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Review Article

Narrative Review: Multifunction Pharmaceutical Excipients in Tablet Formulation

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ABSTRACT

The pharmaceutical sector needs innovation to enter the market quickly in order to obtain new items. Working with excipients and active substances is the focus of formulation. The cost of bringing a product to market increases with the number of excipients used in the manufacturing process. Multiple-functioning excipients aid in the resolution of these problems since the industry places a high premium on cost-effectiveness. Multifunctional excipients, or "smart excipients," are essential for ongoing development and much-needed innovation. In order to improve their current characteristics and impart good compatibility, flowability, dissolution, disintegration, hygroscopicity, and palatability to formulate new products with the goal of minimizing associated costs, the existing excipients have been modified, co-processed, altered with existing ones, or cross-linked. Multifunctional excipients such as F-MELT®, Ludipress®, Galen IQ 721, MCC SANAQ® burst, and others have been identified as the smart excipients that facilitate the development of robust formulations with minimal issues during technology transfer.

INTRODUCTION

Excipients are important in the procedures involved in the formulation of drugs. They perform a wide range of tasks to provide the desired qualities for the final drug formulation. Additionally, they provide patients with safer and more effective final products. They are essential for obtaining stability, cutting costs, increasing manufacturing effectiveness, and creating a stable dosage form that is resistant to changes in other constituents or process factors (1). The pharmaceutical business is undergoing changes that are placing more commercial pressure on research and development teams to expedite the time it takes to launch new drugs. Consequently, formulators are asking their pharmaceutical

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excipients to provide greater functionality and performance. Developing formulas is all about experimenting with the excipients.Increasing medicine formulation quality while using fewer excipients is currently imperative.With a variety of uses, including fillers and diluents, binders, coating agents, disintegrants, flavors, colorants, lubricants and glidants, solvents, preservatives, sweeteners, and antiadherents, there are more than 1,200 pharmaceutical excipients on the market. An increase in the number of constituents means more steps in the production process, more complicated formulations, and eventually higher costs (2). Nowadays, formulators are looking for excipients that may be employed for a variety of purposes. For instance, native corn starch was utilized as a disintegrant and a binder in formulations for the creation of novel pharmaceutical products. Before adding the starch to the wet granulation, it was made into a paste as a binder. It was added dry to the powder blend as a disintegrant. Concerns about flow and compressibility prompted comparable investigation of substitute excipients and excipient combinations. Using starch 1500 as a binder, disintegrant, filler, and lubricant in a wet granulation formulation eliminates the need for numerous expensive excipients and extra processing steps (3).

Multifunctional excipients

An inactive ingredient that serves as a vehicle for a medication's active ingredients is called an excipient. These days, the creation of new excipient strategies is driven by the market (excipients are created in response to market demands), which limits the opportunity to work on new projects because these excipients have the highest costs. Therefore, evaluating the excipients' functionality is a crucial step. A desirable attribute of a [material] that facilitates and enhances the creation, quality, or performance of the drug product is called functionality. Every formulation will have unique functional requirements in the context of pharmaceutical formulations and products (4). The current grades of excipients have been updated to obtain improved qualities and gain multifunctionality. Coprocessing is the process of using two or more excipients, cross-linking polymers, and other methods have also been used to achieve multifunctionality.

1. **PAR T**

The ideal neutral carrier is tartaric acid pellets, or TAP for short. These pH-modifying starting pellets adhere to the monongraphs Ph (1) and are made entirely of natural tartaric acid. Use in food goods, drinks, confections, and medicine formulations. Properties that are highly optimized to facilitate layering and coating procedures and produce consistent product qualities.TAP® can be used into prolonged release pellet formulations to lessen the drug release's reliance on pH (2).

2. **Nutra-Tab T**

Dicalcium Phosphate Anhydrous, Granular (Tricalcium Phosphate) Uses Co-processing to preserve the molecular identities of each component while working in concert to boost functional performance even in intricate formulations. Good flowability, little sticking, excellent content homogeneity, good hardness, and minimal friability are among its properties (4).

3. **Tri-Tab® PVP Formulation**

96% of the homopolymer of poly(1vinyl2pyrrolidinone) is hydroxylapatite (Ca5(OH) (PO4)3) (5).

Applications: utilize in hot melt extrusion, film coating, dry granulation, wet granulation, and direct compression (6).

Qualities Flowability, High compressibility and improved particle bonding because of the hollow particle morphology's large surface area. Hot melt extrusion's ideal glass transition temperature (Tg) (6)

4. **GalenIQ Elements:**

obtained using a two-stage manufacturing method from beet sugar sucrose. It is a filler-binder with several excellent features combined into one.

