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Process of Manufacturing Oral Drugs (Capsule)

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Review Article

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ABSTRACT

Capsules are solid dosage forms in which substances are enclosed in either a soft or hard, soluble container or shells of suitable forms of gelatins. Capsules have the advantage of being tasteless, easily administered and easily in large quantities commercially. Capsule can be categorized into three – based on their mode of fabrication, based on their use and based on their physical form. For the production of the capsule starts with the dispense of the raw material. The raw material then undergoes the process of granulation where sieving is done and various binders are added. This is followed by drying, sizing and blending of the material. This material now goes for capsule filling after that goes for capsule polishing. After that all the capsules goes for primary packaging then secondary packaging.

INTRODUCTION

In pharmaceutical drugs or medicines, is chemical substances are used to treat, prevent, diagnoses a diseases or promote well-being [1-4]. Mostly drugs were obtained through the extraction from medicinal plants and but Pharmaceutical drugs may be used for a limited duration, or on a regular basis for the chronic disorders [5-7].
The routes of administration of drugs by:-
Oral
Transdermal
Nasal
Gastrointestinal tract
Capsules: In the manufacturing of pharmaceuticals capsules are solid dosage forms in which substances are enclosed in either a hard or soft, soluble containers or shell of a suitable form of gelatin [8-12]. Capsules have the advantage of being tasteless, easily administered or in large quantities commercially [13-18].
The two main types of capsules are:

Hard shelled capsules, which are the typically made using gelatins and contains dry, powdered ingredients or pellets made by e.g. processes of extrusion [19-21]. These are made in the two halves: a lower-diameter "body" that is filled and sealed with a higher diameter "cap" [22-25].

Soft shelled capsules, primarily used for oils and for active ingredients that are dissolved or suspended in oil [26,27].

Advantages of Capsules

It is smooth, slippery and easy to swallow.
It is Suitable for substances having bitter taste and unpleasant odour.
Minimum excipients required.

It is stable than liquid dosage forms.
It is easy to store and transport [28-30].

Disadvantages of Capsules

It is not suitable for the highly efflorescent materials.
Special conditions are required for storage.
It is not suitable for very soluble ingredients such as KCl, $CaCl_2$, KBR, and NH_4Br. When the capsules are broken contact with the wall of the stomach, then the solution will be concentrated so that irritate the stomach and the stomach becomes tense [31-34].

Methods

The methods involved in the manufacturing process are carried out in different rooms. There are different rooms all ocated for each procedure and careful testing or checks occur after a period of steps [35-39].
When the raw materials come they are kept in a room known as “Raw Material Room”. From there taken to the Lab for testing [40-44]. The different common tests that take place for the raw materials are:

UV test
IR test
HPLC test, etc.

Then the tested raw materials are taken to another room. From there on the manufacturing process of the capsules start [45-48].

Raw Material Testing of Capsules

Amoxycillin Trihydrate is (6R)-6-(α-4-hydroxyphenyl-D-glycylamino acid Trihydrate.

Amoxycillin Trihydrate contains not less than 95.0 per cent and not more than 100.5 per cent of $C_{16}H_{19}N_3O_5S$. It is c alculated on the anhydrous basis. Its molecular weight is 419.4 [49-52].

Category: - Antibacterial.

Dose: - The Equivalent of 750mg to 4.5 g of Amoxycillin daily in divided doses.

Description: - A white or crystalline powder.

Identification

Tests B may be omitted if tests A are carried out.

A. Determine by infrared absorption spectrophotometer. Compare the spectrum with that obtained with Amoxycillin Trihydrate RS or with the reference spectrum of Amoxycillin Trihydrate [53-58].

B. Place about 2 mg in a test tube. Moisten with 0.05 ml of water and add 2 ml of sulphuric acid formaldehyde rea gent. Mix the contents of the tubes by swirling; the solution is practically colourless. Place the tube in a water-bath f or 1 minute; a dark yellow colour develops [59-64].

