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FILM FORMER IN FILM COATING

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ABSTRACT: The presentation of this work aims to update professionals on issues associated with selecting the film former in the film coating process. Film coating finds applicability in a diverse field that may be for conventional (immediate) release and modified-release intended for enteric/ delayed-release or barrier membrane controlled release (extended-release). In the pharmaceutical field, film coating of the substrate is achieved by spraying the coating material in liquid medium onto them. The formulation of coating material is a solution or dispersion of film-forming polymers and excipients in aqueous or organic solvents. Film formers are the chief amongst the component of coating formulation that delineates the functional properties of the film-coated pharmaceutical along with other factors like additives, process, equipment, technology and many others. Polymers used as film former are available in different grades, determined by their molecular weight and viscosity. Their glass transition temperature (Tg), along with the grade of polymer, influences the film coating process along with the functional properties of the film coat. Summarised information on the technical aspect of film former is rare, necessitating this work. The information was studied, summarised, and attempted to be presented for convenience and enrichment of stakeholders in the pharmaceutical field. The contained information will be updating professionals in this regard.

INTRODUCTION: Coating is a process by which an essentially dry outer layer of coating material is applied to the surface of a solid dosage form or materials (usually referred to as the substrate) in order to confer specific benefits over the uncoated variety that broadly ranges from protecting products (like from the action of light, moisture, air, gastric acid), facilitating production, product identification, modifying drug release, and many more [1, 3]. The coating may be applied to a wide range of oral solid dosage forms (that is, substrate) like tablets, capsules (hard/soft), multi-particulates (pellets or beads), and drug crystals [2, 4].

Coating involves the application of coating material, as solutions/ dispersion in aqueous or organic solvents, as a uniform layer, one upon other, onto moving bed of substrate with simultaneous removal of the solvent by way of drying of preceding layers with concurrent use of heated air to facilitate evaporation of solvent till a uniform coat of wished attribute is achieved [1, 4].

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Nowadays coating techniques/process relies on water as a solvent because of its significant benefits over organic solvents like material cost, toxic effects, environmental issues, pollution, and many others [1, 2]. Thus aqueous solvent-based coating system has rapidly replaced organic solvent-based one for safety and economic and ecological reasons [1, 3, 6]. Sugar-coating is an aqueous solvent-based coating system comprising a multi-step process, and the duration ranges from few hours to few days [1, 6].

Panning technique is typically used, whose simplest form is a traditional sugar-coating pan with a supply of drying air (preferably of variable temperature and thermostatically controlled) and a fan-assisted extraction process to remove dust and moisture-laden air [4, 7]. This results in increased substrate weight by 50-100% and elegant, highly glossed finished tablets [7, 8]. To reduce the processing time and the requirement for operator skill, as in sugar coating, the film coating was developed [1, 5, 6]. Furthermore, the film coating can improve stability by protecting substrate from light, temperature and moisture; improving the aesthetic property by masking undesirable taste or odour, improving the appearance, facilitating swallowing; providing tablet identity; and controlling or modifying the release of the drug [2, 5]. Despite that the elegance of sugar-coated tablets is thought to be superior, sugar-coating had been replacing by the film coating process due to the following advantages [6, 7, 9].

- Substantial reduction in the quantity of coating applied (*i.e.*, 2-4% for film coating, comparing 50-100% for sugar coating) [6, 7].
- Faster processing times.
- Improvement in process efficiency and output.
- Greater flexibility in optimising formulations, results of the availability of a wide range of coating materials and systems [6, 7].
- Comparing sugar coating, a simplified process that facilitates automation.
- Ability to be applied to a wide range of pharmaceuticals like tablets, capsules, granules, pellets, powders, drug crystals [6, 7].

In film coating, factors that delineate the film-coated pharmaceuticals' functional properties are the film formers and other factors like process, equipment, technology, additives, and many others; amongst these, the film former is the chief. Available source that summarises information relating technical aspect of film former is scare. In this regard current situation warrants to study and summarise information and to present them for convenience and enrichment of professionals in the pharmaceutical field. The presented information will be updating professionals in this regard, and the consequence is productivity and profit, ultimately the welfare of mankind.

