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Preparation and Evaluation of Enteric Coated Tablets of Misoprostol

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ABSTRACT
Enteric coated tablets are prepared by direct pressure technique. standard graph of Misoprostol was prepared using acidic buffer Enteric coating of Misoprostol compressed tablets by dipping method. In this current research, employed digestive covering highest definition. CAP and EudragitL100 were utilized at 6% & 8%, respectively, with optimal arrangement. From the crumbling focus, it was discovered that digestive-covered ideal for 2 hours in pH 1.2. The specification assigned to best definition is C2F9, plan number 9 is covered by 8% CAP.

I. INTRODUCTION

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.

Ulcers are crater-like sores (generally 1/4 inch to 3/4 inch in diameter, but sometimes 1 to 2 inches in diameter) which form in the lining of the stomach (called gastric ulcers), just below the stomach at the beginning of the small intestine in the duodenum (called duodenal ulcers) or less commonly in the esophagus (called esophageal ulcers). In general, ulcers in the stomach and duodenum are referred to as peptic ulcers

Prostaglandin analogues are a class of drugs that bind to a prostaglandin receptor Prostaglandin analogues such as misoprostol are used in treatment of duodenal and gastric ulcers. Misoprostol and other prostaglandin analogues protect the lining of the gastrointestinal tract from harmful stomach acid and are especially indicated for the elderly on continuous doses of NSAIDs.

This medication is used to prevent stomach ulcers while you take NSAIDs (such as aspirin, ibuprofen, naproxen), especially if you are at risk for developing ulcers or have a history of ulcers. Misoprostol helps to decrease your risk of serious ulcer complications such as bleeding. This medication protects your stomach lining by lowering the amount of acid that comes in contact with it. This medication is also used in combination with another drug (mifepristone) to end a pregnancy.

Aim
The main objectives of the present study was
To formulate and evaluate enteric coated tablets Misoprostol by direct compression method
Selection of suitable coating material to develop the dosage form
To overcome the drug degradation by the gastric enzymes as well as the acidic environment of the stomach.

Plan Of The Work

1. **Pre-compression parameters**
- Bulk density
- Tapped density
- Carr's index
- Haussner ratio
- Angle of repose

2. **Post compression parameters**
- Weight variation
- Hardness test
- Friability test
- Drug content
- Disintegration time

3. **Tablets coating**
- Filmthickness
- Film solubility

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- In-vitro dissolution studies

II. METHODOLOGY

1. Determination of absorption maxima (λmax)

In a 100 mL volumetric cup, 100 mg of Miso-prostol sesqui-hydrate were carefully weighed & separated in 100 mL of acidic solution with pH 1.2. 2 mL withdrawn plan, container, & degraded support. The final strategy referred to normal functioning course of action. 2 mL of working plan was extracted & reduced to container with pH 1.2 acidic help. This approach was carried out using a UV-recognizable spectrophotometer range. Misoprostol sesquihydrate was determined at 283 nm.

2. Preparation of standard graph

To measure use a pad cup absorbance each course of action was measured using a UV-observable spectro-photometer help as clear.

Formulation studies

Preparation of Misoprostol tablets

Preparation of powder blend

Misoprostol was manufactured using a direct pressure approach. Misoprostol, croscarmellos Na, measured recipe until well combined. Granules were obtained by sifting the material via sifter 80. Finally, tablets were made by adding & combining appropriate proportions of magnesium stearate & powder.

Preparation of Misoprostol tablets

An optimal combination simply roughly Misoprostol sesqui-hydrate, using a rotating pressure with 8 mm distance across inward punches. The various clumps Misoprostol were collected & stored in hermetically sealed chambers.

Composition of Misoprostol enteric coated sodium tablets

Composition	F1	F2	F3	F4	F5	F6	F7	F8	F9
Misoprostol (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

Evaluation

Bulk density

Accurately weighed granules were carefully transferred into graduated measuring cylinder. The granules bed was then made uniform and the volume occupied by the granules was noted as per the graduation marks on the cylinder as mL. It is expressed in gm/mL and is calculated using the following formula.

Tapped density

It is the ratio of total mass of granule to the tapped volume of granule. The graduated measuring cylinder containing accurately weighed granule was manually tapped for 50 times. Volume occupied by the granule was noted. It is expressed in gram/mL and is calculated by following formula.

Angle of repose

The frictional forces in a loose powder can be measured by the angle of repose. This is the maximum angle possible between the surface of a pile of powder and the horizontal plane. Sufficient quantities of Misoprostol granules were passed through a funnel from a particular height (2 cm) onto a flat surface until it formed a heap, which touched the tip of the funnel. The height and radius of the heap were measured. The angle of repose was calculated using the formula.

Angle of repose $(\theta) = \tan^{-1}(h/r)$ Where, h – Height of the pile in cm r – Radius of the pile

In vitro drug release studies

The USP disintegration mechanical

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assembly was used study under various definitions. The disintegration process included cushion two hours cradle for one hour kept in a jar. The temp kept tests were removed at regular with an equal volume of fresh disintegration material. A UV spectrophotometer was used to measure samples at clean background. The delivery conducted in three phases, with mean characteristics shown against time.

Stability studies

Security conducted in accordance with ICH guidelines. Misoprostol sealed for 90 days. Tests from each detailing that were saved for evaluation were eliminated at different time intervals. The removed instances were evaluated their genuine look, hardness drug content.

Pre compression parameters of Misoprostol

Formulation Code	Parameter				
	Bulk density (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 Misoprostol core tablets

Formulation Code	Parameter				
	Hardness (Kg/cm^2)*	Friability (%)*	Weight variation (mg) *	Drug content (%)*	Disintegration time(min) *
F1	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
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

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Stability studies of cellulose acetate phthalate coated tablet formulation

Evaluation parameters	Observation in month			
	Initial	**1st month**	**2nd month**	**3rd month**
Physical Appearance	white color 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

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