



VALIDATION OF FILM COATED MULTIVITAMIN TABLETS

Vipin Kumar^{*1}, A. C. Rana², Rajani¹

¹Department of Pharmaceutics, Rayat Institute of Pharmacy, Rail Majra S.B.S Nagar (Punjab) India

²Department of Pharmacology, Rayat Institute of Pharmacy, Rail Majra S.B.S Nagar, Punjab, India

*Corresponding Author Email: vipinrayat@gmail.com

Article Received on: 10/03/13 Revised on: 01/04/13 Approved for publication: 11/05/13

DOI: 10.7897/2230-8407.04607

IRJP is an official publication of Moksha Publishing House. Website: www.mokshaph.com

© All rights reserved.

ABSTRACT

The validation is fundamental segment that supports to a commitment of company towards quality assurance. It also assures that product meets its predetermined quality specification and quality. Validation of each steps of manufacturing during multivitamin tablet formulation is called process validation of multivitamin tablets. During past film coating is not much favorable but now for multivitamin tablets film coating is used. The objective is to present a review and to discuss aspects of validation of film coated multivitamin tablets in terms of unit operations; that is, those individual technical operations that comprise the various steps involved in product design and evaluation.

KEYWORDS: Coating polymer, Lubrication, Screening, Granulation

INTRODUCTION

Validation of multivitamin tablets is establishing documented evidence which provides a high degree of assurance that a specific process will continuously produce a product meeting its predetermined specification and quality attributes¹. In the pharmaceutical industry, GMPs are essential to ensure that consistent quality products are manufactured and delivered to the patients. Validation is now a key requirement of all GMP Guidelines, as a validated process enables consistent manufacturing and packaging of products in accordance with the product quality and market requirements in a cost effective and secure manner.

There may be specific groups of people who may benefit from multivitamin supplements (for example, people with poor nutrition or at high risk of muscular degeneration. Individuals who use dietary supplements (including multivitamins) generally report higher dietary nutrient intakes and healthier diets. Additionally, adults with a history of prostate and breast cancers were more likely to use dietary and multivitamin supplements².

Types of validation for Film Coated Multivitamin Tablet

1. Prospective validation - Validation conducted prior to the distribution of either a new product or product made under a revised manufacturing process.
2. Retrospective validation - Validation of a process for a product already in distribution based upon accumulated production, testing and control data.
3. Concurrent validation - In process monitoring of critical processing steps and end product testing of current production is involved in concurrent validation³.

Validation of multivitamin helps in getting the acceptance criteria such as acceptable quality level and unacceptable quality level, with an associated sampling plan that are necessary for making a decision to accept or reject a lot or batch of raw material, intermediate, packaging material, or active pharmaceutical ingredient⁴.

Reasons for Tablet Coating

1. Core material may contain such material which has a bitter taste in the mouth or has an unpleasant odour.

2. Coating will protect the drug from the surroundings with a view to improve its stability.

3. The core alone is inelegant.

4. Coating will increase the ease by which a tablet can be ingested by the patient.

5. Coating provides mechanical integrity, means coated materials are more resistant to mishandling like abrasion, attrition etc.

6. Coating will protect the drug from light and subject to atmospheric oxidation, i.e. a coating is added to improve stability.

7. Active substance is colored and can easily migrate to stain hands and clothes.

8. The coated tablets are packed on high-speed packaging machine as it reduces friction and increases packaging rate.

9. Coating helps in modifying the drug release profile, e.g., enteric coating, osmotic pump⁵.

Strategy for the Process Validation of Film Coated Multivitamin tablets

1. The different lots of raw materials should be used.
2. The batches should be processed one after another.
3. Equipments and facilities should be the same as used for the manufacturing purpose.
4. Range for the critical process should be fixed and should not undergo over these upper and lower limits during operation.
5. In case of failure to meet the requirement of protocol, whole process must be subjected to process qualification and followed by revalidation⁶.

Stages for Validation of Film Coated Multivitamin tablets

1. During Mixing
2. During Drying
3. During Lubrication.
4. During Compression
5. During Coating

Manufacturing Process

Weighing of the active ingredient and excipient is done in raw material stores. The weights of all the ingredients are rechecked and noted at production floor by production

chemist. The weighing balances are checked and certified regularly by State Govt. Department of weights and measures⁷.

Sifting

Weighed quantity of Sodium Metabisulphite BP and Gelatin BP is dissolved in predefined amount of purified water in Stainless Steel vessel. Heat to boil with constant stirring till uniform solution is achieved. Sieve the solution through # 100. Sieved quantity of Maize Starch BP dispersed in about 12 L purified water in Stainless Steel Vessel to form slurry. The slurry is then sieved through the # 100. Add the slurry to the sieved boiling solution. Stir continuously till a translucent paste is formed and allow the paste to cool. Raw Material quantity and other parameter are studied before and after the sifting and all the parameters are studied^{7,8}.

Mixing

Transferred bulk material in the Double Cone Blender and add starch to it. Now make a different combination of time and quantity of starch added to observe the difference. Note down the readings and compare them to get the desired results^{7,9}.

Dry mixing

After loading of mixed material in the Rapid Mixer Granulator, mixing is done for 10 minutes at slow speed (80 rpm). In order to standardize the mixing time, samples are taken at different times and from 5 different locations of the RMG and Ampere meter reading is noted during dry mixing⁷.