Film Coating: In film coating, a thin layer/coat of a polymer is deposited surrounding the substrate by spraying the coating compositions through one or more spray guns onto a small portion of rotating or fluidised bed of the substrates using conventional panning equipment or more sophisticated equipment, to achieve efficient drying, high degree of automation and coating time [1, 4, 10]. The coating liquid (solution or suspension) contains polymer in a suitable liquid medium (aqueous or organic solvents) and plasticizers and other excipients like pigments [1, 2]. This liquid is sprayed onto the rotating/fluidized bed of the substrate using atomizing/ spraying systems [4, 6]. The spray-application process atomizes bulk coating liquids into a fine droplet. It delivers in such a state that droplets of coating liquid retain sufficient fluidity to wet the surface of the substrate, spread out, and coalesce to form a film [2, 4]. The drying conditions permit the removal of the solvent to leave a thin deposition of coating material, usually between 20 and 200 μm, around each substrate core [2]. High-quality film coating must be smooth, uniform, and adhere satisfactorily to the substrate surface and ensure chemical stability of a drug [7, 10].

Classification of Film Coating: Film coating, a contemporary coating process, can be classified in a number of ways; refer **Fig. 1.** However, based upon the requirement of the selected topic, the film coating can be classified as follows [1, 2, 4, 5]. Conventional/non-functional film coating. It is the barrier coating conferring protection to the product from atmospheric degraded ants like moisture, air, light. Functional /non-conventional/modified release film coating.

Enteric Coating: For the protection of the drug from degradation in the stomach.

Delayed-release: For delaying onset of drug release.

Sustained Controlled Extended Release (SCER): for lengthening duration of the drug release.

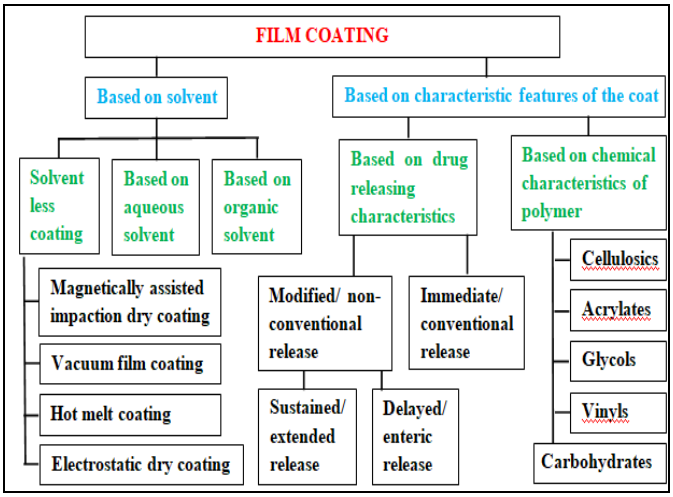

FIG. 1: CLASSIFICATION AND CLASSES OF FILM COATING [1, 2]

Conventional Film Coating: Conventional, non-functional, or immediate release film coating is the regular film coatings that do not modify the release profile and have no significant effect on biopharmaceutical properties of the active pharmaceutical ingredients but are mostly for pearly appearance, ease of ingestion, and taste and odour masking for improving aesthetic property; light and moister protecting barrier coating for product stability; and colour identification for solving handling and marketing issues [1, 2, 5].

