Journal of Wasit for Science and Medicine 2024: 17, (4), 20-28

Prednomel Preparation Utilizing Novel Method

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Abstract

The World Anti-Doping Agency (WADA) lists Prednisolone as an anti-inflammatory steroidal medication that belongs to the glucocorticoid class. Due to their strong immunosuppressive and anti-inflammatory qualities, glucocorticoids (GC) are frequently used to treat acute multiple sclerosis (MS) relapses. According to pharmacopeia, every tablet passed the weight variation and hardness, thickness, friability, disintegration, and dissolution tests. This research aims to create quality control parameter prediction models. The following characteristics were evaluated: assay, dissolution, hardness, thickness, friability, and disintegration.

Keywords: Prednisolone, Glucocorticoids, pharmaceutical, Modification.

1. Introduction

Based on strong immunosuppressive and anti-inflammatory qualities, glucocorticoids (GC) are frequently used in therapy to treat acute relapses of multiple sclerosis (MS) [1]. A synthetic corticosteroid, prednisone, treats several medical conditions [2, 3]. Prednisolone is a significant ingredient in pharmaceutical formulations [2-4]. The medication cures several illnesses, such as blood disorders, skin conditions, allergies, infections, inflammation, and cancer [3]. One glucocorticoid easily absorbed from the gastrointestinal tract is prednisolone, an active metabolite of prednisone and a derivative of cortisol [4]. Comparing prednisolone and prednisone to their structurally equivalent endogenous glucocorticoids, cortisol, and cortisone, they have more extended pharmacological activity and greater anti-inflammatory effectiveness [5]. Prednisolone is only available as tablets and a liquid that may be swallowed with a prescription. Prescription mistakes are common with high-risk medications like prednisolone pills, which come in a wide range of permitted dosages [6]. Tablets have benefits, including their ease of manufacturing, physicochemical stability, and affordable cost for patients, making them one of the most popular and advantageous

dosage forms [7]. The functionality and manufacturing feasibility of tablet formulations have been improved by new raw materials. These include altering already existing excipients with better purity or physical characteristics (such particle size) and co-processing with other materials to improve their effectiveness in manufacturing processes. Furthermore, the development and use of multifunctional materials might result in significant cost gains due to the possibility for lean production [7].

2. Materials and Methods

General procedure for producing the 5 formulas (F1, F2, F3, F4, and F5) product name: prodromal 20 mg premix: A total of 400 g of prednisolone, 2000 g of lactose monohydrate, 180 g of croscarmellose, 40 g of aerosol, and 80 g of PVP k30 were sieved separately through a 0.25 mm screen (sieve) and mixed for 15 min in a rapid mixer granulator. Then, a prep mixture of the binding solution containing 120 g of PVP and 500 g of distilled water was added. Subsequently, the blend was mixed in the mixer granulator for another 10 minutes at slow speed with a cut-off of 1-2 minutes and continued mixing at slow speed, respectively. The load was then transferred to the fluid bed dryer for drying and granulating at 35 °C from 60 to 75 minutes with frequent fluxing every 20 minutes. Then, the tablets were produced using a tableting machine and sieved through a 0.25 mm screen. Finally, the sieved tables were mixed with the pre-sieved compounds of 80 g Talc, 80 g magnesium stearate, 140 g croscarmellose, 40 g aerosol, and 480 g maize starch in the double cone blender.

