IJBPAS, December, 2024, 13(12): 6058-6069

ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

COMPARATIVE ANALYSIS OF COATED TABLETS: FORMULATION, PERFORMANCE, AND BIOAVAILABILITY

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Received 24th Aug. 2023; Revised 25th Oct. 2023; Accepted 20th Jan. 2024; Available online 1st Dec. 2024

https://doi.org/10.31032/IJBPAS/2024/13.11.8412

ABSTRACT

Although coating solid dosage forms, like tablets, is a standard practice, it is an important step that gives tablets unique properties. It improves the effectiveness of solid dose forms when taken orally and so satisfies a variety of clinical needs. Tablet coating is a technologically driven process; therefore, it depends on improvements in coating methods, coating equipment, coating tablet evaluation, and coating material. Each of the procedures utilized for coating purposes—which may be based on the use of solvents or solvent-free has advantages and disadvantages, and the techniques themselves require ongoing development. Particularly for those medications that have an active medication in the coating layer, inter- and intra-batch consistency of coated material on the tablets is seen to be a crucial factor that ensures the value of the final product. The impact of operational parameters on the quality of the finished product was actively predicted, and tablet coating variables were optimized, using computational modelling and experimental evaluation. The work done through computer modelling or experimental evaluation results in time and cost savings for the coating process. This paper provides a succinct overview of film coating in solid dosage forms, such as tablets, with an emphasis on the polymers and coating procedures.

Keywords: Tablet, Coating, Enteric Coating, Dosage Form

1. INTRODUCTION:-

Tablets are very essential in today's busy life, it is just like a part of our daily routine or a part of our life, because in today's busy generation no one has time to take a proper rest and every person in his life never wanted to take rest or to stop. Whenever a person gets injured or has a kind of disease he always tries to over- come from it in small amount of time. He never wants to take rest for one day or for a few weeks. So, tables are very essential in our daily life. The tablets are the simplest form of medicine to cure a disease with a small amount of time after taking a medicines, the person can easily do its work without taking rest. A tablet is composed of many things, and they all have different taste as well as different – different odors which is not good for patients that they have so bad odor which means if someone intake that medicine he can do vomit very easily. To over- come from this problem a new technique is introduced which is commonly known as 'Coating'. Coating is a technique develops to over-come the taste, odor, and stability problems prevent them from contamination from tablets **[1]**. Doing coating on tablets is the best way to over-come from all these problems. The coating mechanism was introduced by W. Brockedon in 1800s he was introducing the concept of sugar coating with gelatine **[2]**.

Our general goal was to achieve a deeper understanding of the processes in terms of residence times and dimensionless scaling laws. With that regard, the results were interpreted in the light of analytical models. The results were presented at various detail levels, ranging from an overview of all variations to in- depth considerations. It was determined that the biggest uniformity improvement in a realistic setting was achieved by increasing the number of spray nozzles, followed the rotation speed and decreasing the fill level **[3]**.

The main purpose for introducing the coating technique are-

- To improving taste odour and colour of the drug.
- For improving stability of product.
- To protect the drug against gastric environment.
- For improving ease of swallowing by the patient.
- Modifying the mechanical resistance of the dosage.
- For modifying release of properties.

1.1 Sugar Coating:- Sugar coating has long been the normal technique of coating pharmaceutical indefinite quantity forms. The method has its origin within the confectionery trade and has been employed

in the pharmaceutical trade since the late nineteenth century. The coating makes the tablet hard and eligible to endure the weight of any hard thing in short the sugar coating increase the strength of tablets due to this the coating increasing the time of disintegration of tablet. Sugar coated tablets are aqueous based tablets unless a seal coat is not covered it **[4]**.

Ideal characteristics of sugar coating:-

- They should have a smooth finishing and rounded contour.
- They have been imprinted that show distinct print with no smudging.
- They must meet requirements as per there official compendia.