Functional Film Coating: Functional, non-conventional, or modified release film coating are in most of the cases are water-insoluble and modifies (sustains/ extends/ delays) the release profile of the active thus significantly affect biopharmaceutical properties [2, 4, 5]. By such coating, the drug-release characteristics, time course, and/or location are chosen to accomplish therapeutic or convenience objectives, not offered by the conventional dosage forms accordingly either extended-release or delayed-release coatings [1, 2, 6]. Controlled/ extended-release coating uses polymer with restricted water solubility or permeability that provides an extremely effective way of conferring a SCER aspect to the substrate or, more usually, to multi-particulate systems that are subsequently encapsulated or compressed as tablets [1, 2, 5, 6]. Enteric film coating is a delayed release film coat, uses enteric polymers capable of forming a direct film, that releases the drug other than the time of administration in the intestine (small or large) but not in the stomach [2, 5, 6]. Sufficient weight of enteric polymer must be used to ensure an efficient enteric effect, that is, normally two or three times that required for a conventional film coating [1, 10].

Formulation of Film Coating Liquid: A typical film coating formulation has followed components [1, 2, 4, 6].

A. Film Former:
B. Plasticiser:

- Internal
- External

C. Colours/opacifiers:
D. Other/auxiliary Excipients:

- Surfactants,
- Flavours,
- Sweetening agent,
- Active pharmaceutical ingredients and
- Preservatives

Solvent:

- Aqua
- Volatile organic solvent

Film Formers (Polymers): Polymers are substances that have high molar weight and are composed of many (large number) repeated subunits, called monomers, which are joined sequentially by chemical reactions forming a chain [2, 6]. The function of the polymer is to provide the main structure and basic physical attributes and chemical properties to the coat [1, 2, 11, 12]. On a technical aspect, it is the chief ingredient of film coating and greatly impacts the substrate coating properties [1, 6]. These have different grades determined by molecular weight and viscosity grades [1, 2]. The polymer is chosen to comply with the prevailing relevant regulatory and pharmacopoeial requirements in the intended marketing area [2, 6].

Properties of An Ideal Film Former (Polymer) Are AS Follows [1, 2, 6]:

- Soluble in wide range of solvent systems, importantly solvent of choice for coating formulation [2].
- Adequate solubility for the intended use that is free water-solubility, slow water solubility, or pH-dependent solubility [6].
- Capacity to produce an elegant looking product [2].
- Stable to the action of heat, light, moisture, air and substrate [1].
- Should be non toxic, odourless, colourless and tasteless [2].
- Compatible with other ingredients and substrate [6].
- No pharmacologic activity [1].
- Capable of forming a continuous film having adequate mechanical properties [6].
- Have the capacity to produce an elegant-looking product even in the presence of additives [2, 6].
- No bridging or filling formation and resistant to cracking [1].
- Ease of application and printing on high-speed machines [2].

Classification of Film Formers: Basing on the physical and chemical properties, the polymers can be classed as follows [1, 2, 6].

Non-enteric Polymers"

a. Conventional release polymers.
- Water-soluble polymers
- Water-insoluble polymers

b. SCER Polymer

Enteric polymers. Basing on the chemical origin, the polymers can be classed as follows [1, 2, 6].

Cellulosics: examples, Ethylcellulose [10, 13], Hydroxypropyl methylcellulose (HPMC) [13, 18], Hydroxypropyl cellulose [1], Methylcellulose [1], Cellulose acetate [19], Cellulose acetate phthalate [20].

Vinyl Polymers: examples, polyvinyl pyrrolidone [1], polyvinyl acetate [21].

Glycols: example, high molecular weight polyethylene glycol [1].

Acrylic Acid Polymers: example, different grades of Eudragit® [11, 12].

Natural: examples, Shellac, fats and waxes, Chitosan [12].

Properties of Film Former: The vast majority of the polymers used in film coating are cellulose derivatives, vinyls, glycols, or acrylic polymers and copolymers [2, 5]. Polymers are a multiplicity of differing chemical types, each in turn often having various grades (as determined by viscosity or molecular weight) [5, 6]. There batch-to-batch variations resulting from the poly-disperse nature for a particular grade of polymers [1, 6]. However viscosity as a sole test will not give a full image for the poly-disperse nature of the polymer [1, 5, 6]. Thus it is necessary to define the material in terms of [2].

