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Formulation and Physical Evaluation of CTM Tablets by Direct Compression Method: A Systematic Literature Review

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A B S T R A C T

The direct compression method is one of the well-known formulation approaches in tablet manufacture. In this method, the active ingredients and additives of the formulation are mixed together and then compressed into tablets using a special device such as a compression machine. This study is a systematic review that aims to explore the formulation and physical evaluation of CTM tablets by direct compression method. The literature search process was carried out on various databases (PubMed, Web of Sciences, EMBASE, Cochrane Libraries, and Google Scholar) regarding the formulation and physical evaluation of CTM tablets by direct compression method. This study follows the preferred reporting items for systematic reviews and meta-analysis (PRISMA) recommendations. The direct compression method enables the manufacture of CTM tablets in a single production step, reducing the complexity and time required. The CTM tablet formulation process using the direct compression method involves homogeneous mixing of the raw materials and direct compression of the mixture into tablets using a compression machine. The direct compression method has advantages in production efficiency, simplicity, and cost-effectiveness, controlling the dosage of the drug contained in the tablet, and physical uniformity of the tablet. However, the direct compression method also has drawbacks, such as the risk of material segregation, difficulty in achieving controlled drug release, and the potential for direct effects on the active ingredients. Physical evaluation of tablets involves measuring the weight, thickness, and diameter of the tablets, as well as hardness or compressive strength tests to ensure the physical quality of the tablets produced. Drug release tests and dissolution tests were carried out to ensure that the CTM tablets released the drug consistently and under control according to regulatory requirements. Stability tests and chemical tests were carried out to check the physical and chemical changes of the tablets during storage and to ensure the integrity and purity of chlorpheniramine.

1. Introduction

Tablets are a popular pharmaceutical dosage form used to administer drug doses to patients orally. In tablet development, effective formulation, and accurate evaluation methods are very important to ensure the quality and consistency of the tablets produced. One of the most commonly used tablet manufacturing methods is the direct compression method. Tablet formulation includes the selection of the right raw material and optimization of the formulation ratio to achieve the desired physical and chemical characteristics. CTM tablets (chlorpheniramine maleate) are examples of tablets that will be discussed in this context. Chlorpheniramine maleate is an antihistamine used to treat allergy symptoms such as runny nose, sneezing, and itching.[1-4]

The direct compression method is one of the well-known formulation approaches in tablet manufacture. In this method, the active ingredients and additives of the formulation are mixed together and then compressed into tablets using a special device such as a compression machine. This method allows tablet manufacture in a single production step, reducing

process complexity and production time. Physical evaluation of tablets is very important to ensure that the tablets produced meet the established quality standards. Physical evaluation includes parameters such as tablet weight, hardness, thickness, friability, and tablet disintegration time. In the direct compression method, this evaluation is carried out to ensure that the tablet has the physical characteristics according to the desired specifications.[5-7] This study is a systematic review that aims to explore the formulation and physical evaluation of CTM tablets by direct compression method.

2. Methods

The literature search process was carried out on various databases (PubMed, Web of Sciences, EMBASE, Cochrane Libraries, and Google Scholar) regarding the formulation and physical evaluation of CTM tablets by direct compression method. The search was performed using the terms: (1) "formulation" OR "evaluation" OR "CTM tablets" OR "tablets" AND (2) "formulation". The literature is limited to preclinical studies and published in English. The literature selection criteria are articles published in the form of original articles, an experimental study about the formulation and physical evaluation of CTM tablets by direct compression method, the control group only received liquid without therapeutic effect or no treatment, studies were conducted in a timeframe from 2013-2023, and the main outcome was the formulation and physical evaluation of CTM tablets by direct compression method. Meanwhile, the exclusion criteria were studies that were not related to the formulation and physical evaluation of CTM tablets by direct compression method, the absence of a control group, and duplication of publications. This study follows the preferred reporting items for systematic reviews and meta-analysis (PRISMA) recommendations.

