INTERNATIONAL JOURNAL OF PROGRESSIVE RESEARCH IN ENGINEERING MANAGEMENT AND SCIENCE (IJPREMS)
(Int Peer Reviewed Journal)
Vol. 05, Issue 09, September 2025, pp : 493-500

e-ISSN : 2583-1062
Impact Factor : 7.001

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# A REVIEW ON FORMULATION AND EVALUATION OF ENTERIC COATED TABLETS OF PANTOPRAZOLE

**Dhanki Vedant Mahesh Bhai[1], Mrs. Deeksha Bhojak[2], Dr. Revathi A Gupta[3]**

[1,2,3]IOP, Dr. APJ Abdul Kalam University, Indore (MP), India.

DOI: https://www.doi.org/10.58257/IJPREMS43790

## ABSTRACT

Pantoprazole is a P.P.I., belongs to group of benzimidazole, Pantoprazole sodium were prepared by direct compression method using different concentration of, microcrystalline cellulose as filler, mannitol and dicalcium phosphate as diluents, crosscarmellose sodium as disintegrating agents, magnesium stearate and talc was used as a glidant and lubricant respectively. Direct compression is economic compare to wet granulation since it requires fewer unit operations. This means less equipment, lower power consumption, less space, less time and less labour leading to reduced production cost of tablets. The prepared tablets were evaluated for hardness, weight variation, friability and drug content uniformity and it was found that the results comply with official standards. The prepared tablets were coated using enteric coating polymer such as cellulose acetate phthalate, Eudragit L100 and by dip coating method. The in vitro release was studied using acidic buffer pH 1.2 and phosphate buffer pH 6.8. Prepared all batch's C2F9 was found best, with hardness 5.60 ± 0.24 (Kg/cm2), drug content 99.08 ± 0.35(%), disintegration time 7.02± 0.21(min), and percentage cumulative drug released which started after 120 min and reached 99.72 after 180 min. Stability studies indicated that the developed tablets were stable and retained their pharmaceutical properties at room temperature and 40°C / 75% RH for a period of 3 month.

**Keywords:** Pantoprazole, Direct compression, Tablets.

## 1. INTRODUCTION

More than 50% of pharmaceutical products are orally administered for several reasons. This route of administration is considered as the most widely used route as it offers advantages like ease of administration, versatility, patient compliance and accurate dosing. Undesirable taste is one of the important formulation problems that are encountered with such oral product. The stomach is continuous with the oesophagus at the cardiac sphincter and with the duodenum at the pyloric sphincter. It has two curvatures. The stomach is divided into three regions: the fundus, the body and the antrum. At the distal end of the pyloric antrum is the pyloric sphincter, guarding the opening between the stomach and the duodenum. When the stomach is inactive the pyloric sphincter is relaxed and open and when the stomach contains food the sphincter is closed.

Gastric Defenses Against Acid - The extremely high concentration of H+ in the gastric lumen requires robust defense mechanisms to protect the esophagus and the stomach. The primary esophageal defense is the lower esophageal sphincter, which prevents reflux of acidic gastric contents into the esophagus. The stomach protects itself from acid damage by a number of mechanisms that require adequate mucosal blood flow, perhaps because of the high metabolic activity and oxygen requirements of the gastric mucosa. One key defense is the secretion of a mucus layer that protects gastric epithelial cells. Gastric mucus is soluble when secreted but quickly forms an insoluble gel that coats the mucosal surface of the stomach, slows ion diffusion, and prevents mucosal damage by macromolecules such as pepsin.

Pathophysiology of peptic ulcer

Classical causes of ulcers (tobacco smoking, blood groups, spices and a large array of strange things) are of relatively minor importance in the development of peptic ulcers. A major causative factor (90% of gastric and 75% of duodenal ulcers) is chronic inflammation due to Helicobacter pylori, a spirochete that inhabits the antral mucosa and increases gastric production. Gastric, in turn, stimulates the production of gastric acid by parietal cells.

Smoking leads to, atherosclerosis and vascular spasms causing vascular insufficiency and promoting the development of ulcers through ischemia. A family history is often present in duodenal ulcers, especially when blood group O is also present. Inheritance appears to be unimportant in gastric ulcers9.