- Chemical Structure:
- Molecular Weight:
- Molecular Weight Distribution

Since, each of these polymers is available in several grades, the common practice is to use the lower molecular weight grades of each in aqueous film coating to optimize the properties of coating solutions concerning solid(s) content and solution viscosity [1, 5, 6]. Cellulosics, many of which have good solubility in an aqueous and organic solvent, facilitates the transition to aqueous film coating [2, 5]. Films of polyvinyl pyrrolidone are brittle and hygroscopic. Polyethylene glycol results in waxy and hygroscopic films that soften readily at only moderately elevated temperatures [1, 5, 6].

Solubility:

Modified-release Film Coating: Polymer with low water solubility or permeability should be chosen.

Conventional Coating: Polymer should have good aqua solubility.

Viscosity: The coating composition with a viscosity above 500 cps is difficult to atomize and will not produce smooth product [2, 5]. Polymers should have a low viscosity for a given concentration [5, 6]. Thus polymers with low viscosity

are preferred as will permit the easy and trouble-free spraying of coating fluid in industrial film coating equipment [1, 6].

Mechanical Properties: Polymer with adequate mechanical strength to withstand the impact and abrasion encountered in normal handling is to be used [1, 2]. Insufficient coating strength will be demonstrated by the development of cracks and other imperfections in the coating [5, 6].

Permeability: Polymers that are an efficient barrier against permeability of water vapour or atmospheric gases can be used to optimize shelf-life [1, 5, 6].

Minimum Film-Forming Temperature: This is the minimum temperature above which film formation will take place using individual defined conditions [22, 24]. It is largely dependent on the Tg [23, 24] of the polymer, a fundamental characteristic of polymers that has a profound effect on polymer properties which can also influence film formation, especially in the case of aqueous polymer dispersions [1, 2, 6, 22]. Tg is the temperature at which the hard glassy form of an amorphous or largely amorphous polymer changes to a softer, more rubbery consistency [2, 22, 24].

Non-Enteric Polymers: These are the regular film coating polymer that does not modify the release profile and have no significant effect on biopharmaceutical properties of the active pharmaceutical ingredients but are mostly for pearly appearance, ease of ingestion, taste and odour masking, light and moister protection, and colour identification [1, 2, 5, 6].

Conventional Release Polymers (Water Soluble): Water-soluble polymers are used widely in moisture barrier coating like hydroxyethyl cellulose, HPMC [13], polyvinyl alcohol, polyvinyl alcohol-polyethylene glycol copolymer, and many others [1, 2, 5, 6]. The aqueous solubility of these polymers makes them the preferred materials for moisture-protective coating AS they do not influence drug release or the therapeutic effect [2, 5, 25, 27].

They can also easily be used in the aqueous coating process. The coating polymers are dissolved in water to form a coating solution, eliminating the issues related to the organic solvent coating. Besides moisture protection, some water-soluble polymers could also be used to achieve a taste-masking coating [1, 6]. However, the coating film formed by the water-soluble polymers has a relatively shorter lifespan than the one formed by the water-insoluble polymers due to the degradation of the coatings caused by the ambient humidity during storage [1, 2, 5, 6].

Conventional Release Polymers (Water Insoluble): The non-enteric water-insoluble polymers are mainly used as coating materials to modify and extend drug release to accomplish sustained or controlled release [1, 2, 28]. Some of them can form a coating film with low permeability and, thus, could also be used as moisture protection coating materials [2, 5, 25, 28]. Polymers include cellulose esters, such as ethylcellulose [10] and cellulose acetate, and acrylic esters, like ethyl acrylate–methyl methacrylate copolymers [1, 6, 25, 26].

