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Review Article

A Review on Enteric Coated Tablet

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Abstract:
Some of the purpose of tablet coating are masking flavour, fragrance overlapping, Environmental protection, prevent drug from gastric acid .Enteric coated tablets are solid unit dosage forms which are designed to bypass the stomach and release the drug in small intestine and are meant for oral administration. The word "enteric" indicates small intestine; therefore enteric coatings prevent release of medication before it reaches the small intestine.Most enteric coating works by presenting a surface that is stable at the highly acidic pH found in stomach, but breaks down rapidly at a less acidic pH. For e.g. they will not dissolve in the acidic juices of the stomach (pH-3), but will in the alkaline (pH7-9) environment present in the small intestine. Materials used for enteric coatings include CAP, CAT, PVAP and HPMCP, fatty acids, waxes, shellac, plastics and plant fibres.

Introduction

Tablet is a pharmaceutical solid dosage form, comprising a mixture of active substances and excipients, commonly in powder form, pressed or compacted right into a stable. Coating is a process by which the coating material is applied to the surface of a dosage form in order to confer specific benefits to the dosage form. An enteric coating is a barrier that controls the release of oral medication in the stomach and promotes its release in the intestine where it is absorbed. The word "enteric" indicates small intestine; therefore enteric coatings prevent release of medication before it reaches the small intestine. The enteric coated polymers remain unionise at low pH, and therefore remain insoluble. But as the pH increases in the GIT, the acidic functional groups are capable of ionisation, and the polymer swells or becomes soluble in the intestinal fluid. Materials used for enteric coatings include CAP, CAT, PVAP and HPMCP, fatty acids, waxes, shellac, plastics and plant fibers.[1]

Ideal Properties of Enteric Coating

- Resistance to gastric fluids.
- Susceptible/permeable to intestinal fluid.
- Compatibility with most coating solution components and the drug substrate.
- Formation of continuous film.
- Nontoxic, cheap and ease of application.
- Ability to be readily printed. [2]

Advantages of Enteric Coating

1. To protect the acid liable drugs from the gastric fluid e. g. enzymes and certain antibiotics.
2. Coatings are necessary for tablets that have an unpleasant taste, and a smoother finish makes large tablets easier to swallow.[3]
3. To forbid gastric distress or nausea due to irritation from a drug, e.g. sodium salicylate
4. To deliver drugs intended for local action in the intestines, e. g. intestinal antiseptics could be delivered to their site of action in a concentrated form.[5]

Disadvantages

1. Process is tedious.
2. Time-consuming.
3. Requires the expertise of highly skilled technician.[4]

Polymers Used In Enteric Coating [2]

Polymers	Dissolution pH
Shellac (esters of aleurtic acid)	7.0
Cellulose acetate phthalate (CAP)	6.2
Poly(methacrylic acid-co-methyl methacrylate)	5.5-7.0
Cellulose acetate trimellitate (CAT)	5.0
Poly(vinyl acetate phthalate) (PVAP)	5.0
Hydroxypropyl methylcellulose phthalate(HPMCP)	4.5-5.5

Process of Coating

Tablet coating takes place in a controlled atmosphere inside a perforated rotating drum. Once you load a batch of tablets into the coating pan, you need to preheat the tablets and allow time for dust and tablet flash to exit the pan. Angled baffles fitted into the drum and air flow inside the drum provides means of mixing the tablet bed. As a result, the tablets are lifted and turned from the sides into the centre of the drum, exposing each tablet surface to an even amount of deposited/sprayed coating. Once the temperature of the outlet air reaches 42° to 46°C, usually within 15 minutes, spraying can begin. The spray guns create a fine mist of coating solution that dries just after it contacts the tablet. The liquid spray coating dried onto the tablets by heated air drawn through the tablet bed from an inlet fan. The air flow is regulated for temperature and volume to provide controlled drying and extracting rates, and at the same time, maintaining the drum pressure slightly negative relative to the room in order to provide a completely isolated process atmosphere for the operator.

As the water evaporates, it leaves the solids behind to form a thin film on the tablet. The key to tablet coating is to get the surface slightly wet and immediately dry. Remember: apply the coating in many short, fast exposures, not in long, slow exposures. Once the base coating is applied, you can increase the rate of solution addition and the pan speed proportionately. Typically, it takes about 20 minutes before increasing the spray rate and pan speed significantly.

Tablets that are very porous may require an initial spray rate that is slower than the average of 100 milliliters per minute per gun. Be sure to monitor spraying to see whether the spray pattern changes. If it does, there is likely a build-up of solids on the gun tips. Correct this

only by cleaning the tips, which means stopping the spray and the pan.

