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A COMPREHENSIVE REVIEW ON FILM COATING TECHNOLOGY.

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Abstract:

Pharmaceutical film coating is considered an important part of solid production dosage forms, because it gives the products excellent organoleptic properties. in In addition, it can improve the physical and chemical stability of dosage forms and modify dosage forms Drug release characteristics. Several troubleshooting issues such as twinning stains, cracks, etc. may appear during or after the shelf life of the film coated dosage forms. These troubleshooting issues can be caused by basic tablet errors, formulation errors in the coating and/or defects in the coating process. These problems must be overcome to avoid unnecessary production problems. Film coating and other parts of pharmaceutical technology are in constant innovation. Innovation can be at various levels including pharmaceutical excipients, processes, software, guidelines and equipment In fact, the growing interest in process analysis technology is particularly noteworthy, design quality, continuous surface treatment and inclusion of new usable products coating compositions. In this review, we tried to explore and discuss the status of pharmaceutical film coating, the challenges associated with its production process and the latest. technological developments in this important production process.

Keywords: film coating, troubleshooting, progress, functionality

1.INTRODUCTION

The Oral solid dosage forms are regarded as the convenient dosage forms available in the market. Their manufacturing was first used more over a thousand years ago. These Dosage forms offer a number of benefits, including their simple and convenient manufacturing process and good patient compliance. With the introduction of methods like tablet coating, double compression, and osmotic systems to ensure controlled and targeted release, tablets—the most important member of this class have been enhanced during the last few decades. coating of tablets can be done by various methods.The most popular methods are sugar coating ,film coating,compression coating and microencapsulation.

The most common and flexible approach is film coating (FC). In the food and pharmaceutical sectors, coating oral solid DFs with FC is a contemporary and frequently used method. The spraying of thin, homogeneous polymer-based formulations onto the surface of solid DFs, such as tablets, capsules, pellets, or granules, constitutes the FC process. It may be divided into two distinct categories: nonfunctional FC, which is used to alter tablet characteristics such as appearance, flavour, and swallowability as well as to protect tablets from environmental hazards such humidity, oxidation, and light impacts. In addition to the advantages of the non-functional coating outlined above, functional FC can be employed to alter or delay medication release.[1-4]

2.IMPORTANCEOF FILM COATING:

- to provide protection from external factors such as air, moisture, temperature, and sunlight.
- as a swallowing aid.
- to cover the flavor and smell.
- to prolong the shelf life.
- to improve the brand's reputation.
- to make formulation easier.
- To the dose form's strength.
- to safeguard the GIT environment for drugs.
- to regulate medication release.[5]

MATERIALS USED: Materials used in film coating are

1. Film formers

2. Solvents

3. Plasticizers

4. Colourants

5.Opaquant-extender

3.TYPES OF FILM COATING:

There are two types of film coating based on its intended use.

3.1 NON FUNCTIONAL FILM COATING:

FC affects the final appearance and organoleptic characteristics of the manufactured tablets, which are regarded as vital parts of the brand image, it helps to improve patient compliance together with tablet shape and size .Furthermore, FC is crucial in aiding senior patients with dysphagia because a film coat on the DF can make it easier for them to swallow. Reports from US FDA showed that FC helps in facilitating the tablet mobility in comparision to the non film coating.[6-8]