Steps involve in sugar coating:-There are five steps involved in sugar coating. In sugar coating eleven layers of coats are applied one by one after that this coating process is completed. On applying the eleven coating layer the sugar coating process take time that's why it is so lengthy process.

- Sealing
- Sub- coating
- Smoothing
- Colour coating
- Polishing **[5]**

Sealing: -It is also known as Waterproofing or protective coating. In sealing of tablet core, specialized polymers are used, or we can say that it involves polymer-based coating to the tablets. Basically this is optional process but pharma- industries always used this process to prevent tablets core and the main concept behind this process is absorbing water, softening and initiating disintegration during other steps. Sealing also prevent the tablets from oil and moisture **[6]**. Shellac is universal polymer and it undergo further polymerization on storage and causing the seal coat tablets to become insoluble at that point where the bioavailability of active drug comprised **[5, 6]**.

Sub- coating:-This step is thought to be the primary major step in sugar-coating method. It involves the applying of huge quantities of sugar-coatings to the pill core, considerably increasing the pill weight by fifty – 100%. Sub-coating provides the speedy build-up necessary to gather the pill edge.

It conjointly provides the muse for smoothing and color coating with any weakness within the final sugar coat typically being due to weaknesses within the sub- coat. There are two steps in sub- coating process. First one is lamination process and another one is suspension sub- coating process **[5]**.

Lamination Process:-The lamination method is probably the older of the 2 techniques used; associate in nursing involves application of"

glue" (in the shape of a solution of an appropriate gum, like gum, or perhaps gelatine) in quite substantial quantities to the sealed pill cores. Once this answer has been distributed uniformly throughout the pill mass, it's followed by a liberal dusting of powder (which serves to scale back tack and facilitate pill build-up) and drying. This method of application of gum answer, spreading, dusting, and drying is continual till a satisfactory coating is achieved. On the drawback, the lamination method is often messy, tougher to use by less-skilled operators, and tougher to automate (as each powder and liquids are involved) **[5]**.

Suspension process:- It is an alternative approach used for particular automated dosing system. The method involves the applying of a suspension sub-coat formulation (essentially a coating formulation wherever the fine mate rials employed in the lot of ancient lamination process square measure distributed into the gum-based solution). Using suspension sub coating approach not solely reduces the complexness of the method however conj ointly permits the less-experienced operator to realize satisfactory results.

Smoothing:-For improving the quality of sugar coating tablets it is necessary to make them smooth with this the tablets gets a unique look which attract the patients toward to him. The smoothing is usually accomplished by sucrose based solutions with some components like starch and calcium carbonate some time it may be accomplished without them. This process is repeated until the tablets get properly smooth and rounded or dry properly. The drying of tablets may be taking more than 20 minutes (it depends upon the batch size of tablets) **[8]**.

Colour Coating: - This is one amongst the foremost vital steps within the sugar-coating method because it has immediate visual impact that's related to overall quality. The character of the colorant chosen usually defines the sort of color-coating procedure to be used. There are two main functions of coating **[6, 7]**.

Polishing: - It is the last step involves in sugar coating process. Here the finishing touch is given to the tablets are they get a classic look whom attracts the patients towards to himself. Sharpening is accomplished by applying mixtures of waxes either as powders (usually in an exceedingly finely processed form) or as solutions/dispersions in varied organic solvents to the coated tablets in an exceedingly sharpening pan **[8]**.

Some polishing chemicals which are basically used: -

- Waxes of alcoholic slurries.
- Mineral Oils.

- Finely powdered mixtures of dry waxes
- Pharmaceutical glazes (typically alcohol solutions of various forms of shellac, often containing additional waxes).
- Organic-solvent-based solutions of waxes (beeswax, carnauba wax, candelilla wax, hard paraffin wax) **[9]**

Materials used in Sugar Coating: -

Gelatin- Gelatin is also known as albuminoid. This word is derived from Latin language word 'gelatus' which means stiff or frozen. It is a colourless, flavourless food ingredient who has a translucent nature. It is an irreversible hydrolyzed form of collagen where its losses protein fibrils into small peptides on the process of hydrolysis **[12]**.

