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# Characterization & Evaluation of Pantoprazole Oral Matrix Tablets with Silica -Based Polymer Material

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***Abstract*****—** *The project work is aimed to prepare solid oral matrix tablets of Pantoprazole using natural, semi-synthetic and synthetic polymers & study the carrier molecule effect on the release profile of the drug. The matrix tablets were prepared by wet-granulation method using sodium alginate, tragacanth, HPMCK4 and SBA-15, total of six formulations were prepared using 1% polyvinyl pyrrolidone solution by wet granulation. The cumulative percentage drug release for 12 hours with 2 hours interval and the results found at the end of 12 hours were 73,74,76,71,88 and 68 respectively. Surface characterization studies, SEM analysis conducted in various dimensions. All the evaluation studies for six formulations Q1-Q6 were found to be within the acceptable criteria with the best optimized formulation as Q6 with controlled release 68 % formulated with synthetic silica-based nanoparticles.*

***Keywords*****—** *Characterization, Nanoparticles, Oral Matrix tablets, SBA-15.*

## I. INTRODUCTION

Pharmaceutical formulations are classified according to the routes of administration, nature of the formulation and can be tailored according to the needs of the patient compliance to support the treatment. Few of the Conventional solid oral dosage forms have been taken over by the controlled solid oral dosage forms to overcome the challenges specifically like frequent dosing, adverse effects observed with routes of administration, drug interactions, insolubility leading to bioavailability problems.

There are many novel delivery pharmaceutical formulations developed to overcome these challenges specially oral-solid dosage forms like controlled drug, sustained drug, matrix forms, coated formulations like sugar, film and compression coating which are popular in the market with wide sales in it.
Speaking about the Controlled Matrix oral tablet formulations, they have advantages of the formulating drug along with the polymer carrier molecule to give a controlled release effect as drug bound/ dispersed within the polymer molecule with its hydrophobic and hydrophilic nature can embed drugs irrespective of their solubility nature without much chemical changes to the drug moiety. This property reduces the addition of many excipients and also the cost of the formulation is made affordable to the patient. Ulcers have been found to be a common disease condition globally in both the developed and developing nations under gastrointestinal infestations. The possible treatments found are

1. Proton-pump inhibitors alone
2. Proton-pump inhibitors in combination with antibiotics.
3. Non-selective NSAID with proton-pump inhibitors.
4. Gastro-protective complexes and chelates.
5. $H_2$ receptor-antagonists (cimetidine, famotidine, ranitidine, nizatidine).
6. Prostaglandin analogues and prostamides.
7. Antacids (sodium alginate with calcium carbonate and sodium bicarbonate).

Here, we discuss exclusively about the Nanoparticles of silica synthesized in the range of 2-50nm referred to as Meso-porous. These are available and developed by Institutions worldwide and research is still going-on them to prepare advanced forms of them as metal-ion linked Nanoparticles for better linkage of drug molecules for targeted therapy required in cancer and other deadly-rare conditions of treatments, where the conventional dosage forms are challenging in providing successful delivery of the drug molecules to the target site without effecting normal cells [ i.e, facing with side-effects, post treatment outweighing the benefits]. To deal with it we need to design the dosage forms in an effective way rather than compromising with the frequent dosing level to reach the target site.

