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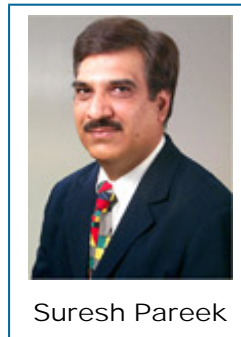


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## MAKE OR BUY FILM COATING SYSTEM ?

By Suresh Pareek

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Suresh Pareek

Make or Buy important excipients used in production of solid oral dosage forms (SODF) could be a dilemma. Some of the excipients can either be purchased as ready to use material or various raw materials required can be bought as individual components and used in the production of SODF by mixing in the production process. Two such examples are Ready Mix for Direct compressible and Film Coating System (FCS). In this article I will discuss various criteria for decision making for make or buy of Ready to use FCS. Traditionally film coating was done for moisture protection, enteric properties or sustained release. Today apart from these, there are many other reasons for which a film coating is done.

Some of the reasons are :

1. For Environmental Protection.
  - a. Air
  - b. Moisture
  - c. Sun Light
2. For protecting the hygroscopic active ingredients.
3. For Delayed Release.
4. For Enteric Coating
5. For Sustained Release
6. For Taste or Odour masking
7. Addition of colourants for easy identification in production, Aesthetic reasons, Brand image in the market, increase in packaging efficiency by reducing product defects caused by tablet breakage edge chipping and to avoid dusting.
8. Aid in Patient Compliance : Ease of swallowing.
9. Improvement in Product appearance.

Thus film coating is an important step in the production of SODF for Pharmaceuticals, nutraceutical, Ayurved and Unani Medicine system.

Film Coating material can be bought as Ready Mix or can be made in house by mixing various ingredients. The main components used in FCS like Polymers, Plasticisers, Opacifiers, Glident, antitacking and antfforming agent, flavors, etc. can be purchased individually from separate vendors or manufacturers or from a single vendor ready to use FCS can be procured. This article will deal with the various aspects of make or buy, which will help the R & D and purchase managers to decide whether to make or buy?

An in depth analysis of various steps involved in buying different components of the FCS Vs buying the FCS from single source, has been made, based on the experince of INSTACOAT Flim Coating Systems in dealing with very large to medium size companies manufacturing SODF. Depending on the formulation of film coating material on an average 6 to 8 ingredients are required.

A Company wishing to make in house preparation will go through various stages as under :

1. R & D sample preparation, coating, approval of marketing for shade, stability studies.
2. Purchase of various Ingredients
3. QA tests
4. Storage and dispensing of materials from stores.
5. Various steps in Production / preparation of FCS.

As a first step the R & D department develops the FCS, performs the coating, submits the samples to marketing dept., for approval and if required prepares two or more shades to meet the requirement of marketing dept.

1. The benefits of using Ready Mix FCS are :

▲ Colour shade chart of INSTACOAT 144 shade box of dummy coated tablets can be shown to the marketing dept., to choose the desired shade, thereby saving precious development time and resources.

▲ Based on the shade box the required sample can be requested.

▲ Coating facilities at the application laboratory of the FCS manufacturer can be used by deputing the person with the core tablets or by sending the core tablets, specifying the coating to be done and the shade required. Ideal Cures application lab is well equipped with manual and automating machines, fluid bed processor with top, bottom and tangential spray system.

▲ Benefit of Continuous R & D carried out by the Ready Mix Manufacturer is available to the product developer there by saving resources and time of the development team.

2. Saving in Purchase procurement of Multiple ingredients vs Single Ready to use FCS.

Generally the following steps are involved in purchasing

1. Floating Enquiry
2. Compansion
3. Ordering
4. Follow up for delivery
5. Gate Entry
6. Preparation of GRN
7. Entry in Bin Card
8. Inventory holding space
9. maintaining minimum level.
10. Ordering minimum quantity
11. Q.C. Analysis
12. Q.C. Reports
13. Accounting Entries
14. Payments

#### TABLE 1 : **RAWMATERIAL IN COATING : PURCHASE TO APPROVAL**

On an average 6 raw materials are needed to be procured for making FCS in house. 14 steps are involved for procurement transaction. Total steps are involved for procurement transaction. Total steps involved in buying FCS will be only 14.

3. About 27 different QA tests as shown, are undertaken for the incoming raw materials procured from various different vendors.

1. Identification
2. Assay
3. pH
4. Particle Size
5. Heavy Metals
6. Sulfated ash
7. Lead
8. Solubility
9. Loss on drying
10. Microbiological tests
11. Arsenic
12. Monormer test
13. Water Solubie subs
14. Botanical Characteristics
15. Dye content
16. Free dye content

17. Viscosity
18. Free ethylene oxide and 1,4 dioxane
19. Limit test for ethylene glycol and diethylene glycol.
20. Average molecular weight
21. Acid soluble substances
22. Organic volatile impurities
23. Assay HPMC - Methoxy and Hydroxy
24. IR
25. Refractive Index
26. Specific Gravity
27. Melting Point

TABLE 2 : **TESTS DONE ON MULTIPLE INGREDIENTS**

In case of single source there are only 8 tests involved as shown in the table 3. Cost of 19 tests is saved apart from saving of manpower resources, equipment usage and the cost of analytical material.

1. pH
2. Particle Size
3. Bulk Density
4. Appearance
5. Ash content
6. Arsenic
7. Heavy metals
8. Viscosity

TABLE 3 : **TESTS ON SINGLE SOURCE**

3. Cost of holding inventory will be much less in case of Ready to use FCS. In case of in house preparation all the raw materials required have to be ordered and kept in stock. Some material may have to be ordered in minimum pack size and thus may remain in stock for more than the shelf life of the product which may have to be disposed.