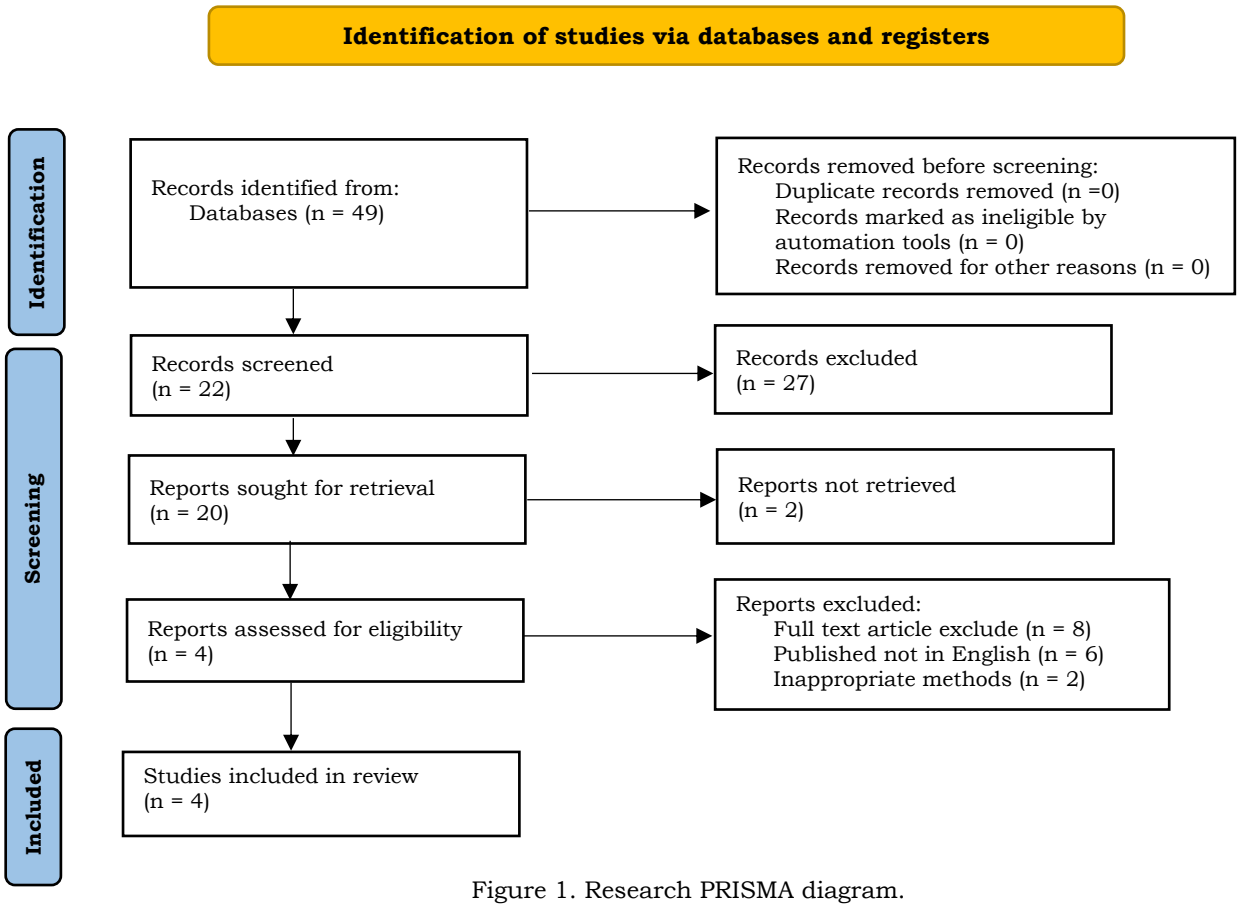

Figure 1. Research PRISMA diagram.

3. Results and Discussion

Direct compression method

A method of making tablets that involve the process of homogeneously mixing the raw materials, followed by direct compression of the mixture into tablets using a compression machine. This method has advantages in production efficiency, simplicity, and cost-effectiveness, controlling the dosage of the drug contained in the tablet and physical uniformity of the tablet. However, this method also has drawbacks, such as the risk of material segregation, the incompatibility of some raw materials, the difficulty in achieving controlled drug release, and the potential for direct effects on the active ingredients.[8,9]

The direct compression method enables the manufacture of CTM (chlorpheniramine) tablets in a single production step, reducing the complexity and time required. With this method, the mixing of raw materials and pressing of tablets is carried out simultaneously so that the production process becomes more efficient. In the direct compression method, the active ingredient chlorpheniramine and other supporting materials are mixed homogeneously. Then the mixture is compressed directly into tablets using a compression machine. This step solidifies the raw material mixture into a solid and firm tablet form. The main advantage of the direct compression method is the saving of time and effort required in the production process. In this method, steps such as granulation and drying, which are generally required in conventional tablet formulation methods, are avoided. This reduces process complexity and speeds up production time. In addition, the direct compression method also allows accurate control of the dose in each CTM tablet produced. By setting the right composition and pressure strength in the compression machine, the dosage of chlorpheniramine in each tablet can be consistent and well-controlled. [10-13]