Applications: Not limited to use as a bulk excipient. It also functions as a taste enhancer, stabiliser, anti-humectant, and anti-caking agent (7).

Qualities:

Easy to use and suitable for a variety of solid and liquid dosage forms, including tablets, sachets, lozenges, and syrups, GalenIQTM is a highly functional filler and binder (8).

5. Calipharm® A Constituent:

Anhydrous Dicalcium Phosphate Applications

Source of calcium and phosphorus in nutritional supplements; used as an excipient in the production of pharmaceutical and nutraceutical goods.

ATTACHMENTS :

Formula for molecules: CaHPO4. Weight in molecules: 136.1 g/mol. Visual aspects: White powder , Odorless Taste: 7.0-8.0 pH (20% slurry): Tasteless

6. Calipharm® T Formulation powdered tricalcium phosphate anhydrate.

Uses:

A selection of products catered to your specific requirements. High potency elemental calcium deliverable at dosage levels equivalent to calcium carbonate and greater than calcium citrate; combined calcium/phosphorus delivery at Ca:P ratios similar to those seen in the healthy body (10)

ATTACHMENTS :

Ca 5(OH)(PO4)310CaO·3P 2O 5·H2O is the molecular formula. Weight in molecules: 502.31 g/mol. Visual aspects: White powder, Odorless, **Taste:**

In appealing (11).

7. Calipharm® D Formulation (Dihydrate Dicalcium Phosphate)

utilized as an excipient in the production of pharmaceutical and nutritional goods.Nutritional supplements as a source of calcium and phosphorus (12). A selection of goods catered to your specific requirements. High potency elemental calcium deliverable at dosage levels comparable to calcium carbonate and greater than calcium citrate • Combined calcium/phosphorus delivery at Ca:P ratios comparable to those seen in the healthy body (13).

ABILITIES:

Formula for molecules: CaHPO4·2H2O. Weight in molecules: 172.1 g/mol. Visual aspects: White powder. pH (20% slurry): 7.0-8.0 Identification A: White precipitate appears; Odor: Odorless Flavor: Tasteless.

8. The composition of PharmaSmoothTM

It is a special excipient that has been demonstrated to increase the bioavailability and solubility of poorly soluble medications.

Applications:

utilized in numerous dose forms, including as oral suspensions, pills, and capsules (12) It gives chewable tablets their distinctive tongue feel and superior flow, compaction, and disintegration qualities (13). Properties demonstrate that they are a reliable and safe excipient to employ in medication compositions. It has been demonstrated to increase the solubility and bioavailability of poorly soluble medications and is utilized in several commercial goods (14).

9. GalenIQ 721 Structure

This is a spherically aggregated isomalt.

Applications: is a pharmaceutical excipient that has the ability to condense probiotic microorganisms into a tablet shape with little compression forces, and it can also be employed for direct compression and powder applications (15).

Properties: It is a high solubility agglomerated spherical isomalt for direct compression applications, has a non-animal origin, and has extremely low hygroscopic properties. It is anticipated to be more stable to changes in formula

composition and process conditions than other excipients (16).

10. MCC SANAQ® Burst17 Formulation cellulose microcrystaline (19, 20, 21).

Applications: Is a versatile excipient that finds application in solid dosage forms, including dry and wet granulation, filling capsules, filling, binding, and blasting material for tableting (22).

Qualities: possesses outstanding compressibility, and its smooth flowing qualities provide high production rates. MCC SANAQ®'s superior absorption qualities, color stability, and high microbiological purity make it successful in all tableting procedures.

11. Pharmatose M200 Formulation

Pharmatose, milled monohydrate lactose.

Applications: utilized as a dry powder inhaler carrier and as an excipient in medicines (23, 24).

Qualities: The M200 trademark refers to a highly crystalline material with higher disintegrability, powder fluidity, compatibility, and fluidity (19, 20, 21).

12. FUJICALIN

Anhydrous dibasic calcium phosphate is the composition.

Applications:

as a direct compression medicinal excipient (25, 26, 27).

qualities:

It is a spherically granulated powder that flows freely and is comparable to dicalcium phosphate dihydrate (25, 26, 27). It has good disintegration qualities, minimal abrasion, excellent compression properties, and facilitation of mixing and improved flowability.

13. StarAc is made up of acacia gum (Ac) and maize starch (MS).

Applications:

Applied in direct compression tableting as multipurpose excipients in direct compression (DC) tablet formulation. The coprocessed excipients, StarAc 955 and StarAc 9010, were created by weighing quantities of MS and Ac at mixing ratios of 95:5 and 90:10, respectively (19,20, 21).