Talcum -Talcum is a type of powder it is also known as 'talc' it is a clay mineral that is composed of hydrated magnesium silicate that has chemical formula Mg3Si4O10(OH)2. It is an exceptionally rare crystal form. It also has two dimensional platy forms with foliated **[12]**.

Calcium Carbonate: -Calcium carbonate is a dietary supplement having formula $CaCo_3$; it is used in that case when the amount of calcium is not sufficient in diet. Calcium carbonate is the main component of eggshells, snail shells, seashells, and pearls **[13]**.

Ponceau 4R- It is type of synthetic colorant, which is used as a food colour, it is known by more than 100 synonyms, like C.I. Acid Red, C.I. 16255, New Cocaine, Cochineal Red, Brilliant Scarlet 4R and many more, E124 by this number it is denoted. It is a strawberry red azo dye which has multiple uses in food products and mainly synthesis by aromatic hydrocarbons, who is stable to light, heat, and acid but sometimes it fades in the presence of ascorbic acid **[14]**.

Carnauba Wax: -It is a type of wax who is also known by Brazil wax and palm wax. This wax is obtained from the leaves of carnauba palm Copernicia purnifiera or copernicia cerifera; this plant is only grown in the north-eastern Brazilian states of Pernambuco, Piaui, Ceara, Maranhao and Bahia. The process of collecting the wax is very simple firstly collects the leaves from carnauba palm, and dried them after it beat them to lose the wax and then finial step reefing and bleaching the obtained wax. The E number of this wax is E903 **[15]**.

Bees Wax: -Bees' wax is also another type of wax which is produced by the natural process by honeybees of the genus Apes. The fresh and new wax is always glass clear and colorless but it is becoming opaque after the process of chewing and contaminated with

pollen by the worker bees, They uses it for making honeycombs cell **[16]**.

Benzene: - It is an organic compound that has molecular formula 'C6H6'. Benzene is made up of six carbons that is arrange in a cyclic manner and have 120 degree angle in each side. It looks like a ring due to the arrangement of carbon atom **[17]**.

Sugar:-It Sugar is type of carbohydrate have generic name for sweet tasting soluble which is used in foods as a sweetening agent. They contain five hydroxyl groups (-OH), and a single carbonyl group(C=O), they have a cyclic property when they mixed with water **[18]**.

Advantages of Sugar Coating: -

- Sugar coating method utilizes cheap and pro mptly obtainable raw materials.
- Constituent raw materials used area unit wide accepted with few regulative is sues (with the exception of maybe colours)
- The process is well documented and controlled to fulfil trendy GMP standards.
- Inexpensive, straightforward instrume ntality will be used.
- Sugar coating method is usually not as vital (as film coating) and recovery (or rework) procedures area unit a lot of promptly accomplished.
- Products area unit sometimes aestheticall y appealing and have wide shopper satisf actoriness.
- Advancement in science and technology have greatly reduced the variability in coating obtained with operated by hand coating pans **[10]**.

Disadvantages of Sugar Coating: -

- This process take too much time, it is a time consuming process.
- It has chances of loose of product while the process.
- The weight and size of ready product increase the cost of packaging and shipping.
- For the high finishing of tablets skilled person is required **[10]**.

1.2 Enteric Coating: -There are so many different types of dosage forms are manufactured by pharmaceutical industries for patient comforts. Enteric Coating it is another type of coating who exists from many years. Some medicines are not stable at the pH of stomach because they can tolerate the ph. of abdomen, so they easily disintegrate there **[7]**. The first form of enteric coating was developed by Unna in year 1884 in the form of keratin coated tablets. After that it was further known that these are unable to with hand gastric digestion. Ceppi also used

Salolin in the first formulation paste of enteric coating. However Shellac was known as the first material used for enteric coating in year 1930. Recently some scientists are applying enteric coating to fish oil supplements. This is for preventing the fish capsules from digesting into stomach who are known as a cause of fishy reflux **[19]**.