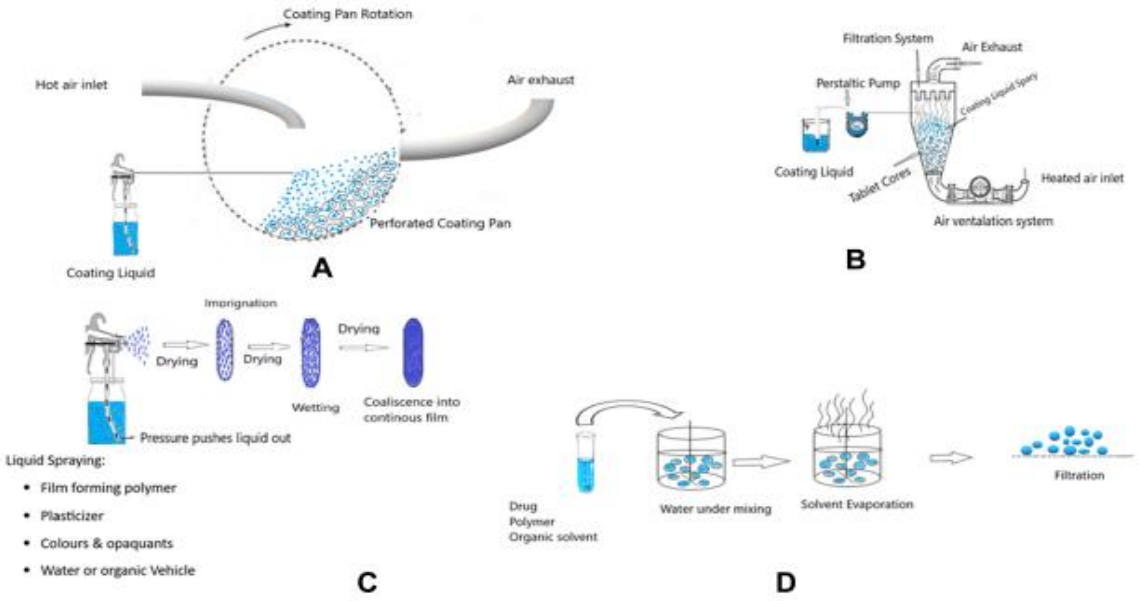

Figure 1: Different FC techniques and processes

(A) Conventional FC pan.

(B) Fluid bed FC.

(C) Phases of FC.

(D) Phases of microencapsulation.

3.2 FUNCTIONAL FILM COATING:

Functional FC is mostly utilized to give the items that are manufactured a new added value. These parameters may serve one or more purposes, such as enhancing the product's stability and altering its release schedule to create drug-targeting products.

4. TYPES OF MATERIALS USED IN FILM COATING:

FUNCTION	MATERIAL NAME
Functional Film Forming Polymer	Cellulose Acetate Phthalate Hydroxy Propyl Methyl Cellulose Phthalate Cellulose Acetate Trimellate Ethyl Cellulose Methacrylic Acid Copolymer Shellac.
Non-Functional Film Forming Polymer	Non-Functional Film Forming Polymer Hydroxy Propyl Methyl Cellulose Hydroxy Propyl Cellulose Polyvinyl Pyrrolidone Polyvinyl Alcohol High Molecular Weight Polyethylene Glycol.
Solvent or Vehicle	Water, Ethanol, Methylene Chloride Plasticizers Propylene Glycol, Polyethylene Glycols, Diethyl Phthalate, Fractionated Coconut Oil, Castor Oil.
Colourants	Water-soluble Dyes (FD&C Yellow 5) Water-insoluble (FD & C Yellow 5 Lake) Inorganic Pigments (Iron Oxide Titanium Dioxide) Natural Colourants (Beta Carotene)

Table 1: Sources of Materials used in film coating

5. TABLET FILM COATING PROCESS:

The tablets coating process consisting of the following steps:

- Dispensing/loading (accurate dosing of all raw materials)
- Warming
- Spraying (applicating and rolling at the same time)
- Drying
- Unloading and cooling

It's vital to address the following:

• Process Air supplied during coating for the pan's volume.

• Keep the temperature between 30 and 70 °C.

• Keep the dew point between 10 and 20 °C.

• A pan and spray system that is easy to clean and sanitize

• Since May coating formulations are dispersion or suspension, the fluid channel in the sprayed system should have the least amount of dead spaces possible.

• Atomization and fun air in spray systems may be easily regulated, ideally from the pan's exterior.

• Inlet and exhaust treatment in accordance with GMP and environmental laws.

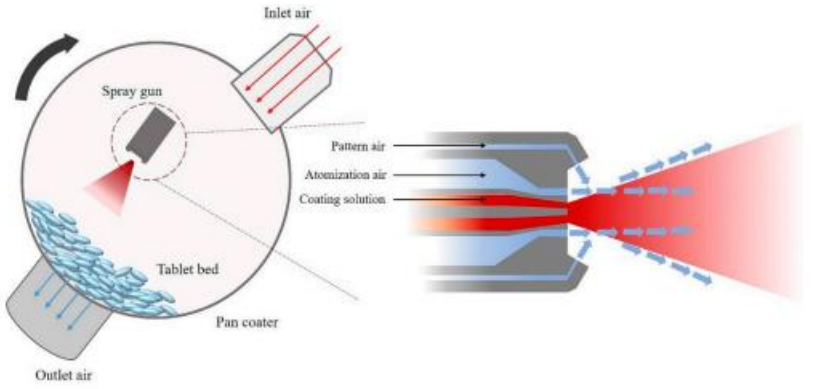

FIG 2: Simplified illustration of a coating pan

5.1 Coating Parameters

Using the proper sensors, process and equipment conditions should be monitored and controlled:

1.Pan rotation

2. Temperature of the inlet air

3. The dew point in inlet air

4. Inlet air flow rate

5. Spray system atomization and fun air flow rate

6. Coating liquid spray rate

7. Exhaust air temperature

8. Product temperature.[12-14]

PROCESS OF FILM COATING:

In film coating, the coating compound is sprayed onto the surface a set of tablets on a rotating moving platform and heated air is to evaporate the solvent, from an industrial point of view film solvent is applied by spraying the polymer dissolved in an aqueous solution and divided into small drops delivered to the preheated surface decreases and the solvent can then penetrate into the core surface dissolution and physical mixing during film formation the surface solvent evaporates, the polymer particle solid pushes the surface of the solid solvent evaporates and the particle comes together under the action of cohesive force there is usually heat between the polymer surface and the solid is added to the coat to facilitate the solvent evaporate and form a filmThe solvent is evaporated Combining into a continuous film.[28-30]

Mechanisms of film formation:

By this, the film is formed from the polymer solution there are several steps in applying the polymer solution cohesive forces form a bond with the tablet surface between the polymer molecules of the coating layer. To get high cohesion, cohesive force of polymer molecules must have a relatively high and continuous membrane surface the material must mix together. Adjacent polymer fusion the formation of molecular layers or surfaces occurs by diffusion. As most of the water evaporates, the viscosity changes the solution grows and leaves the polymer chain close close to each other and save compared to the previous one polymer layer if uniform attraction is sufficient between molecules and sufficient diffusion and fusing more completely with evaporation of water, individual polymer chains line up to form a single film.[26-27]

6. PHARMACEUTICAL APPLICATIONS OF FC:

6.1 MODIFIED DRUG RELEASE:

In many cases, modified drug release is useful to improve drug and patient efficacy or extension of the duration of the activity . Therefore, the film coating of the tablet with different polymers are actively sought to achieve modified drug release by controlling rates and/or sites of release of drugs.[31]

6.1.1 DELAYED DRUG RELEASE:

The main advantage of the enteric coating is to increase the stability of the drug in harsh gastric environments and/or reducing unwanted stomach irritation caused by medications. To prevent premature release of the drug in the stomach and ensure drug release mainly in the small intestine, pH-dependent polymers soluble or water-insoluble polymers are applied to the enteric coating. These polymers can be used alone, in combination or sequentially to provide delayed release of the drug. Proton pump inhibitors including rabeprazole, pantoprazole, omeprazole, esomeprazole and lansoprazole are acid labile and requires an enteric coating to increase drug stability in the stomach. Covered with an enteric coating Esomeprazole tablets are developed using different polymers such as Eudragit® L-30 D-55, hydroxypropyl methylcellulose phthalate, cellulose acetate phthalate an9d Acryl-EZE® . Similarly, Gobinath et al. developed enteric-coated tablets of pantoprazole (which also irritate stomach lining that causes nausea and vomiting) with cellulose acetate phthalate (CAP) and Eudragit® L100.[32-34]

6.1.2 SUSTAINED DRUG RELEASE:

The rate of drug release can be controlled by the physicochemical properties and the amount of polymers is used as a surface coating. It is also controlled by changing the thickness, tortuosity and permeability of the coating layer. Sustained release coatings are generally water insoluble and pH independent and examples include ethyl cellulose, polyvinyl acetate and polymethacrylate copolymers. These polymers have good film-forming properties and mechanical strength, which makes them suitable for durable release coatings. Combined use attempts were also made to optimize the use of hydrophobic and hydrophilic polymers.[35-37]

6.2 IMPROVED DRUG STABILITY:

An example is a film coating method used to improve the stability of drugs or pharmaceutical products as follows. Tablets containing medicines that increase photosensitivity (eg sorivudine, nifedipine, sulfisomidine and molsidomine) is coated for light stabilization. The stability of the light largely depends the thickness of the coatings and it can also be affected by the content of the indicator. Film coating of the tablet core has also been tested to improve the product stability of moisture-sensitive drugs using various waterproof coatings including polyvinyl alcohol (PVA), Eudragit® EPO, hydroxypropyl methylcellulose (HPMC), hydroxyethyl cellulose (HEC) and polyvinyl alcohol polyethylene glycol (PVA-PEG copolymer). Performance of the humidity membrane coating depends on the type of polymers used and the coating conditions. Combined use of different coatings polymers in various ratios are also promising for improving moisture-sensitive stability.[42-44]

