscopic studies were conducted for optimized MUTs and SUTsformulations and omeprazole magnesium pure drug. Samples were analyzed by using a Shimadzu FT-IR 8300 Spectrophotometer and the spectrum was recorded in the region between 4000-400 $cm^{-1}$.The procedure consisted of dispersing 200-400 mg of sample in KBr and compressing into discs by applying a pressure of 5 tons for 5 min in a hydraulic press. The pellet was placed in the path of light and the spectra wasrecorded[9].

**Analysis of release data**

Similarity factor (f2) calculations are used to compare the dissolution tests results of different formulations with the marketed product. The similarity factor (f2) is a logarithmic reciprocal square root transformation of the sum of squared error and is a measurement of the similarity in the dissolution percent between two curves:

$$f2 = 50 \log \{[1 + (1/n) \Sigma n (Rt - Tt)2] 0.5 \times 100\}$$

Where,$n$ = number of pull points;$Rt$= reference profile at time point; and $Tt$= test profileat the same time point.

The f2 value should be between 50 and 100. An f2 value of 100 suggest that the test and reference profiles are identical, and as the value becomes smaller, the dissimilarity between release profiles increases.

**Stability study**

This study include storage at both normal and accelerated temperature conditions, with the necessary extrapolations to ensure that the product over its designed shelf-life, provide absorption for medication at the same rate as when originally formulated. Specification, which is list of tests, references to analytical procedures and their proposed acceptance criteria, including the concept of different acceptable criteria for release and shelf life specifications, is mentioned in ICH guidelines.Temperature dependent stability studies were carried out on the optimized formulation batches. While performing stability studies, acid resistance, assay and drug releases were determined at the starting of study, end of first, second and third month.Selected batch tablets were packed in 90 counts in HDPE bottle.The bottles were subjected to accelerated conditions like 40ºC/75%RH for first, second and third month periods[10].

## Results and Discussion

### Preformulation studies

The study involves Preformulation studies of drug and excipients. Physical characters of omeprazole magnesium powder found to be white to off white powder, bulk density is 0.187±0.01gm/ml, tapped density is 0.26±0.01gm/ml, compressibility index is 28.0±0.25 %, hausner's ratio 1.39±0.02 %, and angle of repose is 34±0.28ºC,from the resultsit was concluded that the omeprazole magnesium had a very poor flow property. Omeprazole magnesium is a fluffy material; it could not be passed through the sieves. Hence, the particle size distribution of omeprazole magnesium was carried out by Malvern technique. The analysed powder containing – 10% (D10) of particle size having below 0.71 µm, 50% (D50) of particle size having below 1.81 µm, 90% (D90) of particle size having below 4.43 µm.

### Optimization studies of MUPs

Multiple-unit tablets were prepared with different compositions by using fluidized bed processor (solution and suspension layering process). For MUPS, 3mg HPMC and 1mg SLS concentration were optimized during drug loading, because fewer agglomerates, less powder generation was observed during coating and less bubbles were observed during preparation of drug loading suspension**(Table 1)**. During sub coating, 4mg binder concentration was optimized because less agglomerates and less powder generation was observed**(Table 2)**. According to literature review, hydroxypropyl methyl cellulose phthalate (HPMCP) forms very harder film when compared with the Methacrylic acid copolymer (type C). So, Methacrylic acid copolymer (type C) was selected as enteric coating polymer. For MUPS, flexible film formation was needed. By type C polymer, it was possible to achieve flexible films. Optimization of enteric coating was done by comparing the parameters like assay, acid resistance and dissolution of the EC pellets with that of the Innovator's product**(Table 3)**.

During enteric coating, it's clear that 14% (EM1), 30% (EM2) and 50% (EM3) enteric build up were not sufficient to resist in acid stage but 70% (EM4) and 60% (EM5) enteric builds up was sufficient to be stable in acid stage up to 2hours**(Table 6)**.Based on the results, there is no significant difference in acid resistance in batches EM4 and EM5, but slight difference observed in % drug release at initial points of dissolutionwere found to be in EM4 (41±3.7%) and EM5 (49±4.9%) batches at 10mins. Hence, 60% w/w (EM5) enteric build up was finalized for further development(James W et *al.*, 1997).