Ideal Properties: -

- It has the ability to resist the gastric fluid found in stomach.
- It should stable and not disturbs the stability of drug.
- It should always non toxic in nature and not any have pharmacological activity.
- It should also the property of ease of printing.
- It should have tendency of compatibility with every other substance.
- Formation of continuous film.
- It has susceptible and permeable to intestinal fluid **[19]**.

What does an Enteric Coating do?

Enteric coating may be a chemical compound applied to oral medication. It is a barrier to stop the stomachic acids within the abdomen from dissolving or degrading medicine once you swallow them. While not full enteric protection, several medicines would collapse chop- chop in abdomen acids. Their supposed impact would be reduced or eliminated altogether completely different medications add other ways, however many forms of medicines and drugs have to be complied to reach the enteric tract interact before they deliver their ingredients **[6]**.

Steps involve in Enteric Coating: -

This process of coating is absolutely opposite form sugar coating. In sugar coating there are layers of coat is applied on the sugar for disappear their bad taste and odor but in enteric coating there is no many layers of coat is applied on the surface of tablets.

There are two different types of enteric coating systems are occurs.

- One layer System.
- Two layer system.

1. One Layer System: -

It is also known as Single layer system. In this system there is a single layer of polymer is applied on the surface of tablets. This is the first and final layer of coating paste who is applied on the surface of tablets **[7]**.

2. Two Layer Systems: -

This system is also known as double layer system because in this system there are two different layers are applied on the surface of tablets one by one. After completion of first layer the second layer is applied on the surface of tablets. But sometimes both the first and

second layer is applied with enteric polymer or sometime only second layer is of enteric polymer but most of the time the second layer is applied with enteric polymer and first layer is of color **[7]**.

Coating materials used in Enteric Coating:

In enteric coating there are less material used as compare to sugar coating, and it takes less time for completion. In this coating following materials are used:

Magnesium Sulphate: -

Magnesium sulphate is a type of salt which contain sulphates and have molecular formula 'MgSo4'. It is also known as Magnesium sulphate anhydrous and sulphuric acid magnesium salt. It has 120.37 gm molecular weight. By the doctors Epsom salts are not prescribe in place of medication. Sometimes it also gives the bad effects on the health of patient's i.e., respiratory paralysis, depression, pulmonary oedema, flushing and etc. **[21]**.

Starch: -

Starch is a polysaccharide comprising glucose monomers that is joined with alpha 1, 4 linkages. It is soluble in water, but it is insoluble in cold water and contains 4.1788 kilocalories per gram. Starch consists of two types of molecules: the linear helical amylase and the branches amylopectin **[22]**.

IPA: -

The full form of PA is Isopropyl Alcohol; it is also called as isopropnol or 2-propnanol. It is widely used in industries for making a wide range of products and as a preservative and it is the most common ingredient for detergents, antiseptics and disinfectant **[22]**.

Colon Coat Blue: -

It is a type of colour which is used for the colouring into many things like cloths, wools and used in the manufacturing of paints basically it is known as Methylene blue color or methylthionine chloride it is a salt used for making dyes and medication **[7]**.

Advantages of Enteric Coating: -

- These types of tablets do not dissolve into mouth and thus area unit excellent for formulations that require to not be activated by acid exposure. The coating prevents the tablets from dissolving whereas within the mouth and passageway areas.
- Many medicines or drug will cause irritation to the abdomen if discharged there with enteric coated tablets. The formulation can undergo the abdomen while not irritating the abdomen lining.
- It will scale back the frequency dosing of tablets or capsules by emotional

ordered medication which may improve patient compliance.

- It will improve the looks of the merchandise by victimisation coating completely different colours **[24]**.

Disadvantages of Enteric Coating: -

- The main disadvantage of enteric coating is that the method is tedious and long leading to costly product.
- Coating material square measure employed in bulk quantities.
- It will interfere with the pharmacodynamic properties of active ingredients.
- Enteric coating takes overtime when the compression of tablets.
- Enteric Coated tablets cannot split or crushed before swallowing. It must be developed intact **[24]**.