6.3 TASTE MASKING:

Film Coating is the most effective and widely used method of taste masking and is particularly so suitable for microencapsulation of small particles to form taste-masked multi-unit dosage forms. Many different polymers are available for taste masking, including natural or synthetic polymers to prevent the rapid release of the bitter medicine in the oral cavity and its contact with the taste receptors of the tongue. In addition, water-soluble polymers including starch derivatives, cellulose ethers, and hydrophilic block copolymers, water-insoluble polymers and gel-form polymers can also be used for coating taste. These polymers are preferably used alone or in combination with different polymers combination with water-soluble and insoluble polymers in different proportions. Nishiyama et al. masked the bitter taste of lafutidine using a combination of film-coated orodispersible tablets of water-insoluble and water-soluble polymers (ethyl cellulose and hypromellose). The Polymer ratio in taste masking layer affected drug release delay time, drug release rate, tensile strength and water membrane permeability.[43]

6.4 ACTIVE FILM COATING:

Active film coating is the coating of a solid dosage unit (tablet or pellet) with a solution or suspension containing APIs as a coating solution. This coating technology meets the needs of the composition such as rapid drug release or improved product stability, and is particularly useful in development fixed-dose combination (FDC) products to control the rate of drug release or physically prevent interactions between APIs. Water-soluble drugs can dissolve in an aqueous coating solution or suspension which can then be sprayed over the tablet core. Therefore, the development of an active coating process is easier for water-soluble drugs than for water-insoluble drugs. With water-insoluble drugs, particle size must be good enough to prevent clogging of spray guns. In addition, suspension of the drug must remain Homogeneous during the coating process to achieve satisfactory content uniformity.

The API is mixed directly with the film forming agent in the active film coating and there are no restrictions on the choice of film-forming agent, including polyacrylates, polyvinyl alcohol, hypromellose and hydroxypropyl cellulose.Since the APIs are located directly in the cover film, Compatibility of film forming agents and APIs must be ensured Functional if necessary, a release layer (eg an enteric layer or a hydrophobic layer) can be inserted between the tablet core and the layer of active coating.[44-45]

CONCLUSION:

FC is commonly used in the pharmaceutical, medical device and food industries. in medicine, especially in word-fixed DFs, FC is used to treat some universal problems such as bad taste, dysphagia, and brand image with broken FC. stability Water-sensitive API can usually be improved by choosing a suitable film coating with reduced moisture permeability, while light-sensitive drugs can be protected. choice of film coating with opacity-increasing agents. A functional membrane can be achieved with pH-sensitive membrane coatings, which are often used to slow or modify drug release to improve patient outcomes. At the same time, the high pH variability observed in certain patient groups can be exacerbated by the simultaneous use of certain drugs, e.g., PPIs, which raise gastric

pH above 4.0, potentially compromising the clinical effectiveness and safety of these functional film coatings. This can be solved by changing the permeability of these film coatings using additives such as alkalizing agents, highly degrading or even microbial sensitive fillers. In addition, recent advances that could improve FC technology were discussed.

REFERENCES:

1. Augsburger LL, Hoag SW. Pharmaceutical Dosage Forms-Tablets. CRC press; 2016.
2. Sastry SV, Nyshadham JR, Fix JA. Recent technological advances in oral drug delivery–a review. Pharm Sci Technology Today. 2000;3 (4):138–145.
3. Remington JP. Remington: The Science and Practice of Pharmacy. Vol. 1. Lippincott Williams & Wilkins; 2006.
4. Porter SC. Coating of tablets and multiparticulates. In: Aulton ME, editor. Pharmaceutics. The Design and Manufacture of Medicines. 3rd ed. Churchill Livingstone: Elsevier; 2007:500–514.
5. Shen RW, Taste masking of ibuprofen by fluid bed coating. Google Patents 1996.
6. Gergely G, Gergely T, Gergely I. Pharmaceutical Preparation in the form of an effervescent and/or disintegrating tablet or an instant granule and process of producing it. PCT Int Appl. 1993; WO9313760.
7. Roche EJ, Taste masking and sustained release coatings for pharmaceuticals. Google Patents. 1991.
8. Roche EJ, Reo JP, Rotogranulations and taste masking coatings for preparation of chewable pharmaceutical tablets. Google Patents. 1994.
9. Waterman KC, MacDonald BC. Package selection for moisture protection for solid, oral drug products. J Pharm Sci. 2010;99 (11):4437–4452. doi:10.1002/jps.22161
10. Bowen L, Mangan M, Haywood A, Glass B. Stability of frusemide tablets repackaged in dose administration aids. J Pharm Pract Res. 2007;37(3):178–181
11. Raimi-Abraham BT, et al. Investigating the physical stability of repackaged medicines stored into commercially available multicompartment compliance aids (MCAs). J Pharm Health Serv Res. 2017;8 (2):81–89.
12. Burke MD, He X, Cook C, et al. Stability enhancement of drug layered pellets in a fixed dose combination tablet. Aaps Pharmscitech. 2013;14(1):312–320. doi:10.1208/s12249-012-9911-3
13. Modi F, Patel P. Formulation, optimization evaluation of fixed dose combination moisture barrier film coated bilayer tablet of artesunate & amodiaquine hydrochloride. Int J PharmTech. 2011;3:2124–2134.
14. Parmar K, Bhatt NM, Pathak NL, et al. An overview: aqueous film coating technology on tablets. Int J Pharm Chem Sci. 2012;1 (3):994–1001.
15. Guideline IHT. Impurities: guideline for residual solvents Q3C (R5). Current Step. 2005;4:1–25.
16. Obara S, Maruyama N, Nishiyama Y, et al. Dry coating: an innovative enteric coating method using a cellulose derivative. Eur J Pharm Biopharm. 1999;47(1):51–59. doi:10.1016/S0939-6411(98)00087-3
17. Bechard S, Quraishi O, Kwong E. Film coating: effect of titanium dioxide concentration and film thickness on the photostability of nifedipine. Int J Pharm. 1992;87(1–3):133–139. doi:10.1016/0378- 5173(92)90236-U
18. Baertschi SW, Alsante KM, Tønnesen HH. A critical assessment of the ICH guideline on photostability testing of new drug substances and products (Q1B): recommendation for revision. J Pharm Sci. 2010;99(7):2934–2940. doi:10.1002/jps.22076
19. Mukharya A, Patel PU, Chaudhary S. Effect assessment of “film coating and packaging” on the photo-stability of highly photo-labile antihypertensive products. Int J Pharm Investig. 2013;3(2):77. doi:10.4103/2230-973X.114903
20. Felton LA, Porter SC. An update on pharmaceutical film coating for drug delivery. Expert Opin Drug Deliv. 2013;10(4):421–435.
21. Ashton P, Chen J, Guo H, Polymer-based, sustained release drug delivery system. Google Patents. 2009.
22. Zaid AN, Qaddomi A. Development and stability evaluation of enteric coated Diclofenac sodium tablets using Sureteric. Pak J Pharm Sci. 2012;25:1.
23. Zaid AN, Natour S, Ghoush A, et al. Formulation and in vitro and in vivo evaluation of film-coated montelukast sodium tablets using Opadry® yellow 20A82938 on an industrial scale. Drug Des Devel Ther. 2013;7:83. doi:10.2147/DDDT.S37369
24. Zaid A, Fadda AM, Nator S, et al. Development and stability evaluation of enteric coated diclofenac sodium tablets using AquaPolish E. J Pharm Invest. 2011;41(4):211–215. doi:10.4333/KPS.2011.41. 4.211 9. Sharma PH, Kalasare SN, Kamble RA. Review on polymers used for film coating. Asian journal of pharmaceutical technology and innovation. ISSN: 234-8810. 01(02), 2013, 01-16.
25. Obara S, Ginity JW. Influence of free films prepared form spray techniques. Int. J. Pharm. 126, 1995, 1-10.