**Table 6: Data of enteric-coating optimization trials**

| | **Multiple unit enteric-coated pellets** | | | | | **Single-unit enteric-coated tablets** | | |
|---|---|---|---|---|---|---|---|---|
| **Batch code** | EM1 | EM2 | EM3 | EM4 | EM5 | ES1 | ES2 | ES3 |
| **Enteric coating** | 14% | 30% | 50% | 70% | 60% | 8% | 11% | 14% |
| **Assay** | 99.78±0.67 | 99.99±0.52 | 99.90±0.84 | 99.98±0.92 | 99.92±0.70 | 99.74±0.48 | 99.60±0.67 | 99.89±0.52 |
| **Acid resistance** | 24±0.21 | 46±0.14 | 89±0.20 | 99±0.16 | 98±0.29 | 91±0.15 | 99±0.20 | 99±0.24 |
| **Dissolution at 45min (%)** | – | – | – | 98±1.2 | 99±0.5 | 90±0.6 | 98±0.5 | 97±0.81 |

From the post-compression data, it is clear that hardness of the tablets behaved slightly different in terms of friability, disintigration time, acid resistance and dissolution. The tablets compressed with hardness 10–14kp and 14-18kp were found to be satisfactory with respective to dissolution, acid resistance and friability. Batch compressed with 18-22kp hardness was found lesser acid resistance and dissolution because the hardness of pellets was high during compression**(Table 7)**.

**Table 7: The results of final batch (MT1) when compressed with different hardness**

| Batch code | CM1 | CM2 | CM3 | CM4 |
|---|---|---|---|---|
| **Hardness (kp)** | 5-10 | 10-14 | 14-18 | 18-22 |
| **Friability (%)** | 1.1±0.06 | 0.7±0.05 | 0.4±0.08 | 0.2±0.04 |
| **Disintigration time (sec)** | 30-90 | 60-120 | 90-150 | 120-200 |
| **Acid resistance (%)** | -- | 99±0.23 | 98±0.40 | 93±0.22 |
| **Dissolution at 45 min (%)** | -- | 99±0.92 | 98±0.80 | 92±0.84 |

Hence, 10-18kp hardness was finalized and film coating was up to 3% (MT1). Evaluation tests were performed for all trials of film coated tablets (MT1). MT1 dissolution complies with Innovator. From the abovetrials, MT1 tablets were found to release98±0.80 % of drug at 45minssimilar with that of Innovator and thus optimized **(Figure 2)**[11].

**Optimization studies of SUTs**

SUT were prepared with different compositions by wet granulation method.For SUTs, during optimization of binder concentration**(Table 4)**, all batches showed significant difference in disintegration time and dissolution at 10-16kp hardness. The batch prepared with no binder showed less disintegration and drug release but was more at the initial point and degradation was also observed at the end points. Batch prepared with 3mg bindershowed less disintegration time and good dissolution without degradation. Batches prepared with 6mg and 9mg showed moredisintegration time and low dissolution. Hence 3mg binder was finalized for further development. Based on the Optimization of disintegrating agent concentration**(Table 4)**, all the batches were observed significantly different in terms of disintegration time and disintegrated particle size. The batch prepared with 6mg intra granular and 6mg extra granular disintigrant showed less disintegration about 90-150sec with 20% of particles retains through #40mesh. The batch prepared with 3mg intra and 3mg extra granular component showed more disintegration about 180-240sec and 40% retains. Hence, based on the above observation 6mg intra granular portion and 6mg extra granular portion were finalized for further development. Based on the physical observation of the film, HPMC 5cps was not found to be proper film former at 1% (3mg) and 2% (6mg) build up. Minimum 3% (9mg) was required for forming proper film with HPMC 5cps during sub-coating**(Table 5)**. Drug was degraded when directly contacted with enteric coating material. Hence 9mg/unit HPMC was finalized for further development.

From the data, it is clear that tablet batches are behaving slightly different in terms of acid resistance, assay and dissolution. Based on the results, there is no significant difference in acid resistance and dissolution in case of batches ES2 and ES3, but lower side results observed in % drug release and acid resistance in batch ES1. Hence, 11% w/w enteric build up was finalized for further development. Enteric-coated tablets of formulation ES2 was finalized for further development and film coating was made up to 3% **(Table 5)**[12].Evaluation tests were performed for all trials of film coated tablets (MT1)**(Table 6)**. ST1 dissolution complies with Innovator **(Table 6)**.From the above trials ST1 tablets were found to release98±0.5% of drug at 45mins similar with that of Innovator and thus optimized **(Figure 2)**.