Properties:

furthermore used as a diluent, binder, and disintegrant in tablet formulation (29).

14. Provosolv ODT Composition:

Microcrystalline cellulose (MCC) and colloidal silicon dioxide (32) make up this co-processed excipient.

Applications:

as a binder and filler for making tablets with instant medication release. Some investigations use ProSolv® ODT, a reference commercial excipient with MCC in its formulation, as a point of comparison (33, 34, 35).

Qualities:

It is well established that the ProSolv® excipient lowers friability and flow issues in tablet formulations (33).

15. SSG SANAQ T

Sodium starch glycolate makes up its composition (19, 20, 21).

Applications:

Made into pills, capsules, and granules (36, 37).formation using the direct compression methodas an extremely disintegrant.

16. Modified cellulose

A subclass of cellulose, makes up UICEL S and UICEL B.- alteration of class 3 fully converted cellulose.

Applications:

disintegrant, binder, and filler.

This formulation's quick dissolving and instant releasing qualities, in addition to its applications (30)

17. MCC 102

Microcrystalline cellulose (MCC), a kind of cellulose, composition:Simplified cellulose, or class 1, is typically (30).

Applications:

employed in direct compression (38, 39). MCC type 102 is one of the most widely used grades of MCC, with a median particle size of approximately 100 mm (38, 40).MCC 102 possesses the suitable flow characteristics needed for the production of pharmaceuticals (38). Advantages are has a strong connection and is employed as a filler, but it is not multifunctional (30).

18. UICEL XL composition Class 4 (modification of cross-linked cellulose)(41)

Uses this article describes UICEL-XL, a novel cellulose excipient that can be used in the creation of solid dosage forms as a disintegrant, filler, or binder.

Qualities:

Good disintegration qualities are provided by the cross-linking agent included in UICEL-XL, which gives the excipient a high degree of crystallinity, a high water affinity, and a high specific surface area. (42)

19. Composition of 19-UNI-PURE WG: pregelatinized corn starch (43)

Uses:

Wet granulation binder at its best

Properties:

UNI-PURE® WG 220 offers significant aesthetic qualities in addition to its utilitarian ones (44).

20. Neusilin® formula

Composition:

Synthetic Excipient (Magnesium Alumino Metasilicate) (45): Improves hardness, enhances flow properties, and protects drugs.

Properties:

Generally acknowledged as a multifunctional excipient that raises the standard of medications. US2 is able to absorb huge amounts of water or oil due to its porous nature and vast surface area. It can also be physically compressed into high-quality tablets (46).

21. Composition of Aerosil®972

Coloidal silica that is hydrophobic (47)

Uses:

viscosity adjuster, stabilizer for water in oil emulsion.

Features:

high purity, hydrophobic, amorphous, and anhydrous colloidal silica suitable for use as an excipient in pharmaceuticals (48).

22. Syloid FP

Micronized artificial amorphous silica gels make up the composition (49). Employs a capillary wetting agent to improve disintegration and release. Adsorption capacity, particle size, density, and internal surface area are combined in new design properties to offer multifunctional advantages or improve an application (50).

23. Sipernat®22 S Constituency

Calcium, aluminum, and precipitated silica silicates (51) Applications. High capacity of adsorption is employed as an anti-caking and flow agent.

Qualities:

For many years, SIPERNAT® has been utilized to streamline production procedures and improve final product performance. Due to its distinct physical attributes, it frequently outperforms other materials in enhancing powder properties like flowability and anti-caking (52).

24. Potassium Content of Polacrilin adapted resin (53).

makes use of a large swelling capacity.

Characteristics:

As an approved excipient for oral medicinal formulations, it is a cation-exchange resin. A cream-colored, tasteless, odorless powder called Polacrilin Potassium is accessible (54)

25. Mannitol:

Mannitol that has been modified is the composition of Orocell 200 and 400.

Uses: as a carrier, filler, and binder while preparing ODT properties. OroCell boasts remarkable processing capabilities.Besides from that, it might be utilized as a starting material for

film-coating and medication substance layering, as well as for capsule and sachet filling processes (56).

26. Cellactose composition

Is a spray-dried, co-processed excipient that is made up of 25% powdered cellulose and 75% alpha lactose monohydrate (57).

Applications:

Both high and low dose formulations can benefit from its use. utilized as coating cores as well.

Properties:

Low segregation tendency results in excellent compactibility, outstanding flowability, and good content uniformity.Capsule filling, dry granulation, and direct compression (58).

27. MCC:

Composition: Alpha-cellulose combined with mineral acids, extracted as a pulp from fibrous plant matter (59).