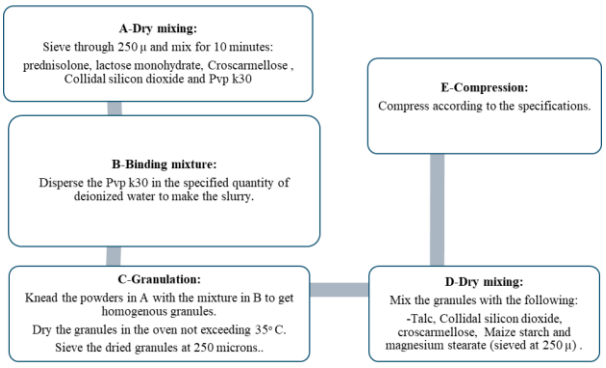
2.1 Friability test

After weighing all 20 pills and place them in the friability tester. After determining the starting weight (W1) of 20 randomly chosen tablets from each brand, they were placed in a friability tester (Type TA, Erweka, Germany) set to 25 rpm for four minutes. The pills were then weighed and powdered (W2). Using the formula $F = [(W1 – W2) / (W1 \times W2)] \times 100$, the percentage friability (F) was determined. Moreover, It must be less than or equal to 1 % for friability (loss percentage). Friability (%) = W1 – W2/ W1 × 100. Where, W1 = Weight of Tablets (Initial / Before tumbling). W2 = Weight of Tablets (After Tumbling or friability). Limit: Friability (%) = Not More Than 1.0 %.

2.2 Hardness test, and disintegration test

Make a hardness tester (D-6072, Erweka) 10 tablets using the hardness meter and then take the average hardness. On the

other hand, for the disintegration test each of the six tubes was filled with one dose unit and add a disc if required. Unless otherwise noted, run the device with water as the immersion fluid and keep the temperature between 35 and 39 °C. After the allotted time, remove the basket from the fluid and check the dose units; they are all fully decomposed.



Scheme 1: Friability test, Hardness test, and disintegration test.

3. Results and Discussion

The composition and pharmaceutical procedures to formulate an API determine its ability to achieve the desired optimal drug delivery system. Such a system would be like a car or airplane, delivering the medication to the right place in the body [8].

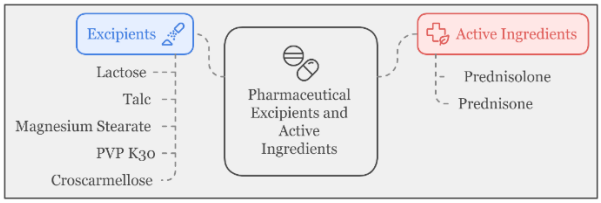
Table 1: shows the structures of the ingredients.

Materials	Quantities
Prednisolone	400 gm
Lactose	2480gm
Croscarmellose	160 gm
Aerosol	40 gm
Polyvinylpyrrolidone (PVP k30)	120 gm
Distilled water	21 L
Talc	80 gm
Magnesium stearate	80 gm

The previous table provides an overview of key pharmaceutical ingredients and excipients commonly used in the formulation of medications, mainly focusing on prednisolone. Understanding these components is essential for developing effective pharmaceutical products to treat various conditions, including inflammation and autoimmune disorders. Prednisolone is the active pharmaceutical ingredient (API) [7]. Synthesized glucocorticoids like prednisolone and prednisone are often used to treat autoimmune diseases and inflammation in humans and animals [8, 9]. In some liquid or chewable medication, lactose can be used as a sweetener to improve the taste. Lactose is the primary carbohydrate in milk is lactose, which has an anhydrous basis concentration of about 4.6 % [8,10].

The pharmaceutical business uses lactose as an excipient. Present in 60 to 70 % registered oral solid dosage formulations. It is one of the most widely used excipients [11]. Furthermore, oral solid dose formulations, such as pills and inhalation, are where lactose is most used for pharmaceutical purposes [12]. Lactose is typically added to tablet formulation to improve wettability and weak flow ability due to its water solubility and acceptable flow ability [11].

A soft, inert mineral, talc has a high potential to absorb organic matter and water [13]. Rubber, medicines, and agricultural goods are just a few of the many items that employ it [13, 14]. However, it is commonly used as a dissolution retardant in developing controlled-release products. Talc is also used as a lubricant in tablet formulations and as a powder coating for extended-release medications, although it should not be used to dust surgical gloves. In addition to being used in food and cosmetics for its lubricating qualities, talc is also used to clear liquids. Talc is used as a dusting powder in topical treatment concentrations between 0.25 % and 5.0 % w/w, and magnesium stearate is primarily used as a lubricant in manufacturing capsules and tablets. According to that, the current findings were consistent with earlier research [15]. Polyvinylpyrrolidone K30, or PVP K30, is appropriate for making tablets with high solubility. This medication can be used topically orally as a solubility enhancer in polar liquids. The findings were consistent with earlier research [16, 17]. Croscarmellose is a pharmaceutical excipient commonly used to formulate tablets and capsules [18]. This type of cellulose has undergone chemical Modification to enhance its breakdown and solubility. Croscarmellose facilitates the release of active tablet components by ensuring they break down appropriately in the digestive system [19].