EXPERIMENTAL:-

1. **Organoleptic Properties: - (Table 1)**
2. **Thickness and weight variation:- - (Table 2)**
3. **Disintegration Test:- - (Table 3)**
4. **Dissolution Test:- (Figure 1)**

Table 1: (Organoleptic Properties)

Properties	Sugar Coating (10/32)	Enteric Coating (12/32)
Shape	Convex	Sphere
Size	7.937	9.525

Table 2: Thickness, Weight Variation and hardness test of Sugar and Enteric Coating Tablets

	Thickness		Weight variation		Hardness	
S. No.	Sugar Coating (10/32)	Enteric Coating (12/32)	Sugar Coating (10/32)	Enteric Coating (12/32)	Sugar Coating (10/32)	Enteric Coating (12/32)
1	4.63 mm	3.55 mm	300.0 mg	456.5 mg	3.5 kg	5.7 kg
2	4.48 mm	3.45 mm	330.2 mg	423.3 mg	3.0 kg	5.0 kg
3	4.42 mm	3.60 mm	360.7 mg	413.3 mg	3.5 kg	7.8 kg
4	4.65 mm	3.32 mm	350.2 mg	422.0 mg	4.5 kg	6.2 kg
5	4.65 mm	3.45 mm	320.0 mg	443.5 mg	2.5 kg	14.0 kg
6	4.66 mm	3.66 mm	320.0 mg	418.9 mg	4.0 kg	6.1 kg
7	4.54 mm	3.59 mm	320.3 mg	430.5 mg	4.0 kg	7.0 kg
8	4.60 mm	3.30 mm	350.0 mg	435.9 mg	3.5 kg	4.5 kg
9	4.57 mm	3.54 mm	330.7 mg	427.0 mg	3.5 kg	5.0 kg
10	4.32 mm	3.52 mm	340.6 mg	437.5 mg	3.9 kg	8.0 kg
11	4.71 mm	3.07 mm	340.5 mg	397.9 mg	2.5 kg	12.3 kg
12	4.51 mm	3.20 mm	300.5 mg	428.1 mg	4.2 kg	7.2 kg
13	4.53 mm	3.49 mm	340.0 mg	425. 9mg	3.5 kg	7.2 kg
14	4.64 mm	3.39 mm	330.2 mg	428.2 mg	2.5 kg	8.0 kg
15	4.55 mm	3.46 mm	340.1 mg	424.3 mg	2.5 kg	8.9 kg
16	4.44 mm	3.42 mm	320.0 mg	443.0 mg	3.1 kg	5.2 kg
17	4.56 mm	3.33 mm	340.0 mg	438.8 mg	3.1 kg	10.0 kg
18	4.70 mm	3.48 mm	320.4 mg	440.0 mg	3.7 kg	5.0 kg
19	4.49 mm	3.26 mm	330.6 mg	445.1 mg	2.9 kg	3.0 kg
20	4.69 mm	3.34 mm	340.2 mg	430.7 mg	3.0 kg	3.2 kg
Total	91.34 mm	68.369 mm	6625.2 mg	8184.5 mg	66.9 kg	139.3 kg

Table 3: Disintegration Time of Sugar and Enteric Coating Tablets

S. No.	Sugar Coating (10/32)	Enteric Coating (12/32)
1	12 Min 50 Sec	32 Min27 Sec
2	14 Min 38 Sec	33 Min 34 Sec
3	15 Min 04 Sec	33 Min 57 Sec
4	15 Min 17 Sec	37 Min 58 Sec
5	16 Min 58 Sec	40 Min 47 Sec
6	26 Min 58 Sec	45 Min 57 Sec