The enteric coating solution dries on the tablet surface because there is a constant supply of hot air entering the drum and passing through the drum perforations into the bed of tablets. Over time, the film builds layer after layer of solids. After finished applying the solution and drying it, the tablets must cool. For coatings to adhere properly, the tablets must remain at a specific temperature, the solution must be applied at a consistent rate, and the motion of the tablets must be active yet tranquil. Disrupt any of these conditions, and this will produce a defective tablet. [5, 9]

Method of Manufacturing Enteric Coated Tablet by Spray Coating Technique

1. Preparation of core tablets

Granules were prepared using wet granulation method. Drug and other excipients were passed through # 80 and add sufficient quantity of binding agent slowly to get dough mass. The mass was sieved through # 8 and dried at 45ºC for about 1 hrs. and then these granules were passed through # 20 and lubricated with magnesium stearate. Mixed blend was compressed into tablets on single punch tablet compression machine to a weight of 250 mg each with thickness of 4.46 ± 0.21 mm and diameter of 7.9 mm using shallow concave plain/plain punch.

2. Coating of core tablets

Preparation of enteric coating solution Weighed amount of pectin was dissolved in 50 ml of water and ethyl cellulose was dissolved in 50 ml of isopropyl alcohol. The two solutions were then mixed well to form a homogeneous solution and PEG-6000 was added as a plasticizer.

3. Coating of core tablets

Enteric coating of the compressed tablets is achieved by standard coating pan technique. Tablets were taken and were coated in a pan coater at 50 rpm at a temperature of 50ºC and at a flow rate of 10 ml/min. Coating was carried out with spraying method and dried. These solutions are applied over tablets using spray gun at appropriate pressure. The coated tablets are primarily dried using heat blower and secondarily dried in tray drier. [9]

4. Coating methodology

Tablet coating was performed in a conventional coating pan with one spray gun. The coating pan was previously cleaned using alcohol 95%. A batch size of 3.5 kg core tablets was selected for coating. The core tablets were loaded into the coating pan. Tablet cores were pre- heated to about 40°C utilizing a dryer and air compressor. Warm air was introduced into the coating pan (up to 50–55°C) during the entire coating process. The spray gun was filled with enteric coating solution and operated at a proper flow rate. The pan was set into motion and seal coating dispersion was sprayed on to the falling cores under a suitable air pressure (87.0- 116.0 psi) 6-8 bar. The air heater was switched off and tablets were blow dried for 20-25 minutes in the coating pan. The core tablets gained 10 ± 2% weights after coating with enteric coating solution. [8]

Characterization of Tablets

Appearance

The general appearance and elegance of tablet was identified visually, which include tablet

size, shape, color, presence or absence of an odour, surface texture etc.

Weight variation

Twenty tablets were weighed individually and average weight was determined. The individual tablet weight was compared with average tablet weight. The coated tablet weight and the maximum percent difference allowed is 5.0%.

Thickness

Tablet was selected at random from individual formulations and thickness was measured by using venire caliper scale, which permits accurate measurement. Tablet thickness should be controlled within a ± 0.2% variation of standard value.[7]

Tablet Friability

Friability is the measure of tablet strength. Roche Friabilator was used for testing the friability using the following procedure. Twenty tablets were weighed accurately and placed in the tumbling apparatus that revolves at 25 rpm dropping the tablets through a distance of six inches with each revolution. After 4 min, the tablets were weighed and the percentage loss in tablet weight was determined. % Loss = Initial wt. of tablet – Final wt. of tablet/ Initial wt. of tablet

Hardness

Tablet was selected at random from individual formulations and measured by using Monsanto hardness tester.

Disintegration test

Disintegration time was determined using the disintegration apparatus USP in 0.1N HCl for 2 hrs and then in phosphate buffer pH 6.8 for 1 hour maintaining the temperature at 37 ± 2°C.

Dissolution test

The tablets were evaluated for in vitro drug release was carried out using USP dissolution. Six tablets were subjected to two hours exposure in 0.1N HCL buffer followed by immediate transfer to a dissolution bath containing 6.8 pH phosphate buffer and % drug released was measured. Buffer phase: - Samples were withdrawn from the dissolution vessels at 0, 60, 120, 135, 150, 165, 180 minutes interval. the % drug release was measured U.V method.[9]

Conclusion

From the above review, we can conclude that tablets are made enteric-coated for avoiding the first pass metabolism, gastric irritation and degradation and to direct the drug to the target intestines. Enteric coating protect the stomach against drugs which causes gastric irritation. Enteric coating protect the drug which is unstable in gastric fluids. Enteric coating provide a delayed- release component for repeat action tablets. The choice of the polymer and the thickness of the coated layer are critical to control the pH solubility profile of the enteric coated dosage form. An ideal polymer should be selected depending upon the type of the dosage form. This dosage form is preferred as it is very convenient and easy to formulate, cost-effective and does not require high cost equipments. For that reason, this dosage form has been gaining so much attention nowadays.

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