Tests

Appearance of solution: - Dissolve 1.0 g in 11 ml of 0.5 M hydrochloric acid, and a further 1.0 g in a mixture of 3 ml of dilute ammonia solution and 7 ml of water [65-67].

pH:- 3.5 to 5.5, determined in a 0.2 per cent w/v solution .

Specific optical rotation: - $+290^0$ to 315^0, determined in a 0.2 per cent w/v solution in carbon dioxide free water.

N, N-Dimethylaniline: - It is not more than 20 ppm, determined by method A.

Water: - 11.5 to 14.5 per cent, determined on 0.1 g.

Assay:- Determine by High Performance liquid chromatography

Solvent mixture: - Dissolve 6.8 g of monobasic potassium phosphate in 1000 ml of the water and adjust the pH to 4 .5 with a 4.5 per cent w/v solution of potassium hydroxide [68-70].

Test solution: - Transfer a weighed quantity of about 120 mg of the substance under examination to a 100 ml volu metric flask. Dissolve in the solvent mixture by shaking and mixing if necessary with the aid of ultrasound and dilute to 100.0 ml with the solvent mixture. Use this solution within 6 hours [71-75].

Reference solution: - weigh a suitable quantity of Amoxycillin Trihydrate RS, Dissolve in the solvent mixture by shaki ng and mixing if necessary with the aid of ultrasound and dilute to obtain a solution having a known concentration o f about 1.2 mg per ml. Use this solution within 6 hours [76-80].

In mobile phase a mixture of 4 volumes of acetonitrile and 96 volumes of the solvent mixture [81].

Flow rate is 1.5 ml per minute.

Spectrophotometer set at 230 nm

Injection volume is 10 µl.

Inject the reference solution: - The test is not valid unless the capacity factor is between 1.2 and 2.8, the column eff iciency is not less than 1800 theoretical plates, the tailing factor is not more than 2.6 and the relative standard dev iations for replicated injections is not more than 2.0 per cent [82-85].

Inject the reference solution and test solution.

Calculate the content of $C_{16}H_{19}N_3O_5S$.

Store at a temperature not exceeding $30^{0.}$

Weighing: According to the calculated amount the tested raw materials are weighed and put in the mixer [86-87].

Mixing in cone blender: This process takes place in the instrument called cone blender mixer. Along with the active i ngredients or raw materials, excipient and preservatives were also added to the mixture [88-90].

Empty capsule loader: All the empty capsules put it into the machine and then all the capsules loaded it into the se quence [91-92].

Capsules filling: After loading it is taken into the capsule filling machine after that it is taken to the capsules into ca psules polishing machine [93-94].

Primary Packaging: There are two types of primary packing. They are:-

Alu Alu packing: In this, on both the sides there's aluminum foil. It's just that on one side, it's printed.
Strip packing: In terms of packing material it's similar to Alu Alu packing but the process of packing is different than it [95-97].
Secondary Packaging: In this step, the packed capsules in the strips are finally packed in the boxes.

CONCLUSION

The study aim of my project is to study the process of manufacturing of oral drugs. The study deals with the processes of how the oral drugs that we consume in our daily life are manufactured. The result was concluded that the manufacturing process of capsules and syrups were easy as compared to tablets. The first set of result tells us whether the raw material is pure or not. If the purity percentage is between 95.0- 100.5% the raw material is pure and it can be forwarded for the manufacturing of the capsules. The steps adopted for the manufacture of capsules are raw material testing, weighing, and mixing in cone blender, capsules filling, capsules polishing, packaging and dispatch. Amoxycillin Capsule obtained was a white or almost white crystalline powder. The Disintegration time for hard capsules is 25 minutes and 05 seconds but the acceptance criteria should be 30 minutes and for soft capsules it is 50 minutes and 05 seconds but the acceptance criteria should be 60 minutes [98-100].

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