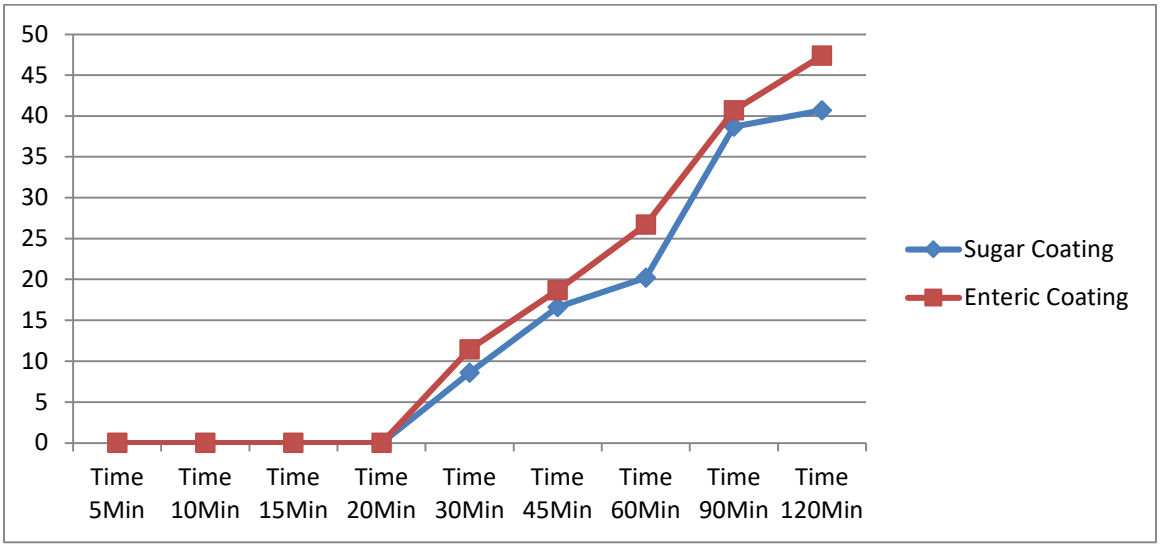

Figure 1: Drug Release (Sugar coating and enteric coating)

5. ACCELERATED STABILITY: -

After six months the weight variation of sugar coated tablets and enteric coated tablets are'331.26 mg' and '409.225 mg' respectively, the hardness is also approximately same for both '3.345kg' and '6.966kg'respectively, also same results are come from thickness test for sugar and enteric coating is '4.567mm and 3.4184 mm' respectively, it has also give the same result for disintegration test '27min 54 sec' and '46 min and 44 sec' respectively, and it also gives the same result for dissolution test for sugar and enteric coating '40.39 and 47.39' respectively .

RESULT: -

The result of all tests of sugar coated and enteric coated tablets are found to be-

Table 4: Results of Both Coatings

S. No.	Test Names	Sugar Coated	Enteric Coated
01	Shape Test	Convex	Sphere
02	Size Test	7.937	9.525
03	Weight Test	331.26 mg	409.225 mg
04	Hardness Test	3.345 kg	6.965 kg
05	Thickness Test	4.567 mm	3.41845 mm
06	Disintegration Test	26 Min 58 Sec	45 Min 57 Sec
07	Dissolution Test	40.39 (At 120 Min)	47.92(At 120 Min)

Here is the result of comparison between sugar coating and enteric coating tablets where sugar coating take too much time in their manufacturing but enteric coating take less time and the bioavailability is also more of enteric coating as compare to sugar coating.

Now for Accelerated Stability-

Table 5: Results of Both Coatings after 6 months

S. No.	Test Names	Sugar Coated	Enteric Coated
01	Shape Test	Convex	Sphere
02	Size Test	7.937	9.525
03	Weight Test	331.26 mg	409.225 mg
04	Hardness Test	3.345 kg	6.966 kg
05	Thickness Test	4.567 mm	3.41845 mm
06	Disintegration Test	27 Min 54 Sec	46 Min 44 Sec
07	Dissolution Test	40.39 (At 120 Min)	47.92(At 120 Min)

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