**Gastroesophageal reflux disease (GERD)**

It is a very common problem presenting as 'heartburn', acid eructation, sensation of stomach contents coming back in foodpipe, especially after a large meal, aggravated by stooping or lying flat. Some cases have an anatomical defect (hiatus hernia) but majority are only functional (LES relaxation in the absence of swallowing). Repeated reflux of acid gastric contents into lower one third of esophagus causes esophagitis, erosions, ulcers, pain on swallowing, dysphasia strictures, and increases the risk of esophageal carcinoma**10**.

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**Epidemiology**

Gastroesophageal reflux disease occurs in both adults and children. Although mortality associated with GERD is rare (1 death per 100,000 patients), GERD symptoms have a greater impact on quality of life than do duodenal ulcers, untreated hypertension, mild congestive heart failure, angina, or menopause. The true prevalence and incidence of GERD

is difficult to assess because (a) many patients do not seek medical treatment, (b) symptoms do not always correlate well with severity of disease, and (c) there is no standardized definition or universal gold standard method for diagnosing the disease.

**Treatment of acid-related diseases**

**Antacids**

Antacids are alkali preparations that neutralize hydrochloric acid in the stomach. Antacids can contain aluminium, magnesium, calcium or combined substances. Antacids are indicated for dyspepsia, GERD, reflux oesophagitis and gastritis. Their onset of action is fast, but they require frequent administration (4 to 6 times a day) because of their short duration of action.

**H2-receptor antagonists**

Parietal cells in the stomach express receptors for acetylcholine, gastric and histamine. Stimulation of these receptors results in gastric acid production. H2-receptor antagonists (H2RAs) inhibit acid production by reversibly competing with histamine for binding to H2-receptors on the parietal cells. Four different H2RAs are available: cimetidine, famotidine, nizatidine and ranitidine. H2RAs are indicated for reflux-oesophagitis, ulcus duodeni, ulcus ventriculi, prevention of recurrent peptic ulcers and the treatment of NSAID related ulcers. These agents are primarily effective in decreasing basal acid production and nocturnal acid breakthrough. They are however less effective in controlling food-stimulated acid secretion during daytime. In general, H2RAs are administered twice a day. Although H2RAs have reasonable efficacy, patients develop tolerance in particular with continuous therapy.

**Proton pump inhibitors**

Proton pump inhibitors (PPIs) suppress gastric acid secretion by specific inhibition of the H+/K+- ATPase in the gastric parietal cell. This process starts with absorption of the PPI in the parietal cell. PPIs are weak bases, so protonation takes place in the acidic region of the secretory canaliculus of the parietal cell.

## 2. MATERIAL AND METHOD

**Table 1:** LIST OF CHEMICALS USED

| SL. No. | Materials | Manufacturer / Supplier |
|---|---|---|
| 1 | Acetone | SD Pharma, Mumbai, India |
| 2 | Calcium phosphate | Fine Chem Industries, India |
| 3 | Disodium hydrogen phosphate | Fine Chem Industries, India |
| 4 | Potassium dihydrogen phosphate | Cipla Pharma, Mumbai, India |
| 5 | Cellulose acetate phthalate | SD Pharma, Mumbai, India |
| 6 | Micro crystalline cellulose | Cipla Pharma, Mumbai, India |
| 7 | Mannitol | Signet Chemical Corporation |
| 8 | Croscarmellose sodium | SD Chemical Corporation |
| 9 | Pantoprazole sodium sesquihydrate | Signet Chemical Corporation |
| 10 | Talc | Spectrochem Pvt. Ltd. Mumbai. |
| 11 | Magnesium stearate | Spectrochem Pvt. Ltd. Mumbai. |
| 12 | Eudragit L-100 | Sd fine Chem. Ltd., Mumbai, India. |
| 13 | Potassium dihydrogen Phosphate | Spectrum reagent and chemicals Pvt. Ltd., India. |
| 14 | Hydrochloric acid | Swastik Pharmaceuticals, Mumbai, |

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| | | |
|---|---|---|
| | | **India.** |