Scheme 2: Pharmaceutical excipients and active ingredients.

Table 2: The test of competency tablets prednisolone.

Quality tests for formula							
Hardness test (N)		Thickness (mm)		Friability test		Disintegration test	
left	Right	Left	Right	Left	Right	Left	Right
70	68	2.5	2.6	Wt1 = 2.0616 Wt2 = 2.0576	Wt 1 = 2.1232 Wt 2 = 2.1177	1 tab 11 min 4 tab 12 min	1 tab 11 min 4 tab 12 min
59	68	2.45	2.54	= 0.19 %	= 0.25 %		
77	61	2.5	2.6				
60	70	2.5	2.53				
64.5	75	2.46	2.5				

Table 1, and table 2 show data on the quality testing and manufacturing of prednisolone tablets. According to pharmacopeia, every tablet passed the weight fluctuation, hardness, thickness, friability, disintegration, and dissolution tests. The table shows the hardness test results (in Newton) for discs tested on both sides (left and right): the measured stiffness was 70 N on the left and 68 N on the right. This test is used to determine the hardness of tablets. As part of the hardness test, a tablet is subjected to a direct compressional force until it fractures [20]. The results demonstrate how resilient the typical tablets are to shocks during handling and transportation without breaking. A tablet is subjected to a direct compressional force until it fractures as part of the hardness test. This alters its density and porosity, which in turn alters its solubility, friability, and disintegration, all of which have an impact on bioavailability [20]. Tablets required to be sufficiently stable to endure the physical abuse they endure. Soft tablets might not survive handling, while hard tablets might not dissolve in the allotted amount of time.

The friability test is an additional mechanical attribute of a tablet with a compendia standard of no more than 1 % [21]. While friability is a surface deformation that the tablet's shape might exacerbate, the hardness test is a bulk deformation of the tablet [22]. Table 2 shows that the right is 0.25 percent, and the left is 0.19 percent. The current results align with the previous studies [21]. Oral tablets and immediate-release dose forms employ disintegration, the initial step of dissolving, as a control [23]. The disintegration test calculates how long it takes a tablet or capsule to break up into pieces or granules small enough to fit through the disintegration. The rate of dissolution and the rate of disintegration are directly correlated [4]. Table 2 shows the disintegration test in 11 min, which indicates that the table is excellent [24].

This result illustrates the production process of prednisolone tablets, showing

each major step in a circular flow. First, the drug, polymer excipient-feeder system: This is the first step, where active pharmaceutical ingredients (APIs) like prednisolone and polymer excipients are introduced into the feeder system for initial processing. The second step includes the rapid mixer granulator. Where the feeder material is transferred to the rapid mixer granulator, and ingredients are mixed thoroughly to form a homogeneous mixture, preparing it for the next steps in the tablet formulation. The third step involves the fluidized bed dryer process where the mixed ingredients are dried using a fluidized bed dryer, which reduces the moisture content and ensures a suitable powder texture for further processing. The fourth step includes the size reduction equipment: After drying, the mixture undergoes size reduction, where large particles are broken down to a finer, more uniform size, optimizing the powder for tablet compression. The fifth step include mixing the fine particles to ensure homogeneity, creating a consistent blend yielding uniform tablets. Finally, the sixth step include the compression of homogeneously mixed powder into tablets using the tablet punching machine to forming the final prednisolone tablet.

4. Conclusion

Pharmaceutical sector manufacturers create various life-saving health items, yet subpar pharmaceuticals may result in therapy. Quality drug products maximize therapeutic efficacy, which may increase customer satisfaction and market demand. The present study found no problems with hardness test, friability, and disintegration time.

5. Acknowledgments

We acknowledge the support of the Alsharq Alawast pharmaceutical labs. Also, the funding and support from Wasit University. The Ministry of Higher Education and Scientific Research in Iraq, and finally Damu Scientific Bureau.

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