TABLE 1: FILM FORMER USED IN FILM-COATING FORMULATIONS (SCER) 1, 2, 6

Film former (polymer)	Membrane characteristics
Acrylic esters	Permeable
Cellulose esters (e. g., acetate)	Semi-permeable
Ethylcellulose [10]	Permeable
Eudragit® RL, Eudragit® RS, Eudragit® NE	Permeable
Fats and waxes (viz. beeswax, carnauba wax, cetyl alcohol, cetyl stearyl alcohol).	Permeable and erodible
HPMC	Permeable and swellable
Polyvinyl acetate [21]	Permeable and swellable
Shellac	Permeable and soluble at high pH
Silicone elastomers	Permeable (when PEG added)
Zein	Permeable and soluble at high pH

SCER Polymers: Drug release from products intended for SCER is moderated by the film coating, which acts as a membrane that allows an infusion of gastrointestinal fluid (GIF) and the outward diffusion of dissolved drug [1, 2, 29, 30]. In some instances, the release process may be

augmented by a coating that slowly dissolves (e.g., shellac), or is subject to digestion by enzymes (e.g., fats and waxes) [2, 5]. Examples of coating polymers used in film-coating formulations for SCER along with membrane characteristics are provided in **Table 11.** [2, 6].

TABLE 2: AQUEOUS POLYMERIC DISPERSIONS FOR SCER FILM COATING 1, 2, 6

Material	Film former (polymer)	Comments
Aquacoat® [2]	Ethylcellulose [2, 10]	Pseudo-latex dispersion. Requires the addition of plasticizers to facilitate film coalescence
Surelease® [2]		Aqueous polymeric dispersion contains requisite plasticizers. The addition of lake colorants should be avoided due to the alkalinity of dispersion
Eudragit® NE 30 D [11]	Poly(ethyl acrylate-methyl methacrylate) 2: 1	Latex dispersion. No plasticizers are required unless improved film flexibility is desired
Eudragit® RL 30 D [11]	Poly(ethyl acrylate-methyl methacrylate) triethyl ammonioethyl methacrylate chloride 1: 2: 0.2	Aqueous polymeric dispersion. No plasticizers are required unless improved film flexibility is desired
Eudragit® RS 30 D [11, 31]	Poly(ethyl acrylate-methyl methacrylate) triethyl ammonioethyl methacrylate chloride 1: 2: 0. 1	

Nowadays, great interest has been shown in using an aqueous film coating system for SCER products [2, 21, 25, 26].

These coating systems typically consist of an aqueous dispersion of water-insoluble polymer(s) [28, 31], which form films by coalescence of submicron polymer particles [2, 22, 24]. Examples of aqueous polymeric dispersions for SCER film coating are presented in **Table 2** [1, 6].

Polymers for Non-Enteric Film Coating: Follows are the film-forming polymers having applicability in non-enteric film coating.

Acrylate Polymers: Acrylate polymers are marketed with the trade name Eudragit® [11, 12]. Eudragit® E [2, 32] (for moisture protection coating) available as powder, Eudragit® RS [2, 33] and Eudragit® RL [2, 34] (for SCER coating), are the polymers of this group which is freely soluble in gastric fluid (acidic media) [1, 2, 6].

The Properties of Eudragit® E Include [2, 32]:

- Soluble in gastric fluid up to pH 5.0.
- Swellable and permeable in fluid above pH 5.0.

The Properties of Eudragit® RL 2, 34 and Eudragit® RS [2, 33] Include:

- Insoluble in water.
- Have high permeability.
- pH-independent swelling.
- Customised release profile by combining the grades RL and RS in different ratios [10].

Ethylcellulose: Depending on the ethoxy substitution, different viscosity grades are available commercially. It is insoluble in water, and GIF thus cannot be used alone for coating, thus used in combination with a water-soluble polymer like HPMC. The combinations are used in SCER coating for tablets and fine particles [1, 2, 6].

The Properties Include [1, 2, 6]:

- Soluble in a wide variety of organic solvents.
- Non-toxic, tasteless, odourless, and colourless.
- Stable at environmental conditions.
- Un-plasticized ethylcellulose coats are brittle.
- Hydroxyethylcellulose

The Properties Include [1, 2, 6]:

- It is soluble in water.
- Insoluble in organic solvents.
- Hydroxypropyl cellulose

The Properties Include [1, 2, 6]:

- It is soluble in water and GIF, whereas in organic solvents are soluble below 40 °C and insoluble at above 45 °C.

