Strada Journal of Pharmacy
ISSN: 2776-34544 (print); 2797-9180
Vol 1 April 2019, pp

Variations in Aerosil concentration in Chlorpeniramin Maleat (CTM) capsule preparations on test results

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ABSTRACT

Capsules are solid preparations consisting of a drug in a hard or soft shell that can dissolve. (Fatmawaty, et al. 2012). 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). Chlorpeniramin Maleat CTM) is used as an antihistamine. Antihistaminics are drugs that oppose the action of histamine on H-1 histamine receptors so they are useful in suppressing allergies caused by the appearance of symptoms due to histamine (Ansel, 1989). Antihistamines work by occupying the place in cells normally occupied by histamine, thereby eliminating histamine's ability to cause allergic reactions (Harkness, 1989). Adsorbents are substances that trap other components such as water. Aerosil is an adsorbent that is widely used in capsule preparations. Apart from having a large water absorption capability and capacity of around 50%, if dried, Aerosil will not reduce the existing water content (Lachman, 1989). The active ingredient used is CTM, where this material is hygroscopic, meaning it is able to absorb water molecules from its environment, so adsorbents are added to prevent moisture from the preparation during storage. Based on the description above, this formulation was made by varying the aerosil concentration, namely 5% (F1); 7% (F2); and 9% (F3) which is intended to observe the ability of the adsorbent as seen from hygroscopic testing of the preparation during storage. The results of this research is disintegration time on our formulations resulted in formulation 1 starting to disintegrate within 01:03 until it was completely dissolved, taking 12:02. formulation 2 started to break down within 01:40 and until everything dissolved with a duration of 12:02. The 3rd formulation started to break down within 02:05 with the total duration until it was completely dissolved was 12:58. These three formulations are in accordance with the FI standard, namely less than 30 minutes.

Keywords : capsul, CTM, granul

INTRODUCTION

Capsules are solid preparations with hard or soft shells in various shapes and sizes, usually containing a single dose of medication in the form of powder or pellets for oral consumption. According to FI IV, capsules are defined as solid dosage forms consisting of a drug in a soluble hard or soft shell.

CTM is used as an antihistamine. Antihistaminics are drugs that oppose the action of histamine on H-1 histamine receptors so they are useful in suppressing allergies caused by the appearance of symptoms due to histamine (Ansel, 1989). Antihistamines work by occupying the place in cells normally occupied by histamine, thereby eliminating histamine's ability to cause allergic reactions (Harkness, 1989).

Adsorbents are substances that trap other components such as water. Aerosil is an adsorbent that is widely used in capsule preparations. Apart from having a large water absorption capability and capacity of around 50%, if dried, Aerosil will not reduce the existing

water content (Lachman, 1989). The active ingredient used is CTM, where this material is hygroscopic, that is, it is able to absorb water molecules from its environment, so adsorbents are added to prevent moisture from the preparation during storage.

METHODS

Weigh the lactose then add it to the mortar and grind it finely, Weigh out 6 mg Benzoic Acid then put it in a homogeneous grinding mortar, Weigh 160 mg of CTM then put it in a mortar, grind until homogeneous, Put the remaining lactose into a homogeneous grinding mortar, Weigh the Aerosil then put it in the mortar, grind until homogeneous, The homogeneous mixture is transferred to parchment paper, Open 40 capsule shells number 2 then arrange them tightly in a circle using paper that has been stapled so that the capsules remain open upwards, Add the powder little by little evenly into the capsule shell, Close the capsule shell then clean the outside of the shell using a tissue. The following is the formulation table.

Table Formulation

Material	F1	F2	F3
CTM	4 mg	4 mg	4 mg
Asam Benzoat	0,1%	0,1%	0,1%
Aerosil	5%	7%	9%
Laktosa	ad 100%	ad 100%	ad 100%

RESULTS AND DISCUSSION

Organoleptic testing or sensory testing is a method of testing using human senses as the main tool for measuring product acceptability. The senses used in organoleptic tests are the sense of sight/eyes, sense of smell/nose, sense of touch/hands. The ability of these sensory organs will be the impression that will later become an assessment of the product being tested according to the sensors or stimuli received by the senses (Gusnadi et al, 2021).

This test includes observing the color, odor and shape of the preparation. Based on the results of both the first and second observations, there were no differences in the three formulas, the capsule preparation had a white color, namely the active substance and additional substances were white. The form of the capsule contents is fine powder which is put into capsule shell number 2 and has a characteristic odor from CTM.

The pH test aims to determine the suitability of the pH of each City-M capsule preparation formula in acidic or alkaline conditions. The pH check of the City-M capsule preparation was carried out using a pH meter. The results of the pH examination of the capsule preparation were carried out twice, for the evaluation results the pH examination results were F1 = 8.17; F2= 8.20; and F3= 8.17. In the test after 24 hours the results were F1 = 8.32; F2= 8.60; and F3= 8.34. City-M capsules show an increase in pH and are alkaline in nature.

pH measurements on City-M capsule preparations showed that the three formulas did not comply with the CTM pH range, namely between 4 and 5, so the capsule preparations were

less stable. If the pH of the CTM capsule preparation is too high, this can affect the stability, bioavailability and effectiveness of the drug. Apart from that, changes in pH are also caused by environmental factors such as temperature, poor storage, the combination of medicinal ingredients used is less stable in the preparation because it is oxidized (Putra, 2014).