26. Harris MR and Ghebre-Sellassie I. Aqueous polymeric coating for modified release oral dosage forms. In Aqueous Polymeric Coating for Pharmaceutical Dosage Forms. Marcel Dekker Inc., New York, 2, 1997, 81-100.
27. Parmar KD, Bhatt NM, Pathak N, Chauhan Vijay V, Patel LD, Kela AN, Nathani HS. An Overview: Aqueous Film Coating Technology on tablets. Int J Pharm. and chem. science ISSN: 2277-5006 Vol.1 (3), 2012, 06-07.
28. Ansal H, Allen L, Jr Popovich N. Ansel's Pharmaceutical Dosage Form and Drug Delivery System; Eighth Edition: 227- 259.
29. American Pharmaceutical review; 4(3), 2001, 28-35.
30. Vyas S, Khar R. Controlled Drug Delivery Concept and Advances; First Edition: 219-256.
31. Shah, H.P.; Prajapati, S.T. Quality by design based development and optimization of novel gastroretentive floating osmotic capsules of clopidogrel bisulfate. J. Pharm. Investig. 2019, 49, 295–311. [CrossRef]
32. Nair, A.B.; Gupta, R.; Kumria, R.; Jacob, S.; Attimarad, M. Formulation and evaluation of enteric coated tablets of proton pump inhibitor. J. Basic Clin. Pharm. 2010, 1, 215–221.
33. Liu, J.-Y.; Zhang, X.-X.; Huang, H.-Y.; Lee, B.-J.; Cui, J.-H.; Cao, Q.-R. Esomeprazole magnesium enteric-coated pellet-based tablets with high acid tolerance and good compressibility. J. Pharm. Investig. 2018, 48, 341–350. [CrossRef]
34. Gobinath, T.; Kamalakkannan, V.; Sambathkumar, R. Formulation and evaluation of enteric tablets of pantoprazole. J. Chem. Pharm. Sci. 2014, 7, 176–184.
35. Rhodes, C.T.; Porter, S.C. Coatings for controlled-release drug delivery systems. Drug Dev. Ind. Pharm. 1998, 24, 1139–1154. [CrossRef] [PubMed]
36. Siepmann, F.; Siepmann, J.; Walther, M.; MacRae, R.J.; Bodmeier, R. Polymer blends for controlled release coatings. J. Control. Release 2008, 125, 1–15. [CrossRef] [PubMed]
37. Mohamed, F.A.A.; Roberts, M.; Seton, L.; Ford, J.L.; Levina, M.; Rajabi-Siahboomi, A.R. Film-coated matrix mini-tablets for the extended release of a water-soluble drug. Drug Dev. Ind. Pharm. 2015, 41, 623–630. [CrossRef] [PubMed]
38. Felton, L.A.; Porter, S.C. An update on pharmaceutical film coating for drug delivery. Expert Opin. Drug Deliv. 2013, 10, 421–435. [CrossRef] [PubMed]
39. Wasilewska, K.; Winnicka, K. Ethylcellulose—A pharmaceutical excipient with multidirectional application in drug dosage forms development. Materials 2019, 12, 3386. [CrossRef]
40. Joshi, S.; Petereit, H.U. Film coatings for taste masking and moisture protection. Int. J. Pharm. 2013, 457, 395–406. [CrossRef]
41. Desai, P.M.; Puri, V.; Brancazio, D.; Halkude, B.S.; Hartman, J.E.; Wahane, A.V.; Martinez, A.R.; Jensen, K.D.; Harinath, E.; Braatz, R.D.; et al. Tablet coating by injection molding technology—optimization of coating formulation attributes and coating process parameters. Eur. J. Pharm. Biopharm. 2018, 122, 25–36. [CrossRef] [PubMed]
42. Roy, S.; Siddique, S.; Majumder, S.; Abdul, M.I.M.; Rahman, S.A.U.; Lateef, D.; Dan, S.; Bose, A. A systemic approach on understanding the role of moisture in pharmaceutical product degradation and its prevention: Challenges and perspectives. Biomed. Res. 2018, 29, 3336–3343. [CrossRef]
43. Almukainzi, M.; Araujo, G.L.B.; Löbenberg, R. Orally disintegrating dosage forms. J. Pharm. Investig. 2019, 49, 229–243. [CrossRef]
44. Chen, W.; Wang, J.; Desai, D.; Chang, S.-Y.; Kiang, S.; Lyngberg, O. A strategy for tablet active film coating formulation development using a content uniformity model and quality by design principles. In Comprehensive Quality by Design for Pharmaceutical Product Development and Manufacture; Reklaitis, G.V., Seymour, C., García-Munoz, S., Eds.; Wiley: Hoboken, NJ, USA, 2017; pp. 193–233.
45. Moon, C.; Oh, E. Rationale and strategies for formulation development of oral fixed dose combination drug products. J. Pharm. Investig. 2016, 46, 615–631. [CrossRef]