- It is very tacky.
- Yield very flexible film that tend to be more elastic (*i.e.*, exhibit lower elastic moduli),
- Possess better adhesive properties.
- It cannot be used alone.
- In combination with other polymers improves film character.

HPMC: HPMCs is for coatings with moderate strength, moderate moisture and oxygen barrier properties, elasticity, transparency, and resistance to oil and fat [13, 18, 35, 36].

The Properties Are [1, 2, 6]:

- Soluble in GIF, organic and aqueous solvent systems [1].
- None interfering with tablet disintegration and drug availability [1, 2, 6].
- Chip resistant and results coat with adequate flexibility [2].
- Odourless and tasteless [6].
- Stable upon exposure to light, heat, air, and a reasonable amount of moisture [1, 2, 6].
- Incorporation of colour and other additives is non-problematic [2].
- Films have superior tensile properties [1].

When used alone may result in bridging and filling, so it should be used in combination or with the right plasticizer. This polymer is widely used in air suspension and pan spray coating [1, 2].

Methylcellulose: This polymer is rarely used in film coating, possibly because of the lack of commercial availability of low viscosity material meeting the appropriate compendial requirements [1, 2, 6].

Methyl Hydroxyethyl Cellulose: Available in different viscosity grades, have properties similar to that of HPMC but is soluble in few organic solvents, thus has limited use [1, 2, 6].

Povidone: It is available in four viscosity grades of K-15, K-30, K-60, and K-90, with the average molecular weight of 10,000, 40,000, 160,000 and 360,000, respectively [1, 2, 6].

The Properties Include [1, 2, 6]:

- It is soluble in water, GIF, and a variety of organic solvents [1, 2].
- Povidone films are clear, hard, and glossy [1].
- It is soluble in both acidic and intestinal media [2].
- Used in the coating composition to increase the dispersion of colour [2, 6].
- It is cross-linked suitably to produce enteric coating material [1, 6].
- Sodium carboxymethyl cellulose
- It is available in low, medium, high, and extra-high viscosity grades [2, 6].

The Properties Include [1, 2, 6]:

- It can easily be dispersed in water to form a colloidal solution [2].
- It is insoluble in most organic solvents [1].
- The film formed is brittle but adheres well to substrates [6].

TABLE 3: ENTERO-SOLUBLE POLYMERS FOR FILM COATING AND THEIR DISSOLUTION pH 1, 2, 6, 10.

Entero-soluble film former (polymer)	Dissolution pH
Cellulose acetate phthalate	6.2
Cellulose acetate trimellitate	5.0
Hydroxypropyl methylcellulose	4.5-5.5
phthalate (HPMCP)	≥5.5
HPMCP 55	≥5.0
HPMCP 50	≥5.5
HPMCP 55S (higher viscosity grade)	≥5.5
HPMCP 55F (fine particle grade)	
Hydroxypropyl methylcellulose acetate	5.0 - 7,0
succinate (HPMC-AS)	5.0
HPMC-AS-L	5.5
HPMC-AS-M	6.5
HPMC-AS-H	
Poly(methacrylic acid-co-methyl	5.5-7.0
methacrylate) polymers	
Polyvinyl acetate phthalate	5.0
Shellac	7.0

Enteric Polymers: Formulations of enteric coatings usually contain enteric polymers that resist its degradation in the gastric (acidic) pH while gets degraded in intestinal fluid (alkaline) [2, 20, 37]. Such polymers, often referred to as poly acids, contain ionizable functional groups that make the polymer water-soluble at a specific pH value, and refer to **Table 3** [2, 37].

Many of these polymers are esters and may be subject to hydrolytic degradation at elevated temperature and humidity, resulting in a substantial change in enteric properties [1, 2, 6, 37].

