Strada Journal of Pharmacy
ISSN: 2776-3544 (print); 2797-9180 (online)
Vol. 2, No 1, April 2020, 1-4

Formlation of capsule preparations with variations in aerosil concentration on the results of preparation evaluation

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ABSTRACT

Capsules can be defined as a solid dosage form, where one or more types of drugs and/or other inert ingredients are contained in a shell or small container that can dissolve in water (Ansel 2005). Gelatin is a suitable material for making capsule shells because it is edible and soluble, forms a strong, thin-layered shell and changes from solution to gel form slightly above ambient temperature. Gelatin immediately dissolves in water at body temperature and does not dissolve if the temperature drops below 30°C (Agoes, 2008).

Based on the test results, the disintegration time for F1 capsules is 2.12 minutes; F2 is 2.21 minutes; and F3, namely 2.27 minutes. These three formulas meet the requirements, namely not less or equal to 15 minutes. Based on the test results, F1 3.44 seconds, F2 3.76 seconds, F3 3.24 seconds, the flow speed of these three formulas meets the flow speed requirements, namely flow speed ≥ 10 g/second. The flow speed of the three formulas is in the good category, namely 2-10 g/sec which is said to be very good while it is said to be good. The flow speed is good because Aerosil has a very small and fine particle size. Apart
from being an absorbent, aerosols are also able to improve flow properties by reducing friction between particles and by averaging test results from angles of repose F1 45°, F2 43° and F3 53°.

In the weight uniformity test at F 1,2,3 it does not meet the requirements for factors that influence weight uniformity, namely lack of accuracy, different drug weights due to uneven distribution.

Keywords : Aerosil, Capsula, Variations

INTRODUCTION

Capsule preparations are a form of drug dosage encased in a hard or soft capsule shell. Capsules have several advantages, namely covering the odor and taste of raw materials which can cause certain problems for consumers, more complete dosage settings, and more practical storage (Lachman et al, 1986). Capsules may contain powdered mixtures or granulated powders. Granulation means that the powder particles are converted into granules, where the powder particles have adhesive power and have better flow properties. With better flow capacity, filling into the capsule space can take place continuously and homogeneously, resulting in a constant capsule weight and good dose consistency.

Capsules can be defined as a solid dosage form, where one or more types of drugs and/or other inert ingredients are contained in a shell or small container that can dissolve in water (Ansel 2005). Gelatin is a suitable material for making capsule shells because it is edible and soluble, forms a strong, thin-layered shell and changes from solution to gel form slightly above ambient temperature. Gelatin immediately dissolves in water at body temperature and does not dissolve if the temperature drops below 30°C (Agoes, 2008).

So capsules are solid preparations in the form of powder particles or granulated powder consisting of one or more and/or inert materials wrapped in a hard capsule shell or soft shell made of gelatin which can dissolve at body temperature. Masks odor and taste, allows for more complete dosage settings, and storage is more practical.

Hard capsules are usually made from gelatin which consists of the capsule shell, the body and the capsule cap. The two parts of the capsule cover will cover each other when brought together and the cover will cover the body of the capsule (Ansel, 2005).

Antibiotics, as we currently know, come from weakened bacteria, no one suspects that these weakened bacteria can kill other bacteria that develop in the bodies of living creatures. Antibiotics are substances produced by microbes, especially fungi, which can inhibit or kill the growth of other

microbes (Nastiti, 2011). Antibiotics are chemical compounds produced by microorganisms, especially fungi or produced synthetically, that can kill or inhibit the development of bacteria and other organisms. One antibiotic that can inhibit protein synthesis is clindamycin (Utami 2011).

Clindamycin inhibits most gram-positive cocci and most anaerobic bacteria, but cannot inhibit aerobic gram-negative bacteria such as 33 Haemophilus, Mycoplasma and Chlamydia (Ministry of Health, 2011). The mechanism of action of clindamycin is the same as erythromycin. Clindamycin is mainly given to treat infections caused by anaerobic bacteria, such as Bacteriodes fragilis bacteria which often cause abdominal infections caused by trauma (Katzung, 2012). Considering the importance of knowledge about antibiotic drugs such as clindamycin, a good and correct method for formulating solid capsule dosage forms has been developed and what must be taken into account when making them.

METHODS

Material	F1	F2	F3
Clindamycin	3 g	3 g	3 g
Talcum	100 mg	250 mg	400 mg
Aerosil	50 mg	50 mg	50 mg
Asam Benzoat	1,25 mg	1,25 mg	1,25 mg

Prepare tools and materials, Weigh out 1.25 mg of benzoic acid, add it to a homogeneous grinding mortar, Weigh 50 mg of Aerosil, add it to a homogeneous grinding mortar, Weigh 3000 mg of clindamycin, add the grinding mortar until homogeneous, Weigh the following amount of talcum: F1 = 100 mg F2 = 250 mg F3 = 400 mg

Then put it in a finely crushed mortar until it is homogeneous, Take out the mixture of all the ingredients then divide each into 20 equal parts, then put them into capsule shell number 2 then close the capsule shell, Clean the capsule shell using a clean cloth or dry tissue.