**Table 2:** LIST OF EQUIPMENT USED

| SL. NO | Equipment | Manufacturer / Supplier |
|---|---|---|
| 1 | Rotary tablet punching machine | Ridhi Pharma machinery, Ahmedabad, India |
| 2 | UV Spectrophotometer | Shimadzu 1800, Japan |
| 3 | Digital Electronic Balance | Citizon, India. |
| 4 | Monsanto Hardness tester | Labtech, India |
| 5 | Friability apparatus | Ketan, Koshish Industries, India |
| 6 | Digital pH meter | Hanna, India |
| 7 | Vernier calipers | Mitutoyo. Japan |
| 8 | Disintegration test apparatus | Electrolab ED-2L,Servewell Industries, India |
| 9 | Dissolution test apparatus | Electrolab TDT-08L Servewell Industries, India |
| 10 | FTIR Spectrophotometer | Bruker,Japan. |
| 11 | Hot air oven | Servewell Industries, India |

**Preparation of powder blend**

Pantoprazole sodium sesquihydrate powder blend for tabletting were prepared by direct compression method. Specified quantity of pantoprazole, croscarmellos sodium, manitol, calcium phosphate, and MCC were weighed accordingly and transferred in a mortar and pestle and mixed thoroughly. The powder was passed through sieve no 80 to obtain the granules. The specified quantity of magnesium stearate and talc were finally added and mixed for the compression of tablets.

**Preparation of pantoprazole sodium tablets**

An ideal mixture of granules were directly punched into tablets weighing about 200 mg containing 40 mg of pantoprazole sodium sesquihydrate, using rotary tablet compression machine (Riddhi 10 stn mini tablet press RDB4-10, Rimek, Ahmedabad, India), using 8 mm diameter concave punches. The different batches of pantoprazole tablets were collected and stored in air tight containers.

**Table 3:** Composition of pantoprazole sodium enteric coated sodium tablets

| Composition | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
|---|---|---|---|---|---|---|---|---|---|
| Pantoprazole sodium (mg) | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 |
| Croscarmellose sodium (mg) | 2 | 4 | 6 | 2 | 4 | 6 | 2 | 4 | 6 |
| Microcrystalline cellulose(mg) | 27 | 25 | 23 | 27 | 25 | 43 | 80 | 50 | 23 |
| Mannitol (mg) | 50 | 75 | 100 | 40 | 85 | 80 | 43 | 50 | 75 |
| Dicalcium phosphate (mg) | 75 | 50 | 25 | 85 | 40 | 25 | 75 | 50 | 50 |
| Talc (mg) | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Magnesium stearate (mg) | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| Total weight (mg) | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 |

**Table 4:** Composition of coating solution

| Ingredients | Quantity (%) |
|---|---|
| Cellulose acetate phthalate/ Eudragit L100 | 6.0 / 8.0 |
| PEG | 1.5 |
| Acetone | 59.4 |

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**Enteric coating of pantoprazole sodium compressed tablets by dipping method**

The compressed tablets were coated with enteric coating polymer (Eudragit L100 or cellulose acetate phthalate) solution by dipping method. Desired tablet coating continued the dipping and weight gain was achieved. The coated tablets were studied for its weight variation, thickness, uniformity of drug content and *in vitro* dissolution study**.**

## 3. RESULTS AND DISCUSSIONS

**Table 5:** Calibration data of pantoprazole sodium in 0.1N HCl (pH 1.2)

| SL. NO. | Concentration (mg /mL) | Absorbance* (nm) |
|---|---|---|
| 1 | 0 | 0 |
| 2 | 2 | 0.082+0.0005 |
| 3 | 4 | 0.145+0.0015 |
| 4 | 6 | 0.231+0.0101 |
| 5 | 8 | 0.289+0.0023 |
| 6 | 10 | 0.361+0.0025 |
| 7 | 12 | 0.459+0.0047 |