TABLE 4: PRODUCTS SUITING ENTERIC RELEASE FILM COATINGS 1, 2, 6, 10

Film former (polymer)	Form	Comments
Aquateric	Spray-dried pseudo-latex	System essentially contains only polymer. Requires dispersing in water
Cellulose acetate phthalate	Dry powder	System contains only polymer. Requires dispersing in water with addition of ammonia. Degree of susceptibility to hydrolysis is high
Cellulose acetate trimellitate	Dry powder	Solid system contains only polymer Requires dispersing in water with the addition of ammonia
Coateric	Dry powder	Complete system. Requires dispersing in water with the addition of ammonia. Degree of susceptibility to hydrolysis-medium
Eudragit® L 100	Dry powder	Soluble at pH 6.0. Relatively high dissolution pH
Eudragit® L 30 D-55 [38]	Latex dispersion	System essentially contains the only polymer
Eudragit® L 100-55 [31]	Spray dried latex	Soluble at pH 5.5. Requires dispersing in water with addition of alkali.
Eudragit® S 100 [39]	Dry powder	Soluble at pH 7.0. Relatively high dissolution pH
HPMCP-F	Dry powder	Requires dispersing in water. System only contains polymer. The degree of susceptibility to hydrolysis is low. The grade 55 is recommended for enteric preparation. The grades 50 and the 55-S are for special applications
HPMC-AS	Dry powder	System contains only polymer. Requires dispersing in water. Degree of susceptibility to hydrolysis is high
Kollicoat® MAE 100 P [40]	Spray-dried latex	Soluble at pH 5.5. Requires dispersing in water with addition of alkali

The Reasons for Enteric Coating are to [1, 2, 6]:

- Protect acid-labile drugs from the action of gastric fluid [2].
- Deliver drug to the intestine for local action or optimal absorption [1, 6].
- Provide a delayed release component for repeat action [6].

Properties of an Ideal Enteric Coating Polymer [1, 2, 6]:

- Resistance to gastric fluids (acidic pH) [2].
- Should dissolve or become permeable near and above pH 5.0 [1, 6].
- Compatible with other ingredients [1].
- Non-toxic and have no pharmacologic activity [6].
- Formation of continuous film [2].
- Be stable, alone and in coating solution [6].
- The properties of resulted film should not change with aging [2, 6].
- Ease of application [1] and
- Ease of printing on high-speed machines [6].

The special aqueous solubility requirements for an enteric polymer have delayed the routine employment of aqueous enteric coating systems [1, 22, 37, 41]. More recently, aqueous enteric coating products have been introduced as diverse systems [2, 6]. Many of these coating systems exist as dry powders, with the coating liquid being prepared shortly before use by dispersing (or dissolving) the polymer in water [2, 37]. The reason for supplying many enteric coating systems as dry powders is to avoid problems of poor stability (due to hydrolysis) when these polymers are exposed to water for extended periods [2, 41]. Examples of products suiting film coating (enteric release) are presented in **Table 4** [1, 2, 6, 10, 24, 28].

Polymers for Enteric Film Coating: Follows are the film-forming polymers having applicability in enteric film coating [1, 2].

Acrylate Polymers

Commercially Available Acrylates (Eudragit®) Are [2, 6]:

- Eudragit® L (soluble at pH 6.0).
- Eudragit® S [39] (soluble at pH 7.0).
- Eudragit® L-100-55 [31], Kollicoat® MAE 100 P 40 (soluble at pH 5.5).

The Properties of These Include [1, 6]:

- Result highly flexible coatings [2].
- Worthy for multiparticulate coating [2].

Cellulose Acetate Phthalate: Cellulose acetate phthalate is a widely used enteric coating polymer, is available under the trademark of Aquateric™ from FMC Corporation [1, 2, 6, 10, 20].

Cellulose Acetate Trimellitate: Cellulose acetate trimellitate is a similar polymer developed as an ammoniated aqueous formulation and shows a more rapid dissolution than the same formulation of Cellulose acetate phthalate [1, 2,] 6.

