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AQUEOUS FILM COATING : CRITICAL ASPECTS

Suresh Pareek

Film Coating technology, the world over, has now advanced to the level where aqueous coating has become a routine rather than an exception says Suresh Pareek and Chetan Raj Sharad.

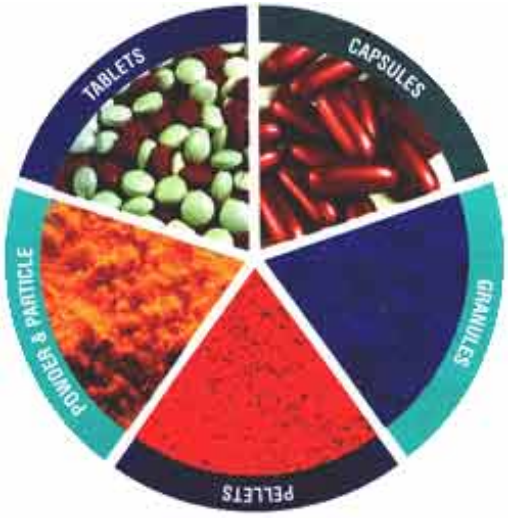
Chetan Raj Sharad

One of the major steps in formulation development activity is the development of film coating formulation and process. Different dosage forms may need different kind of coating formulation, technique and process. Therefore a formulation development scientist has to understand the critical aspects associated with each case. Different dosage forms which can be coated are : tablets, capsules, pellets, granules, particles and powder.

All the above mentioned dosage forms may need coating for different reasons such as :

1. Change in appearance - to impart colour for easy identification and brand image building.
2. To eliminate dust generation – to reduce handling problems and to reduce dust induced toxicity.
3. Taste masking – mask the bitter or unpleasant taste.
4. Odour masking – mask the unpleasant odour of active ingredients like vitamins, antibiotics etc.
5. Isolation of incompatible materials – some of the ingredients may be incompatible to each other, and these can be separated by putting a barrier coating inbetween them.
6. Protection from environmental conditions – Some of the ingredients may not be stable in the presence of moisture, light, oxygen etc. The product stability can be improved by coating.
7. Change in release characteristics – drug release profile from the dosage form can be tailored by coating techniques for example – delayed release (by enteric coating), extended release (by semi permeable membrane coating or mixing of pellets which are coated to various degree or with different coating materials).

View
PRESENTATIONS



The application of coating, which is an additional step in the manufacturing process increases the overall processing time and cost of production. Therefore, the decision regarding the coating technology has to be based on :

1. Available facility
2. Overall productivity desired (film coating process is always much faster than sugar coating)
3. Environmental and regulatory considerations (all organic solvents are toxic and inflammable)
4. Overall cost of the product

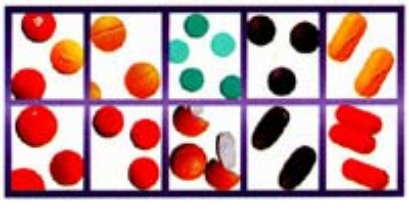
Aqueous film coating technology

As the sugar coating process is very time consuming and is dependant on the skills of coating operator, this technique has been replaced by film coating technology. This technique was started with the use of organic solvents but now has been replaced with aqueous film coating due to environmental and regulatory considerations. Moreover the cost of any organic solvent is far more than the cost of purified water. Therefore, the conversion from organic solvent based coating to aqueous based coating makes the coating process more economical, though initially it may need a little investment to upgrade the coating facility. The need of this upgradation arises due to the need of higher drying capacity (the latent heat of water is 2200 kJ as compared to 550 kJ for methylene chloride which implies that to evaporate water one will need 4 times more energy as compared to organic solvent).

The problems associated with organic solvent-based film coating and the advantages of aqueous based syatems have long been recognized. Film coating technology has now advanced to the level where aqueous coating has become a matter of routine rather than the exception. The successful introduction of a wide variety of aqueous based film coating products (by M/s. Ideal Cures Pvt. Ltd., under the brand name INSTACOAT) has resulted in easy conversion from organic solvent based coatings to aqueous film coating for several companies; many of them still use the conventional coating equipment.

Development of film coating formulation

The optimization of film coating formulation may be necessary to improve adhesion of the coating to the core, to decrease bridging of intagliations, to increase coating hardness or to improve any other property that the formulator deems deficient. The development scientist has to consider three major factors which affect the film quality - tensile strength of the film coating formulation (mainly dependant on polymer properties), elasticity of the resultant film (mainly dependant on properties and quantity of plasticizer used) and the film-tablet surface interaction (each and every ingredient used in the coating formulation can affect this interaction and can change the adhesion properties of the film on the tablet surface).
Due to these considerations, it becomes very important to use the most optimized coating formulations in order to get the best results.



Problems in film coating

It is very common to see that though one may have a decent coating equipment, the final product is still not very satisfactory. One may find various defects in the final products. The basic source of these defects could be any three listed below :

1. Defects arising due to defective core formulation or the tablet shape (like high friability, capping, logo or embossing, cratering, high contact surface area causing twinning.
2. Non-optimised coating formulation (problems like logo bridging, poor colour dispersion, film cracking and peeling)
3. Non-optimised coating conditions (like pricking & sticking, surface roughness, colour variation, spray drying, orange peel, poor coating efficiency)

The development scientist, therefore has to critically evaluate the problem and find out the basic reason for the problem, then only the most optimized solution to the problem can be ascertained.

Equipment requirement for film coating

Tablet coating has undergone numerous developments during the last few decades. These changes have resulted in increased interest in equipment designed for film coating – from conventional set-up to side-vented pan to fluid-bed coater for different applications. However the process is complex and requires careful monitoring and control to ensure satisfactory results.

The film coating process as such is a combination of four processes going on simultaneously :

1. Distribution of coating material on large number of tablets
2. Mixing of large batch for homogeneous result
3. Drying or evaporation of solvent
4. Solvent vapour removal

In order to achieve best results, one has to optimize each process in relation to each other. The major difference between sugar coating and film coating is that generally film coating is a continuous process and is run in almost dry conditions, which implies that the rate of drying has to match the rate of spray. This being the most important aspect in film coating process, ensures good/poor finish of the final product.

Coating equipment set-up, therefore, has to have provisions to meet these criteria. With careful designing such conditions can be achieved in different set-ups – be it conventional pan/side-vented pan or fluid-bed coater.

Companies like Ideal Cures Pvt. Ltd. have helped several pharmaceutical manufacturers in designing the conventional pan set-up for aqueous film coating which are working very successfully.