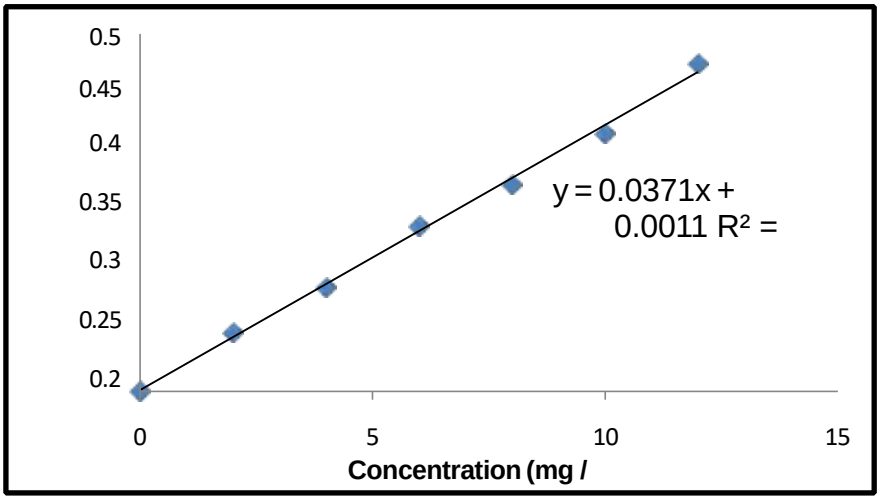


**Figure 1:** Standard graph of pantoprazole sodium in 0.1N HCl (pH 1.2)

**Table 6:** Calibration data of pantoprazole sodium in phosphate buffer (pH 6.8)

| SL. NO. | Concentration (mg /mL) | Absorbance*(nm) |
|---|---|---|
| 1 | 0 | 0 |
| 2 | 2 | 0.085±0.0040 |
| 3 | 4 | 0.149±0.0036 |
| 4 | 6 | 0.243±0.0015 |
| 5 | 8 | 0.305±0.0075 |
| 6 | 10 | 0.373±0.0051 |
| 7 | 12 | 0.468±0.0020 |

*Mean±SD, $n = 3$

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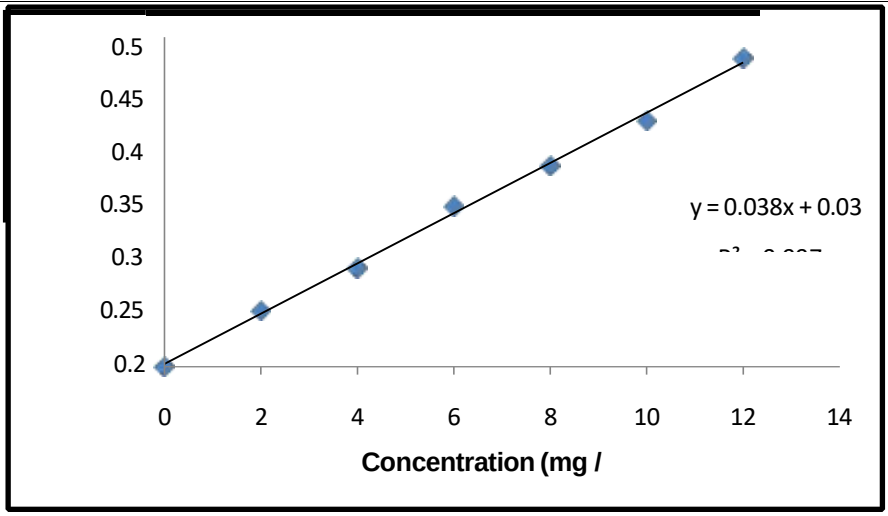


**Figure 2:** Standard graph of pantoprazole sodium in phosphate buffer (pH 6.8)

**Table 7:**

| Formulation Code | Parameter | | | | |
|---|---|---|---|---|---|
| | Bulkdensity (gm/mL) * | Tapped density (gm/mL) * | Carr's Index (%)* | Hausner's ratio* | Angle of repose (Θ)* |
| F1 | 0.357±0.03 | 0.384±0.05 | 7.03±0.09 | 1.075±0.04 | 28.31±0.26 |
| F2 | 0.312±0.04 | 0.335±0.02 | 6.86±0.15 | 1.073±0.05 | 27.20±0.14 |
| F3 | 0.306±0.03 | 0.326±0.03 | 6.13±0.12 | 1.065±0.02 | 29.13±0.34 |
| F4 | 0.312±0.03 | 0.334±0.06 | 6.58±0.14 | 1.070±0.06 | 26.13±0.26 |
| F5 | 0.306±0.03 | 0.334±0.05 | 8.38±0.17 | 1.091±0.08 | 26.78±0.18 |
| F6 | 0.384±0.04 | 0.429±0.05 | 10.48±0.20 | 1.117±0.07 | 25.79±0.24 |
| F7 | 0.358±0.05 | 0.385±0.04 | 7.01±0.13 | 1.075±0.03 | 29.52±0.14 |
| F8 | 0.286±0.05 | 0.313±0.04 | 8.62±0.07 | 1.094±0.03 | 26.95 ±0.15 |
| F9 | 0.348±0.08 | 0.328±0.05 | 5.74±0.13 | 1.06±0.08 | 26.13±0.26 |