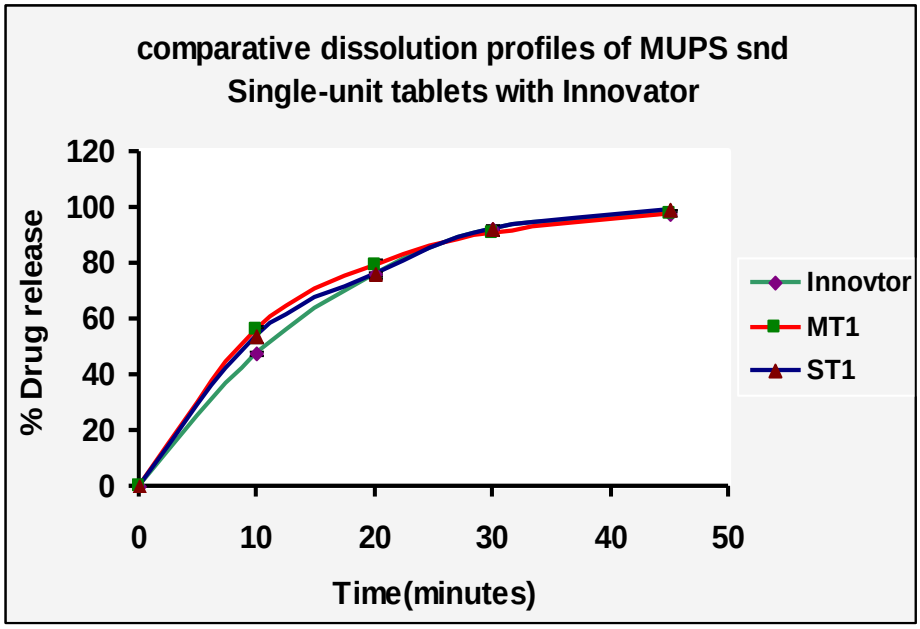


**Figure 2: Dissolution profile of optimized formulations with that of Innovator**

**Comparison data**

Single unit tablets were compared with the MUPS and Innovator product. ST1 (Single unit) tablets were found significantly similar with MUPS (MT1) in terms of assay, acid resistance and drug release **(Figure 3)**. When compared tablets with MUPS, the Single unittablets were most suitable formulation in terms of process feasibility, cost factor and process time[13].

**InnovatorMUPS SUTs**

**Figure 3: Schematic diagram of prepared tablets**

**Analysis of release data**

The dissolution release at different time points were taken for all trial batches and compared with that of the innovator's product. The $f_2$ values, which indicated the extent of similarity between two products, were calculated. The f2 or similarity factor values for optimized formulationsMT1 and ST1were found to be75.7491 and88.9076 respectively,and it was considered to be similarto the marketed product. The FDA prescribes the range of 50-100 for similarity between two dissolution profiles. Accordingly, MT1(optimized formulation of Multiple unit tablet) trial had similarity to the innovator release profile and ST1(optimized formulation of Single unit tablet) trial had similarity to the MUPS release profile.

**Fourier transform infrared spectroscopic studies [FT-IR]**

FTIR study of pure drug and optimized formulations are shown in **Figure 4**. The studies revealed that the IR spectra of pure omeprazole magnesium showed characteristic peaks at 3419 $cm^{-1}$, 1600 $cm^{-1}$, 1480 $cm^{-1}$, 1015 cm-1, corresponding to aromatic N-H stretching, C=N aromatic stretching, S=O aromatic stretching, C-N aromatic. The formulations showed the prominent characterizing peaks for omeprazole magnesium, are at 3446 $cm^{-1}$, 1590 $cm^{-1}$, 1469 $cm^{-1}$and 1017 $cm^{-1}$for MT1 and 3427 $cm^{-1}$, 1600 $cm^{-1}$, 1467 $cm^{-1}$and 1017 $cm^{-1}$for ST1corresponding to N-H stretching, C=N stretching, S=O stretching and C-N, respectively, which confirmed that no chemical modification of the drug took place when formulated into tablets (Sumn Malik et *al.*, 2010).