## II. METHODOLOGY:

*Preparation of phosphate buffer solution of pH 6.8:* Phosphate buffer pH 6.8 was prepared based on I.P standards by mixing two solutions [A and B]. Solution A was prepared by dissolving 9.073 grams of potassium dihydrogen phosphate in distilled water to make a 1 liter solution. Solution B was prepared by dissolving 11.87 g of disodium hydrogen phosphate in an adequate quantity of distilled water to make upto 1L solution. 534 ml of solution A was mixed with 466 ml of solution B. the prepared phosphate buffer solution of pH 6.8 was checked to determine its pH using digital pH meter.
*Preparation of pantoprazole standard graph:* 100 mg of PML pure drug was accurately weighed and dissolved in small amount of methanol and the volume was made upto 100 ml using phosphate buffer of pH 6.8 having 1000ug/ml which was labeled as primary stock solution. From the primary stock solution 10 ml was withdrawn using pipette and diluted to 100ml with phosphate buffer pH 6.8 which gives 100ug/ml concentration labeled as secondary stock solution. Further dilutions were made to give concentrations of 1,2,3,4,5,6,7,8,9,10 ug/ml. the absorbencies of these concentration solutions were made at 251nm using double beam UV-Visible spectrophotometer. A standard graph was done between the known concentration of solutions on x-axis and noted absorbencies on y-axis.



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*Preparation of inorganic silica nanoparticles SBA-15:* The inorganic silica nanoparticles of type SBA-15 series is synthesized by using a template of pluronic material as a triblock-co-polymer PLURONIC 123 in completely high acidic conditions along with materials like TMOS [Tetramethyl-orthosilicate] and TEOS [Tetraethyl-orthosilicate] any of them as a source of forming Silica based Nanoparticles at very high temperatures of $1400^0$c.

*Preparation of Pantoprazole Matrix tablets of various formulations:* The matrix tablets of pantoprazole of various formulations F1-F6 were prepared by first taking carrier material and drug together were mixed by geometric dilution method, and then remaining materials were added according to the working formula. After mixing they were turned to wet mass using 1% Polyvinyl pyrrolidone solution to get damp mass of the formulation, which was passed through sieve no.10 and the wet mass granules were dried in hot air oven at $40^0$c for 1 hour and the dried granules were triturated in a mortor & pestle to make fine powder and finally added magnesium stearate and talc materials and once again sieved through sieve no.18. The final powder mass was collected and weighed according to the working formula and punched in a rotary type compression tablet machine.

## III. Results & Discussion

Evaluation studies of the prepared six Q1-Q6 matrix tablet formulations of pantoprazole performed were given in the following table 1 & 2.

TABLE 1. Physical Parameters Evaluation Studies

| Batch formulation | Evaluation parameters | | | | |
|---|---|---|---|---|---|
| | Hardness [kg/cm$^2$] | Thickness [mm] | Diameter [mm] | Percentage friability | Average Weight [mm] |
| Q1 | 7 | 3 | 9 | 0.52 | 288 |
| Q2 | 7.4 | 3 | 9 | 0.54 | 297 |
| Q3 | 7.3 | 3 | 9 | 0.62 | 295 |
| Q4 | 8 | 3 | 9 | 0.64 | 296 |
| Q5 | 5.8 | 3 | 9 | 0.51 | 289 |
| Q6 | 6 | 3 | 9 | 0.58 | 296 |

TABLE 2. Cumulative Invitro Drug Release % Q1-Q6

| Time [min] | Cumulative invitro drug release % | | | | | |
|---|---|---|---|---|---|---|
| | Q1 | Q2 | Q3 | Q4 | Q5 | Q6 |
| 120 | 6.2 | 6.4 | 6.8 | 5.8 | 8.0 | 7.8 |
| 240 | 24 | 25 | 26 | 27 | 47 | 22 |
| 360 | 46 | 42 | 45 | 43 | 54 | 38 |
| 480 | 51 | 57 | 55 | 52 | 63 | 45 |
| 600 | 63 | 68 | 64 | 61 | 76 | 56 |
| 720 | 73 | 74 | 76 | 71 | 88 | 68 |

*SEM analysis:* The surface characterization for the oral matrix formulation for the optimized Q6 conducted both with drug loaded and drug unloaded at low maginification and in dimensions at 200um and 500um respectively shown in Fig 1 & 2.

*Discussion:* The calibration curve of Pantoprazole drug was found to be $R^2$ =0.9987. The pH of the prepared buffer solution was checked by digital pH meter and found to be 6.81.