Uses:

Adsorbent, antiadherent, capsule binder/diluent, tablet disintegrant, and tablet binder/diluent (59) are some of its uses.

Properties:

Odorless, free-flowing, fine, white or almost white, crystalline powder.Water, ethanol, ether, and diluted mineral acids do not dissolve it. In a solution of sodium hydroxide, somewhat soluble (60).

28. Starch Composition

Based on a-(D)-glucose, it is made up of two polysaccharides: branching amylopectin and linear amylose.

Applications:

it serves as a disintegrant, diluent, and binder (61, 62).

Properties:

Starch is a fine, white to off-white powder that has no flavor or odor.

29. Methocel K4M:

Partially O-methylated and O-(2-hydroxypropylated) cellulose in its composition.

Uses:

It is frequently used into topical, nasal, ophthalmic, and oral medicinal formulations.

Properties:

It is a white, creamy-white, fibrous or granular powder with no flavor or odor (63, 64).

30. Polyox Comprocessed:

Composition:

nonionic polyoxyethylene–polyoxypropylene co-polymers mainly utilized as solubilizing or emulsifying agents in medicinal formulations.

Uses:

Tablet lubricant; wetting agent; emulsifying agent; dispersion agent; solubilizing agent.

Properties: Usually manifest as cast solids or as white, waxy, freely-flowing prilled grains. They have almost little flavor or smell (65,66).

31. Xylitab 200

Consists of 2% sodium carboxymethylcellulose FCC and 98% xylitol, USP/NF, FCC (67)

Utilizes a binder or filler for direct compression while making tablets.(68)

Proprieties:

It is important to distinguish between XYLISORB, another excipient with filler/binder capabilities, and Xylitab 200 (69).

32. ProSolvT Textual Analysis

Colloidal silicon dioxide with microcrystalline cellulose (70) Applications

as an ingredient in the production of pharmaceutical industry tablets and capsules (71).

Qualities:

PROSOLV® 730 (72) and PROSOLV® EASYtab Nutra, an all-in-one excipient compound, are additional items in the PROSOLV® portfolio.

33. The Composition of Ludiflas

It is a blend of polyvinyl acetate (73), Kollidon CL-SF, and D-mannitol. is a co-processed excipient that is utilized as a one-stop shop for making tablets in the pharmaceutical business. a co-processed excipient that has several advantages in the pharmaceutical industry. It is a one-stop

shop that can be used to dissolve pills orally and as a filler, binder, and disintegrant (74, 75).

Proprieties: Ludiflash is renowned for producing fast-acting tablets with remarkable hardness and minimal friability.

34. Cellulose METHOCEL®

composition of polymers based on cellulose, such as hydroxypropyl and methyl cellulose (77)

Proprieties: METHOCEL cellulose ethers have a number of benefits for use in construction and building applications (77).

35. Avicel CE-15

Chewable tablets with minimal friability, quick disintegration, and better mouth feel are made using 85% MCC and 15% guar (78).

Proprieties: aims to enhance sensory qualities by lowering friability, tooth packing, and grittiness to provide a creamier mouthfeel (79).

36. Ludipress

Ingredients: lactose monohydrate, crospovidone (80), and povidone K30 (Kollidon® 30)

It has been demonstrated that Ludipress® has strong compression capabilities and is appropriate for direct compression in the formulation and production of tablets (80).

Proprieties:

Filler, binder, and disintegrant are all combined into one system called Ludipress, which has outstanding flowability and very little hygroscopicity (80,81).

37. PanExceaTM

The components of PanExceaTM are hydroxypropylmethylcellulose USP, crospovidone USP, and MCC USP (82,83).

Applications: As a pharmaceutical industry performance enhancerIt is intended to enhance the drug application of oral disintegrating tablets (ODT) by improving its compressibility, flow characteristics, disintegration, and dispersibility (82,83).

Qualities:

There are various variations, including GR100G and MC200G (83).

38. F-Malt

The spray-dried powder composition of F-Malt is made up of five medicinal excipients, which include disintegrants, inorganic compounds, and carbohydrates (84, 85). Applications in the manufacturing of ODTs (oral disintegrating tablets) (85)

Qualities:

A particular kind of F-MELT® called FMELT® Type C is intended to deal with issues and assist pharmaceutical companies in bringing medicines to market as soon as possible (85)

39. Pharmatose® DCL40

The composition of Pharmatose® DCL40: 95% anhydrous lactitol ν with 5% beta-lactose

Properties: Used as a filler in tablet formulation. Compared to other lactose-based products that are sold commercially, it has a higher potential for dilution.(86,87)

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