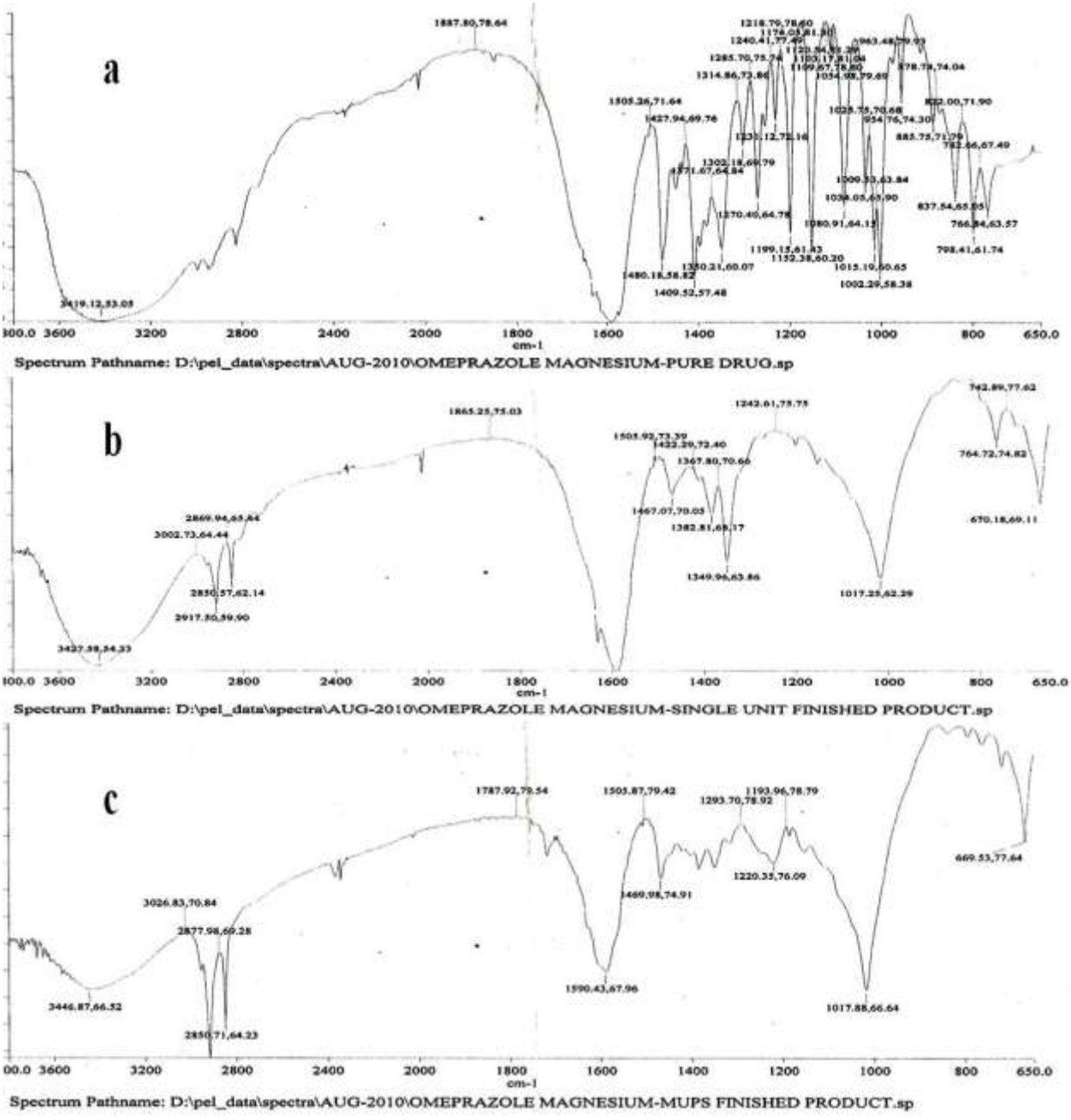


**Figure 4: FTIR spectra of a) pure drug b) optimized single unit formulation (ST1) c) optimized multiple unit formulation (MT1)**

**Stability testing**

Stability studieswere conducted at 40ºC / 75% RH for about 3 months in stability chamber (thermo lab). Samples were collected at 1, 2 and 3 months. Optimized formulation (MT1 and ST1) was kept for stability

studies and observed that assay, acid resistance and dissolution profile after 1, 2and 3 months.From the results, it was found that there was no significant change (i.e. <1 %) in all the parameters. Hence, it was found that formulations MT1 and ST1 were stable[10].

## Conclusion

The Omeprazole magnesium delayed release tablets were successfully prepared by using the optimized formula. The SUTs and MUPS were found to be satisfactory with respect to physical as well as chemical characteristics. The dissolution profile of the manufactured Omeprazole magnesium delayed release tablets of different process were generated and compared with that of the reference product - Prilosec®. The comparisons of the drug release profiles are found to be satisfactory. Undoubtedly, the availability of various technologies and the manifold advantages of single unit tablets will surely enhance the manufacturing problems, based on the above data SUTs and MUPswhich were similar with the reference product in terms of drug release, acid resistance and dissolution.SUTs method process is very cheap, effective and easy to prepare the tablets. SUTsprocess would be an effective, low cost and simple alternative approach compared with the use of more expensive process like fluidization process and adjuvant in the formulation of oral dosage tablets.

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