RESULTS

Organoleptic testing, also known as sensory testing or sensory testing, is a testing method that uses human senses as the main tool for measuring product acceptability. The senses used in organoleptic tests are the sense of sight or eyes, the sense of smell/nose, the sense of taste or tongue, the sense of touch or hands (Gusnadi, 2021).

Organoleptic tests found F1 color: yellowish white, odor: pungent, taste: bitter. In F2 and F3, color: white, odor: pungent, taste: bitter. in F1 the color is yellowish white and the smell is more pungent than in F2 and F3 because the clindamycin used seems to be no longer usable because in FI III page 168 the description of Clindamycin is crystalline powder, white, odorless whereas in the laboratory clindamycin was found to be slightly brown in color yellowish, lumpy and has a strong odor.

pH testing is carried out to determine the alkalinity and acidity contained in the sample. This pH test is carried out by dissolving the sample with a homogenizer in distilled water solution, and testing using a pH meter. From testing, it was found that the ingredients clindamycin, benzoic acid, aerosil had an acidic pH.

Water content is the amount of water contained in a material expressed in percent. Water content is also one of the most important characteristics of food ingredients, because water can affect the appearance, texture and taste of food ingredients. The water content in food also determines the freshness and durability of the food. High water content makes it easy for bacteria, mold and yeast to breed, resulting in changes to the food.

The water content test of all formulations did not meet the requirements <10%, F1 20.67%, F2 16.32%, F3 14.34%, perhaps this high water content was due to the clindamycin material used clumping together, perhaps because it was not tightly enough when closing the container, and it also takes a while to grind it to form a fine powder.

DISCUSSION

This test is intended to determine the suitability of the destruction time limits stated in each monograph. The disintegration time test does not state that the preparation or active ingredient is completely dissolved. The disintegration time for each tablet or capsule is recorded and meets the time specification requirements (within 15 minutes) (Dirjen POM, 1979). Disintegration time is the time required for a number of tablets to disintegrate into their constituent granules/particles. Disintegration time is a requirement for dissolution to occur. The capsule will first disintegrate then the active substance is released, dissolved, absorbed and distributed to its site of action.

Disintegration time test This test is carried out to see how long it takes for a preparation to disintegrate in body fluids. Disintegrant is a tool used to test the disintegration time of capsule preparations. Based on the test results, the disintegration time for F1 capsules was 2.12 minutes; F2 is 2.21 minutes; and F3, namely 2.27 minutes. These three formulas meet the requirements, namely not less or equal to 15 minutes.

Based on the test results, F1 3.44 seconds, F2 3.76 seconds, F3 3.24 seconds, the flow speed of these three formulas meets the flow speed requirements, namely flow speed ≥ 10 g/second. The flow speed of the three formulas is in the good category, namely 2-10 g/sec which is said to be very good while it is said to be good. The flow speed is good because Aerosil has a very small and fine particle size. Apart from being an absorbent, aerosols are also able to improve flow properties by reducing friction between particles and by averaging test results from the angle of repose.

In the results of the flow rate and angle of repose from the three formulas, in the first formula the flow rate is 3.44 seconds with an angle of repose of 45°, in the second formula the flow rate is 3.76 seconds with an angle of repose of 43°, in the third formula the flow rate is time 3.24 with an angle of repose of 53° falls within the range and has different results, this could be due to the angle of repose factor which consists of particle shape, funnel diameter, method of pouring and the influence of vibration (Oktavia Eka, 2023).

Weight uniformity was carried out by weighing 20 capsules at once and weighing the contents of each capsule again one by one. Then weigh all the empty shells of the 20 capsules. Then the weight of the capsule contents and the average weight of the capsule contents were calculated. The difference between 99% of the weight of the contents of each capsule and the average weight of the capsule contents must not exceed that specified in column A and for 2 capsules no more than that specified in column B.

The weight uniformity test is carried out to see the uniformity of the drug dose entering the body so that the dose for each capsule is expected to be the same and in accordance with the therapeutic safety of the preparation. In the weight uniformity test results in formula 1 Does not meet the standard 5 capsules more than column A not a single capsule more than column B, in formula 2 Does not meet the standard 13 capsules more than column A 1 capsule deviates from column B, in formula 3 Does not meet the standard 3 capsules more from column A, 3 more capsules than column B. In the weight uniformity test at F 1,2,3, the factors that influence weight uniformity do not meet the requirements, namely lack of weighing accuracy and uniform filling of all ingredients in the capsule shell, different drug weights due to inadequate distribution. evenly (Ansel, 2008).

CONCLUSION

Clindamycin inhibits most gram-positive cocci and most anaerobic bacteria, but cannot inhibit aerobic gram-negative bacteria such as 33 Haemophilus, Mycoplasma and Chlamydia (Ministry of Health, 2011).

Organoleptic tests found F1 color: yellowish white, odor: pungent, taste: bitter. In F2 and F3, color: white, odor: pungent, taste: bitter. in F1 the color is yellowish white and the smell is more pungent

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This pH test is carried out by destroying the sample with a homogenizer in distilled water solution, and testing using a pH meter. It was found that f1, f2 and f3 had an acidic pH.

Test the water content of all formulations which do not meet the requirements <10%, F1 20.67%, F2 16.32%, F3 14.34%, perhaps this high water content is because the clindamycin we use is clumping, perhaps because it is not tightly enough when closing the container. , and also takes a while to grind it to form a fine powder.

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