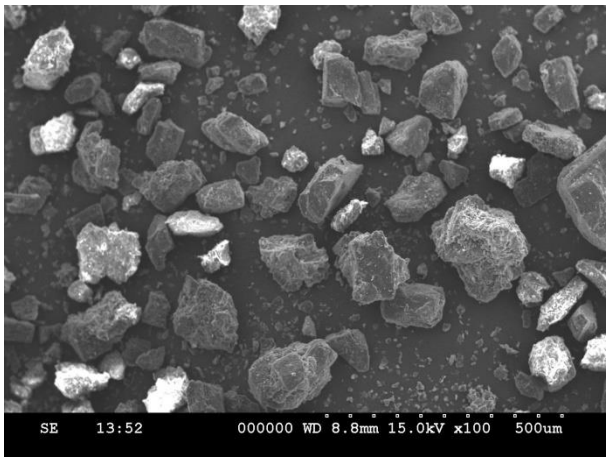


Fig. 1. Tablet formulation with SBA-15 in 500um dimension

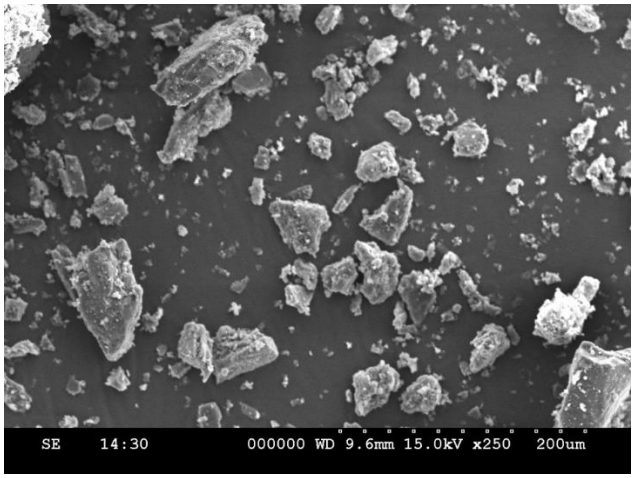


Fig. 2. Tablet formulation drug loaded SBA-15 in 200 um dimension

The Hardness of the tablet tested by Monsanto hardness tester was found to be in the range 5.8-8 kg/cm$^2$. The Thickness of the six formulations was found to be uniform as 3mm.The diameter of all the six matrix tablet formulations were found to be uniform as 9mm. The friability of all the six matrix formulations was found to be in the range of 0.51-0.64 found to be within the limits of 0.5-1%. The average weight of all the six formulations found to be in 288,297,295,296, 289 and 296 mg respectively formulated for 300mg and was found to be within the acceptable limits. The cumulative % drug release of the six formulations was performed at the 2,4,6,8,10,12 hours with the time interval of 2 hours, at the end of 12 hours was found to be as 73,74,76,71,88 and 68 respectively. The surface characterization of the drug loaded and drug unloaded tablet formulations at low magnification at 5,10,20,50,100,200 and 500 um respectively. The images visualized at different dimensions found to have same surface characteristics for drug loaded and drug unloaded tablet matrix formulations. Hence, all the prepared six tablet matrix formulations evaluated various parameters were found to be uniform in appearance, weight, friability and dimensions all found within the acceptable criteria. The optimized formulation was found to be Q6 with good controlled release behaviour.



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## IV. CONCLUSION

The present project work aimed to enhance the solubility of the drug and improve the formulation with mesoporous silica-based nanoparticle as a drug carrier providing multifunction's like stability enhancing, controlled release nature, solubility enhancer without addition of solubility enhancers, good adsorption properties and high drug loading capacity. All the formulations have shown good formulation properties and the evaluation results comply with the acceptable criteria. The optimized formulation was found to be as Q6. The usage of silica based polymer as carrier for Pantoprazole proven to be good drug carrier and giving scope for further research.

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