CTM (Chlorpheniramine maleate) has a weak base titration. This means that in water, CTM can dissociate into positive ions (chlorpheniramine) and negative ions (maleate). This maleate ion has weak basic properties, so it can raise the pH of the solution. The solubility of CTM is that it easily dissolves in water, and when it dissolves, it dissociates into chlorpheniramine and maleate ions. This maleate ion, as mentioned previously, has weak basic properties and can increase the pH of the solution (Winandy, 2016).

Apart from the factors above, CTM capsules generally contain fillers such as lactose. Aqueous solutions of lactose usually have a pH between 6 and 7 depending on the lactose concentration and temperature of the solution. However, in the preparation the amount of lactose used as a filler is greater than the active ingredient CTM itself, so the lactose slightly influences the final pH to alkaline.

The disintegration time test is intended to indicate that the capsule preparation can disintegrate and dissolve shortly after being swallowed, so that the desired pharmacological effect can be obtained quickly. The disintegration time test was carried out using a disintegration time tester containing distilled water at a temperature of 37°C. The disintegration time of the capsule shell according to the standards of the Indonesian Pharmacopoeia, VI edition of 2020, is <30 minutes.

In the disintegration time test, it was discovered that Formulation 1 began to disintegrate within 1 minute 30 seconds until it was completely dissolved, taking 12 minutes 2 seconds. Formulation 2 starts to break down within 1 minute 40 seconds and until everything is dissolved with a duration of 12 minutes 2 seconds. The final formulation is the 3rd formulation which begins to break down within 2 minutes 5 seconds with the total duration until it is completely dissolved is 12 minutes 58 seconds. From the disintegration time that has been tested, it can be concluded that the preparation made has a disintegration time that is in accordance with the FI standard, namely less than 30 minutes.

The resulting difference in disintegration time can be caused by the levels of each ingredient contained in the formulation. (according to the scientific journal US National Library of Medicine National Institutes of Health, the disintegration time of capsules can also be influenced by the filler in the capsule formulation, this formulation uses different amounts of lactose F1 5.53 g, F2 5.41 g and F3 5.29 g Apart from that, Aerosil also affects the length of time it disintegrates because Aerosil is non-polar so it is difficult to dissolve in water. Aerosil is practically insoluble in water, organic solvents, acids (except fluoride acid). and forms a colloidal dispersion with water, and thus will inhibit the release of efficacious ingredients. Of the three formulas, there are differences in disintegration times which are influenced by the different concentrations of aerosil for each formula, namely at F1 5% F2 7% and F3 9% the most, the disintegration time is the longest.

Testing the water content of the capsule contents was carried out using a moisture balance tool. In this test the results obtained for F1 = 0.30%; F2 = 2.13%; F3 = 0.45%. The three formulas meet the requirements for good capsule powder water content, namely <10% (Dewi, 2021). This water content test is intended to observe the resistance of the capsule shell which can be damaged due to the presence of substances that melt easily (hygroscopic). This substance not only absorbs moisture from the air but will also absorb water from the capsule itself until it becomes brittle and breaks easily (Robert, 2018). After retesting the following day, F1 and F3 experienced an increase, namely 0.59% and 0.60% respectively. However, F2 experienced a decrease of 0.31%. Formula 1 has the lowest water content because the lactose

content in it is greater than the other two formulas. The addition of lactose (a neutral inert ingredient) will inhibit this process (Robert, 2018).

CONCLUSION

1. Organoleptic test, the capsule preparation has a white color obtained from the color of the active additives. has a characteristic CTM odor, and is in the form of a fine powder. after 24 hours storage there was no change (remained stable).
2. The pH in the city-M formulation does not match the CTM pH range, namely (4 and 5), so this preparation is less stable. Changes in pH are caused by environmental factors such as temperature, poor storage, the combination of medicinal ingredients used is less stable in the preparation because it is oxidized (Putra, 2014).
3. In the water content test, the results obtained for F1 = 0.30%; F2 = 2.13%; F3 = 0.45%. All three formulas meet the requirements for good capsule powder water content, namely <10%. Formula 1 has the lowest water content because the lactose content in it is greater than the other two formulas. The addition of lactose (a neutral inert ingredient) will inhibit this process (Robert, 2018).
4. Testing the disintegration time on our formulations resulted in formulation 1 starting to disintegrate within 01:03 until it was completely dissolved, taking 12:02. formulation 2 started to break down within 01:40 and until everything dissolved with a duration of 12:02. The 3rd formulation started to break down within 02:05 with the total duration until it was completely dissolved was 12:58. These three formulations are in accordance with the FI standard, namely less than 30 minutes.
5. Based on the results of the weight uniformity test, formulas one and three meet the requirements, while formula two does not meet the requirements because there are three capsules whose percent deviation exceeds column A and one capsule whose percent deviation exceeds column B. The average weight of each formula is different due to the concentration Aerosil is different for each formula and Aerosil's volume properties and Lactose weighing uses conventional scales so the weighing is less accurate.

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