**Post compression parameters of pantoprazole sodium core tablet**

The pantoprazole tablets were prepared by direct compression method and were evaluated for their hardness, weight variation, content uniformity, friability and *in vitro* drug release (Table 9). Hardness has to be controlled to ensure that the product is firm enough to withand handling without breaking or crumbling and not so hard that the disintegration time is unduly prolonged. The average hardness of the tablets to be in range was found within 4.93 ± 0.15 to 6.20 ± 0.35 Kg / cm2. Friability value which also affected by the hardness value of tablets should be in the range 1% limits, which is the usual friability range of tablets. The friability of the prepared tablets was found less than 1% w/w. The drug content uniformity of pantoprazole sodium present in tablets formulation ranged from 96.28 ± 0.15to 100.34 ± 0.13%. The average weight found 198 ± 0.15 to 206 ± 0.24 mg. Disintegration time varied between 11.48 ± 0.15 to 5.38 ± 0.23, hence all shows favorable result.

**Table 8:** Post compression parameters of pantoprazole sodium core tablets

| Formulation Code | Parameter | | | | |
|---|---|---|---|---|---|
| | Hardness (Kg/cm2 )* | Friability (%)* | Weight variation (mg) * | Drugcontent (%)* | Disintegration time(min) * |
| 1 | 5.80 ± 0.12 | 0.69 ± 0.015 | 199 ± 0.12 | 96.28 ± 0.15 | 10.6± 0.62 |
| F2 | 5.56 ± 0.24 | 0.51 ± 0.017 | 206 ± 0.24 | 97.62 ± 0.27 | 8.26± 0.56 |
| F3 | 5.83 ± 0.08 | 0.48 ± 0.014 | 201 ± 0.17 | 99.51 ± 0.36 | 5.38± 0.23 |

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| | | | | | |
|---|---|---|---|---|---|
| F4 | 4.93 ± 0.15 | 0.64 ± 0.015 | 208 ± 0.20 | 98.17 ± 0.16 | 11.48± 0.15 |
| F5 | 5.73 ± 0.25 | 0.71 ± 0.016 | 203 ± 0.16 | 98.92 ± 0.42 | 9.32± 0.18 |
| F6 | 5.12 ± 0.34 | 0.68 ± 0.026 | 206 ± 0.14 | 100.34 ± 0.13 | 6.13± 0.25 |
| F7 | 5.66 ± 0.17 | 0.54 ± 0.026 | 199 ± 0.22 | 98.50 ± 0.48 | 10.54± 0.43 |
| F8 | 6.20 ± 0.35 | 0.49 ± 0.025 | 204 ± 0.18 | 98.41 ± 0.34 | 9.12± 0.71 |
| F9 | 5.60 ± 0.24 | 0.42 ± 0.018 | 198 ± 0.15 | 99.08 ± 0.35 | 6.02± 0.21 |

*** Mean ± SD, n=3**

**Table 9:** Physicochemical evaluation parameters of enteric coated tablets

| Polymer | Batch Code | Parameter | | |
|---|---|---|---|---|
| | | Weight Variation (mg) * | Hardness Kg/cm2* | Drugcontent (%)* |
| CAP | C1F3 | 211 ± 0.035 | 6.5 ± 0.15 | 96.75 ± 0.14 |
| | C2F3 | 214 ± 0.016 | 5.9 ± 0.24 | 93.65 ± 0.35 |
| | C1F9 | 212 ± 0.006 | 5.4 ± 0.09 | 94.45 ± 0.26 |
| | C2F9 | 210 ± 0.024 | 6.3 ± 0.14 | 98.54 ± 0.12 |
| Eudragit L 100 | E1F3 | 214 ± 0.021 | 5.5 ± 0.16 | 93.47 ± 0.23 |
| | E2F3 | 213 ± 0.012 | 6.0 ± 0.06 | 94.56 ± 0.14 |
| | E1F9 | 215 ± 0.015 | 6.5 ± 0.31 | 98.27 ± 0.45 |
| | E2F9 | 211 ± 0.024 | 5.7 ± 0.20 | 96.35 ± 0.12 |