Some of the drawbacks that may be associated with this method are the risk of substance segregation, the difficulty in achieving controlled drug release, and the potential for direct effects on the active ingredients. During the process of mixing raw materials, there is a risk of segregation, namely separation or uneven movement between the particles of ingredients in the mixture. This can lead to non-uniformity in the composition of the tablets, both in terms of the dosage of the active ingredients and other physical properties. In the direct compression method, the tablet formulation usually has a high degree of hardness to ensure the toughness and stability of the tablet. This can make it difficult to achieve controlled drug release, especially if the drug requires gradual or specific release in the digestive system. During the direct compression process, the pressure exerted on the raw material mixture can affect the stability of the active material, especially if the active material is sensitive to pressure or heat. The potential direct effect of these active ingredients needs to be evaluated and well understood to ensure the quality and stability of the drug in CTM tablets.[14-16]

CTM tablet formulation process with a direct compression method

The process of making CTM tablets by direct compression method includes the process of selecting the active ingredient chlorpheniramine as the main antihistamine agent. In addition, select supporting materials such as binders, fillers, lubricants, and other additives suitable for CTM tablet formulations. Determination of the correct dosage composition for chlorpheniramine in CTM tablets, for example, 4 mg per tablet. Based on these doses, determine the percentage of active ingredients and supporting ingredients needed to achieve the desired formulation composition. Homogeneous mixing of chlorpheniramine raw materials and other supporting materials in the specified amount. Ensure even mixing to distribute the ingredients uniformly. Use suitable mixing equipment to achieve optimal results. Perform pre-formulation evaluations to check flow properties of raw material mixtures, measurement of powder density, and physical and chemical compatibility between ingredients used.[17]

Use a compression machine to compress the raw material mixture into tablets. Prepare tablet molds according to the desired size and shape. Fill the mold with the raw material mixture, then press using pressure according to the desired CTM tablet specifications, ensuring that each tablet contains the correct dose of chlorpheniramine. After the tablets are formed, do a physical evaluation to ensure the quality of the CTM tablets. Measure tablet weight and thickness individually or collectively. Use a hardness tester to test the mechanical strength of the tablets. If necessary, perform dissolution tests to test controlled drug release. If the CTM tablet formulation requires additional protective or coating coatings, this step involves applying the coating using a suitable coating technique. After the physical evaluation is complete, standard-compliant CTM tablets can be packaged in a suitable container, such as a blister or bottle, with proper labeling and instructions for use.[18]

The evaluation process for making CTM tablets using the direct compression method

The evaluation process for the manufacture of CTM (chlorpheniramine) tablets using the direct compression method involves a series of steps to ensure the quality, uniformity, and suitability of the tablets produced. Tablet physical evaluation was carried out on the CTM tablets produced. This physical evaluation includes measuring tablet weights individually or collectively to ensure consistent dosing. Measure the thickness and diameter of the tablets to ensure uniformity of size. Also, check the integrity and mechanical strength of the tablets using a hardness or compressive strength test. A drug release test was carried out to ensure that the CTM tablets released chlorpheniramine consistently and under control. Drug release test methods can be adapted to regulatory requirements and drug characteristics. Testing can be carried out using the basketball or paddle method in the appropriate body fluid simulation medium.[19]

The dissolution test was performed to evaluate the release rate of chlorpheniramine from CTM tablets. The dissolution test involves placing the tablet in a dissolution medium maintained at a specified temperature and agitation rate. Dissolution samples were taken at specified time intervals, and the level of dissolved chlorpheniramine was measured to evaluate the drug release profile. Tablet stability was performed on CTM tablets to examine the physical and chemical changes that occurred during storage under specified conditions. This is important to ensure that the tablets remain stable and do not experience significant degradation during their shelf life. Chemical tests were carried out to check the integrity and purity of chlorpheniramine in CTM tablets. This test involves the use of analytical methods such as high-performance liquid chromatography (HPLC) or spectroscopy to measure the concentration of chlorpheniramine and detect the presence of contaminants or drug degradation.[20]

4. Conclusion

The direct compression method enables the manufacture of CTM tablets in a single production step, reducing the complexity and time required. The CTM tablet formulation process using the direct compression method involves homogeneous mixing of the raw materials and direct compression of the mixture into tablets using a compression machine. The direct compression method has advantages in production efficiency, simplicity, and cost-effectiveness, controlling the dosage of the drug contained in the tablet, and physical uniformity of the tablet. However, the direct compression method also has drawbacks, such as the risk of material segregation, difficulty in achieving controlled drug release, and the potential for direct effects on the active ingredients. Physical evaluation of tablets involves measuring the weight, thickness, and diameter of the tablets, as well as hardness or compressive strength tests to ensure the physical quality of the tablets produced. Drug release tests and dissolution tests were carried out to ensure that the CTM tablets released the drug consistently and under control according to regulatory requirements. Stability

tests and chemical tests were carried out to check the physical and chemical changes of the tablets during storage and to ensure the integrity and purity of chlorpheniramine.

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