Granulation

After the addition of binder, material is mixed for 20 minutes at slow speed. Ampere meter reading should be optimum and mix for 20 seconds at fast speed (2700 rpm), add more quantity of the purified water till a consistent cohesive mass is obtained. Run the rapid mixer granulator till ampere meter reading goes to 24 -27 amperes^{7,10}.

Semi Drying

The granules made in granulation are dried in the Fluid Bed Dryer at inlet air temperature 60 °C – 70 °C and this drying operation is validated by checking the moisture content (by I.R moisture balance at 105 °C) at different intervals of time during the drying process. Samples are pooled from different locations from the bowl. Outlet temperature is maintained at 40 °C – 50 °C.

Screening of semi dried granules

The material after drying of 30 minutes in Fluid bed dryer is milled through Multimill of # 8 mm screen and then dried in Fluid bed dryer for remaining time⁷.

Drying

After screening, granules are dried in the Fluid bed dryer for 45 minutes at inlet air temperature 60 °C – 70 °C. Samples are pooled from different locations from the bowl. Outlet temperature is maintained at 40 °C – 50 °C.

Dry Screening

After complete drying, material is sifted through the screen of # 24 and then milled through mill. After milling the material is again screened through the # 24 till all granules are sieved and stored in the labeled double polythene bag lined drums

and weights are recorded. After that shifting/mixing of vitamins and lubricants are done⁷.

Compression

The granules are compressed initially to set the appropriate desired parameters using the required tooling. The machine is adjusted against the desired weight.

After adjusting the desired weight, physical parameters adjusted are

1. Hardness
2. Friability
3. Thickness⁷

Coating

After making a good tablet, you must often coat it. There are several ways of tablets coating but mainly sugar and film coating is used. We have used film coating during preparation of multivitamin tablets. The coating can have several functions like -

1. It can strengthen the tablet
2. Control its release
3. Improve its taste
4. Provides color to it
5. Make it easier to handle
6. Protect it from moisture⁸

The major classes of solvents being used for coating are

1. Water
2. Alcohols
3. Ketones
4. Esters
5. Chlorinated hydrocarbons⁹

Miscellaneous coating solution components

To provide a dosage form with a single characteristic, special materials may be incorporated into a solution⁸.

Flavours and sweeteners are added to mask unpleasant odours or to develop the desired taste. For example, various fruit spirits (organic solvent), water soluble pineapple flavour (aqueous solvent) etc.

Surfactants are supplementary to solubilize immiscible or insoluble ingredients in the coating. For example, Spans etc.

Antioxidants are incorporated to stabilize a dye system to oxidation and colour change. For example oximes, phenols etc.

Antimicrobials are added to put off microbial growth in the coating composition. Some aqueous cellulosic coating solutions are mainly prone to microbial growth^{8,10}.

Components of coating systems

1. Coating pan
2. Spraying system
3. Air handling unit
4. Dust collector and controller¹¹

Process parameters

1. Spray rate
2. Atomizing air pressure
3. Inlet air temperature
4. Rotating speed of pan¹²

DISCUSSION

Analytical parameters at various critical steps were strictly found to be under control. The bulk and release data for three

different batches manufactured by said procedure were found to be comparable.

CONCLUSION

On the basis of analysis of critical process involved in manufacture and comparison of three batches optimum manufacturing process and conditions are fixed and validated for production in future.

REFERENCES

1. Lachman Leon, "Process and method validation", Inc. FDA subcommittee meeting, 2002: 46-51.
2. Cheryl L Rock. (2007), "Multivitamin- Multimineral supplements: who uses them?" *American Journal of Clinical Nutrition*, 85(1), 277S-279S.
3. Nash R A., Wachter A.H., *Pharmaceutical process validation*, 3rd edition, Marcel Dekker publication, p.g. no-xxx-xxxiv, 173-182.
4. <http://www.live strong.com/article/500614-what are coated vitamins>.
5. Agalloco J. *Validation: an unconventional review and reinvention* PDAJ.Pharm.Sci.Tech. 49:175-179 (1995).

6. Welankiwar Abhijeet, Tope Susant, "Review- Industrial Process Validation of Tablet doses form" page no: 3-4.
7. Narula Jaiprakesh and Gupta Piyush "Process Validation of Multivitamin Tablets" in *International Journal of Drug Discovery and Herbal Research (IJDDHR)* 2(2): April-June: (2012), 344-364.
8. Hogan J. *Pharmaceutical Coating Technology*, Taylor and Francis Ltd 1998; 6-52.
9. Rowe R. "The effect of some formulation and process variables on the surface roughness of film-coated tablets" *J. Pharm. Pharmacology* 1978a, 30, 669-672.
10. *The Merck index an encyclopedia of chemical, Drugs and biological*, published by Merck research laboratories, div. of Merck and co. Inc. USA 2006, 14th edition: 2314-2315.
11. Obara S, McGinity J. "Influence of processing variables on the properties of free films prepared from aqueous polymeric dispersions by a spray technique" *Int. J. Pharm.* 1995, 126, 1-10.
12. Porter S, Versept R, Cunningham C. *Process optimization using design of experiments*. *Pharm. Technol.* 1997, 21, 60-70.

Cite this article as:

Vipin Kumar, A. C. Rana, Rajani. Validation of film coated multivitamin tablets. *Int. Res. J. Pharm.* 2013; 4(6):31-33