***Mean±SD, *n* = 3**

**Table 10:** *In vitro* drug release of pantoprazole sodium (C1F3)

| Time (min) | Absorbance | Conc. (µg/mL) | Conc. in 900 mL (mg /mL) | Loss | Cumulative loss | Cumulative drugreleased | Cumulative percentage drug released * |
|---|---|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 15 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 30 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 45 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 60 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 75 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 90 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 105 | 0.024 | 0.6469 | 5.822 | 0 | 0 | 5.822 | 14.62±0.52 |
| 120 | 0.06 | 1.6172 | 14.555 | 0.0064 | 0.0064 | 14.561 | 36.58±0.40 |
| 135 | 0.091 | 2.3884 | 21.496 | 0.0161 | 0.0226 | 21.518 | 54.05±0.90 |
| 150 | 0.121 | 3.1758 | 28.582 | 0.0238 | 0.0465 | 28.629 | 71.91±0.39 |
| 165 | 0.142 | 3.7270 | 33.543 | 0.0317 | 0.0782 | 33.621 | 84.46±0.17 |
| 180 | 0.162 | 4.2519 | 38.267 | 0.0372 | 0.1155 | 38.383 | 96.42±0.40 |

*** Mean±SD, *n* = 3**

**Table 11:** Stability studies of cellulose acetate phthalate coated tablet formulation C2F9

| Evaluation parameters | Observation in month | | | |
|---|---|---|---|---|
| | Initial | 1st month | 2nd month | 3rd month |

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| | | | | |
|---|---|---|---|---|
| **Physical Appearance** | **whitecolor tablets** | **No change** | **No change** | **No change** |
| **Hardness (Kg / cm2) *** | **6.3 ± 0.14** | **6.2 ± 0.56** | **6.2 ± 0.64** | **6.2 ± 0.26** |
| **Drug Content (%)*** | **98.54 ± 0.12** | **98.36 ± 0.52** | **98.16 ± 0.36** | **98.07 ± 0.28** |

***Mean ± SD, n=3**

## 4. CONCLUSION

The aim of the present study was to formulate and evaluate of enteric coated pantoprazole sodium sesquihydrate tablets by using manotol, dicalcium phosphate, microcrystalline cellulose, crossrmelose sodium, magnesium starate and talc.

FT-IR study was carried out to check any possible interactions between the drug and the excipients manotol, dicalcium phosphate, microcrystalline cellulose, crosscarmelose sodium, Pantoprazole sodium sesquihydrate were prepared by direct compression method using different concentration of, Avicel PH (MCC) as filler, mannitol and dicalcium phosphate as diluents, croscarmellose sodium as disintegrating agents, magnesium stearate and talc was used as a glidant and lubricant respectively. The granules were evaluated for the precompression parameters like angle of repose, bulk density, tapped density and compressibility index. The flow characteristics of the granules were assessed by determining their angle of repose and Carr's Index. The values of compressibility index and angle of repose signify good flowability of the granules for all the batches. This shows that the granules had smooth flow properties ensuring homogenous filling of the die cavity during the compression (punching) of tablets.

Coating has been done for the selected formulation from the proposed formulation 1-Coating materials like CAP and Eudragit L100 with the difference concentration.

The *in vitro* dissolution studies were carried out for compressed and coated tablets using USP dissolution apparatus type II. The cumulative percentage of drug release from the tablets varied and depends on the type of polymer used and its concentration.

Formulation 3 and formulation 9 was selected for the coating. CAP and Eudragit L 100 was used for the coating polimer. In this present study coating material was used with 6 and 8 percentage on the above-mentioned formulation.

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