

The evolution of tablet coatings

Applied to various oral dosage forms such as particles, powders, granules, crystals, pellets and tablets, coatings have advanced from an art of earlier years to technologically advanced and controlled processes centred around compliance and good manufacturing practices. **By Lonsdale O'Donovan of Quantum Colours**



TRADITIONALLY, TABLETS WERE sugar-coated. Yet sugar coating is a long and tedious process of building layer upon layer, followed by polishing, with some variable results in certain cases. The advantage of this process is the fact that the equipment is simple and inexpensive and yields an attractive appearance.

Subsequent to sugar coating, film coating became the preferred way of coating tablets. This involved solvents (alcohol or methylene chloride) used with solids. The process was easy but posed a flammable hazard and the equipment had to be flame-proof.

8 REASONS WHY TABLETS SHOULD BE COATED:

1. A tablet coating gives brand recognition to a tablet by adding colour.
2. A coating can mask an unpleasant taste or smell, such as a B-complex tablet, which can be masked with a flavoured coating.
3. A coating acts as a moisture barrier, protecting active ingredients against oxidation.
4. Coatings protect the core against light.
5. They can be used to separate incompatible material.
6. A coating is used to hide discolouration of the core over time.
7. By using polymers that are pH specific, a coating can modify drug release.
8. Coating aids structural strength to the core and can increase the hardness of the core by about 60N.

Did you know?

The majority of pharma manufacturers in the East African region produce non-sterile products. The major focus is on solids (capsules/tablets), consisting of mainly non-complicated formulations. About 56% of the products manufactured throughout East Africa's pharma industry are solid dosage forms, mostly tablets. Most of the solids are presented as strip/blister/bulk packs.

Source: African Centre for Technology Studies



Because the coating process has many variables, everything needs to be controlled and correctly done in order to obtain the desired result

Finished tablets also had an undesirable solvent or chemical-like smell. In most instances the solvent process was replaced with the aqueous-based film coatings, which are more challenging to use as the coating has to be applied to the tablets without wetting and could affect the integrity of the tablets.

SELECTING THE RIGHT COATING

Depending on its required functionality – be it moisture, taste barrier, controlled sustained release or enteric – a film coating is generally based on a powder blend of different low viscosity, film-forming polymers (PVA) or cellulose (HPMC), plasticisers, pigments, fillers and flow agents etc. This powder base is then mixed with R/O water or a solvent base, depending on the physical properties of the tablet.

It is critical that the correct type of coating is selected. Solvents are used when rapid drying is required, especially when hygroscopic material is used in the tablet core like some calcium/magnesium (Ca/Mg) preparations. For a Ca/Mg preparation that absorbs moisture from the atmosphere, one should not select an enteric coating as this will compromise the absorptivity as the calcium and magnesium needs to be exposed to the acidic medium of the stomach in order to activate the minerals to become more bio-available. The incorrect selection of an enteric coating can account for an 80% loss in availability of calcium and magnesium and should not be the first choice.

POLYMER-BASED COATINGS

Film coatings based on high molecular weight polymers are safe to use as these cannot be absorbed into tissue. They have no physical action at the recommended dosage and are non-toxic.

Polymer-based coatings yield a smooth, glossy finish on tablets which is easy to swallow and compatible with most active ingredients. Enteric coatings can be based on methacrylic acid copolymers type A, B and C, which are pH specific. The delivery systems can be specific to the jejunum (pH 6.0), colon (pH7.0) and duodenum (pH5.5). Enteric preparations can be used for targeted-specific drug delivery, or to protect the active ingredients in the tablet against the acid medium of the stomach.

HPMC-based coatings yield a matte finish and are not as smooth as polymer-based coatings, though HPMC-based coatings give good moisture protection.

THE COATING PROCESS

Because the coating process has many variables, everything needs to be controlled and correctly done in order to obtain the desired result of an aesthetically pleasing tablet to the functionality of the actual coating.

Some critical parameters begin with the integrity of the raw materials used to manufacture the cores through to the manufacturing process of the tablets and on to the processing and coating of the tablets.

Remember, it's critical to obtain the recommended weight gain on the cores to achieve the desired efficacy of the functional coating. To identify and resolve defects associated with the coating process, readers are invited to request a complimentary troubleshooting guide in poster format from Quantum Colours, by sending an email to sales2@quantumcolours.com. This detailed poster covers issues such as orange peel, film peeling, picking, twinning, film cracking, logo erosion, film chipping, colour variation, logo bridging and logo infilling. ■

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