Major Disadvantages of Cellulose Acetate Phthalate and Cellulose Acetate Trimellitate Are [1, 2, 6]:

- They dissolve at pH above 6.0 thus delaying the drug release, as the ideal material may dissolve around pH 5.0 [1, 2, 6].
- These delays drug absorption [2].
- Are hygroscopic and relatively permeable to gastric fluid [1, 6].
- Are permeable to moisture compared with other enteric polymer [1, 2, 6].
- The resulted film is brittle thus requires plasticiser [2].
- Acetic acid changes film properties [1].
- Should be formulated with hydrophobic film-forming materials to achieve better enteric coating [1, 2, 6].

HPMCP: These polymers dissolve at a pH lower (5.0 to 5.5) than that of acrylates and cellulose acetate phthalate. Thus, resulting in higher bioavailability of some specific drugs [1, 2, 6, 14, 15].

Available In Follow Grades [1, 2, 6]:

- HPMCP 55 (HP 50): soluble at pH ≥5.5 [2],
- HPMCP 50 (HP 55): soluble at pH ≥5.0 [2],
- HPMCP 55S (HP 55S): soluble at pH ≥5.5, higher viscosity grade [1, 6].
- HPMCP 55F (HP 55F): soluble at pH ≥5.5, fine particle grade [2, 6].

Grade 55 is recommended for enteric preparation, whereas grades 50, 55-F, and 55-S are for the special applications [1, 2, 6].

HPMC-AS:
Available In Trade Name Aquasolve™ and with Follow Three Grades [1, 2, 6]:

- HPMC-AS-L for low pH (5.0) [2].
- HPMC-AS-M for medium pH (5.5) [2].
- HPMC-AS-H for high pH (6.5) [2].

These are intended for use as an enteric coating agent, carrier for solid dispersions, and an enteric agent in tablets/caplets, granules, pellets, and capsules at levels ranging from 5-80% w/w of the final product [1, 2, 6].

Polyvinyl Acetate Phthalate:
The Properties of Polyvinyl Acetate Phthalate Are [1, 2, 6]:

- It is similar to HP 55 in stability and pH dependant solubility [2, 6].
- It is less prone of hydrolysis [1].

Shellac:
The Properties of Shellac Are [1, 2, 6]:

- Shellac is a purified resinous secretion of the insect Laccifer lacca [1, 2].
- It is insoluble in water but shows solubility in aqueous alkalis [2, 6].
- It is moderately soluble in warm ethanol [2].
- It is a material of natural origin and consequently suffers from occasional supply problems and quality [variation 1, 6].
- Increased disintegration and dissolution times on storage [1, 2].

CONCLUSION: Earlier, in the film coating process, the use of organic solvents is preferred over aqua, as the latter inherits problems like over wetting, picking, and sticking, many others [2]. Momentum for using aqueous solvent-based film coating process and replacing the organic solvent-based one with the aqua-based one got accelerated from last few decades for safety, toxicity, stricter regulation on environmental pollution, and

economic reasons [2, 6]. The continued popularity of the aqueous film coating process mainly focuses on the environmental limitations on the use of organic solvents, significant benefits of aqueous solvent over organic solvents, and recent advances in the formulation of aqueous film-coating materials and major improvements made in the coating machines and their ancillaries [2, 4, 42]. Nowadays, aqueous solvent-based coating systems are preferred and are rapidly replacing organic solvent-based systems, irrespective of the purpose of the film-coating applications: conventional (immediate) release and modified-release [43] for enteric/ delayed-release or barrier membrane controlled release (extended-release) [2, 4].

Here the Tg [44] of film-forming polymer influences film formation along with other polymer attributes and the coating process/ technique/ technology [2, 23, 24]. Selection of film formers be basing upon their chemical nature, Tg and physical parameter of grade (that is determined by molecular weight and viscosity grades), as these influence the properties of film coat and substrate coating properties to a greater extent [2, 4, 24]. Furthermore, a polymer that complies with the prevailing relevant regulatory and pharmacopoeial requirements in the intended marketing area should be selected [2].

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