

Research and Reviews: Journal of Pharmacy and Pharmaceutical Sciences

A Review on the Quality Control Analysis of Oral Dosage Form: Tablets

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Review Article

Received: 08-06-2016

Accepted: 24-06-2016

Published: 28-06-2016

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Keywords: Tablets, Dosage form, Capsules, Quality Control, Disintegration, Tablet evaluation, Excipients, Dissolution, Pharmacopoeia, Active Pharmaceutical ingredient API, Disintegration.

ABSTRACT

The most popular of the oral dosage forms are the tablets which are easily administered by patients and many people rely on these. The pharmacists prescribe the right drug to be administered to patients; this is based on the quality, brand, and product availability in the market. The quality tests are so performed to meet the criteria in advance. Quality control Analysis is to regularly check in each step to produce a good quality of the products. There are many dosage forms available in the markets in many brands. In this review article tablet evaluation techniques and methods have been explained which are applicable to all the dosage forms production.

INTRODUCTION

Tablets and capsules are the dosage forms that are manufactured for pharmaceutical and dietary supplements which are under regulated terms and laws. Regulations are imposed in the manufacturing process to ensure the quality, efficacy and safety of the tablets and capsules. To test these qualities the products undergo many quality tests to meet the regulations and standards in the market [1-20].

The testing procedures induce physical, chemical and biological tests for both the tablets and capsules. These are done with the standard quality control procedures under the pharmacopoeia of the respective countries. Many nations follow the British Pharmacopoeia to meet the required regulated standards in the world market. Manufacturing, production, packaging, Testing are the main phases of pharmaceutical products in every industry.

TABLETS

The most common form of the oral route administration which comes on mind are the tablets which have the most substantial and significant place among the entire pharmaceutical formulations. The oral dosage forms have more importance in the pharmaceutical markets. They are manufactures in large scale and small scale units of pharmaceutical production. Tablets size, shape and thickness are more important in the packaging process while the organoleptic properties include the colour and odor of the tablets [21-31].

Different pharmacopoeia quality control tests of tablets:

According to the British Pharmacopoeia, Tablets are tested for 1 Active Ingredients Content; 2 Disintegration; 3 Uniformity of Content; 4 Labeling.

Tablets are of different types based upon the API. The different types are:

- Uncoated Tablets
- Effervescent tablets
- Coated tablets
- Gastro Resistant Tablet
- Modified Release Tablet
- Dispersible Tablet

- Enteric Coated tablet
- Soluble Tablet
- Controlled release tablets
- Sustained release tablets

The quality control tests of these tablets depend on the nature of the tablet. The quality control tests remove the damaged or broken tablets or which are unblinded to the ingredient.

Quality Control test for Tablets

Disintegration Test: This is the official test which testifies the time required for a tablet to disintegrate in the solution. The time required to break the tablet into fine particles. Disintegration test helps in knowing the API solubility in the gastric fluids of the digestive system. This test is ideal for all tablets but is not performed for controlled and sustained release tablets. Temperatures are maintained accordingly for each tablet. It is calculated by the time required to dissolve the tablet in the liquid and compared with the standard time in the pharmacopoeia [41-50].

Hardness: It is the load required to crush the tablet when placed on its edge. The test is performed to meet the need for pressure adjustments on the tableting machine. Hardness affects the disintegration test. If the tablet is too hard, it may not disintegrate in the required period of time. And if the tablet is too soft, it will not withstand the handling during subsequent processing such as coating or packaging. If the tablet hardness is too high, we first check its disintegration before rejecting the batch. If the disintegration is within limit, we accept the batch.

General Appearance: The general appearance of a tablet, its identity and general elegance is essential for consumer acceptance, for control of lot-to-lot uniformity and tablet-to-tablet uniformity. The control of general appearance involves the measurement of size, shape, color, presence or absence of odor, taste etc. Size and shape may vary from tablet to tablet [51-70].

Unique Identification marking: These are used in the form of embossing, engraving or printing. These can include the company identification marks, or any other symbols related to the dosage form.

Friability: The Roche Friabilator is used to check the friability of the tablets. Initial weight of the tablets is checked before placing them in the device and batches are separated to check accordingly. Initial and final weight of the tablet is checked. Compress tablet that lose less than 0.5 to 1.0 % of the Tablet weigh are consider acceptable. Friability is a often related to hardness testing [71-90].

Thickness test: Thickness test is performed for very few tablets as it is not a official test to perform. Thickness of tablet is measured by Vernier caliper/screw gauge.

Weight Variation test: It is performed to check the uniformity of the tablet.

Dissolution test: Dissolution is an official test. Dissolution is performed to check the percentage release from the dosage forms.

Before the tablets are processed they undergo evaluation tests which determine the right granule testing procedure to compress the tablets.

Granules are the API formulations which are compressed to form the tablets. Granules are prepared by combining the API, excipients and binders. This dough is used to prepare granules which are dried and then undergo evaluation test.

1. Particle Size and Shape determination: The size and shape depends upon the processing requirements and during granulation. The methods for determining the shape are: Sieving, Sedimentation rate, Microscopy, Light screening.

2. Surface area of granules: This is generally used for drug substances but not for the granules.

3. Density: Density is the compressibility, porosity and dissolution of tablet. Methods for density are: Granular density- It is calculated by using the equation Figure 1.

Density $D = M / (V_p - V_i)$

V_p - total Pressure; V_i - Volume of intrusion



Figure 1: Bulk density apparatus.

Granular strength and friability: To determine the changes in the particle size distribution of granulations and compressibility.

Flow properties: This is to determine the granule flow from hopper to die cavity for tablet uniformity for tablet uniformity. Flow properties of granules are determined by three parameters:

Angle of repose: Static angle of repose and Dynamic angle of repose.

$\tan \theta = h/r$

Hausner's ratio: To predict the powder flow property.

Hausner's ratio = tapped density / bulk density

Moisture Content: It is the amount of moisture present in the granules.

%moisture content = $\frac{\text{initial wt} - \text{final wt}}{\text{Initial weight}} \times 100$

DISCUSSION

- The tablets are evaluated based on the biological types, API and nature of tablet.
- Uncoated Tablets include Aspirin 400 mg, Paracetamol 500 mg, Acetazolamide 250 mg, Cetirizine B.P 10 mg, Atenolol and Amlodipine I.P. 50 mg etc.
- Effervescent tablets include Ranitidine, Co-codamol, Sodium dichloroisocynuarate, Ascorbic acid etc.
- Coated tablets include enteric coated Aspirin, Enteric coated Diclofenac etc.
- There are many tablets in the pharmaceutical market which are determined with various brand names and are formulated with the standard procedure and API content [91-100].

CONCLUSION

The quality control testing is assigned to production or quality control depending on the company basis of large scale and small scale. The Quality executives evaluate the quality tests of the tablets to pass the products into markets. These are regularly checked by the RA and FDA bodies. The Quality tests are performed as discussed above, these tests brings out the errors, and misbranded and bad quality products. The standard of the products are based upon this analysis and results of the tests which achieve therapeutic and quality goals. It is the duty of the of the pharmaceutical companies to manufacture the dosage forms which can sustain rattling and handling to have more shelf life and demand in the pharmaceutical markets.

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