

FORMULATION AND EVALUATION OF DUSTING POWDER BY USING CLOTRIMAZOLE

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ABSTRACT

The objective of this study is to prepare and evaluate clotrimazole dusting powder for its physical characteristics and anti-fungal efficacy. Clotrimazole dusting powder is prepared using clotrimazole, talc, and Salicylic acid, Benzoic acid and menthol. In the present study dusting powder was formulated. The dusting powder is prepared by mixing all the ingredients in an ascending order (Geometric mixing) in mortar pestle for uniform mixing of all ingredients. The prepared dusting powder is then evaluated for various parameters such as colour, odour, appearance (physical characteristics), particle size, bulk density, tapped density and flowability. The results showed that the prepared clotrimazole dusting powder has uniform particle size, good flowability, and suitable bulk density. The powder exhibited significant antimicrobial activity against microorganisms. This study demonstrates the potential of clotrimazole dusting powders as a topical formulation for the treatment of fungal infections is sufficed.

KEYWORDS: Clotrimazole, Dusting powder, Antimicrobial activity, bulk density, tapped density.

INTRODUCTION

Powders: A powder is a homogeneous mixture of more or less finely divided particulate material in dry form. Powders are one of the oldest dosage forms and are used both internally and externally.^[1]

Dusting powder

Definition: Dusting is a type of topical pharmaceutical preparation which is used on the skin or on wounds especially for allaying irritation or absorbing moisture is called as Dusting powder.

Dusting powders are finely divided powders that contain one or more active ingredients with or without auxiliary substances including, where necessary, authorised colouring matter. They are free from grittiness. Dusting powders are intended to be applied to the skin for therapeutic, prophylactic or lubricant purposes. They are presented as single dose or multidose preparations.

Dusting powders are usually mixtures of two or more substances in fine powder, intended for external application on to the skin (wounds, burns, surgical incision). Powder bases absorb secretions and exert a drying effect, which relieves congestion and imparts a cooling sensation. Starch and talc are used as inert bases for dusting powders. These are dispensed in sifter- top packages. They have particle size about 0.1 micrometer to 10 micrometers.

Dusting powders are used to prevent and treat minor skin infections caused by small cuts, scrapes, or burns. Some skin infections can also be treated by using dusting powders such as athlete's foot, jock itch and ringworm. It also relieves burning, itching, cracking of the skin and discomfort caused by these infections.^[2]

Types of dusting powders

There are 2 types of dusting powder:

1. Medical dusting powder
 2. Surgical dusting powder
- 1) **Medical-** For superficial skin conditions, medical powders are used. They must be free from pathogens. Some mineral ingredients may contain spores of tetanus, gas gangrene etc. and so they must be sterilized properly. They are not used for open wounds or area of broken skin which is mentioned in the label also.
- 2) **Surgical** -Surgical dusting powders are used in body cavities and major wounds, on burns and on umbilical cords of infants also. They are sterile powders.^[3]

PROPERTIES

- It should be homogeneous.
- It should not cause local irritation.
- It should flow easily and spread uniformly.
- It should cling to the skin on application.
- It should have adsorptive and absorptive capacity.^[4]

Advantages

- Good chemical stability compared with fluids.
- Easy to carry than the liquid dosage forms.
- Suitable for small children and elderly patients.
- Easy to apply over wounds
- Economical
- Rapid onset of action.

Disadvantages

- Difficult to protect powders containing hygroscopic or aromatic materials from decomposition.
- Risk of overuse.

- It can be challenging to achieve uniform coverage of affected area with dusting powder.
- Not suitable for drugs which are unstable in normal atmospheric condition.
- Susceptible to physical instability.^[5]

MATERIALS AND METHODS

- Grinding
- Weighing
- Mixing
- Wrapping

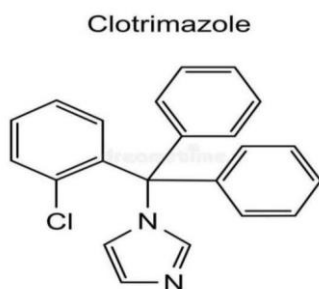
Formula

Table 1: Formulation of Clotrimazole dusting powder.^[6]

S. no.	Ingredients	Quantity (g)
1.	Clotrimazole	1.00 g
2.	Talc	58.20 g
3.	Salicylic acid	3.00 g
4.	Benzoic acid	6.00 g
5.	Menthol	0.08g
6.	Starch	31.00 g

INGREDIENTS

- 1. Clotrimazole:** It is an antifungal agent commonly used in dusting powders due to its effectiveness in treating various fungal skin infections. Clotrimazole is primarily used to treat fungal infections such as athlete's foot, ringworm, jock itch, and other dermatophyte infections. It works by inhibiting the growth of fungi, disrupting their cell membrane, and preventing the spread of infection. Dusting powders containing clotrimazole are effective for preventing and treating fungal infections, especially in areas of the body prone to sweating, such as the feet, groin, and underarms. These areas are more susceptible to fungal growth due to moisture accumulation.^[7]



Molecular Formula: C₂₂H₁₇ClN₂

Clotrimazole is 1-(2-chlorophenyl)imidazole.

Molecular Weight: 344.84.

Category: Antifungal

Description: White or pale yellow, crystalline powder.

Solubility: Freely soluble in acetone, in chloroform, in ethanol (95%) and in methanol, practically insoluble in water.

Storage: Store in tightly-closed, light-resistant containers.

2. **Talc:** It is clay mineral composed of hydrated magnesium silicate. Talc in powdered form, often in combination with corn starch, is widely used substance known as dusting powder. This mineral is used as a thickening agent and lubricant. It is also used for the adsorbent action.^[8]
3. **Salicylic acid:** It is commonly included in dusting powders for dermatitis. Salicylic acid helps reduce inflammation and irritation, making it beneficial in managing skin conditions like psoriasis, eczema, or other forms of dermatitis. It can help alleviate redness and swelling, improving the overall appearance and comfort of the skin. Salicylic acid has mild antiseptic properties, which can help prevent bacterial infections that might arise from scratching or skin irritation.^[9]
4. **Benzoic acid:** Benzoic acid has antimicrobial properties that help prevent bacterial growth, making it useful in preventing infections, especially in skin conditions where dusting powders are applied to absorb moisture and reduce friction. Benzoic acid acts as a preservative, extending the shelf life of dusting powders by inhibiting microbial growth and degradation of the powder's components.^[10]
5. **Menthol:** Menthol produces a cooling sensation on the skin by triggering the cold receptors in the skin, which can help soothe skin irritation, minor rashes, or itching. This cooling effect can provide immediate relief in conditions like diaper rash, heat rashes, or after shaving.^[11]
6. **Starch:** It is used as adsorbent in the formulation. It is insoluble residue which remains after a granular starch is partially solubilized by an enzyme. This is used as the base for dusting powder either alone or in combination with other ingredients like talc.^[8]

Procedure

- ❖ **Weighing:** Accurately weigh the required amount of clotrimazole and excipients (such as above mentioned in Table 1).
- ❖ **Mixing:** Thoroughly mix the clotrimazole with the excipients. This step should be done to ensure that the clotrimazole is evenly distributed throughout the powder, ensuring consistent dosing when the powder is applied.
- ❖ **Sieving:** Pass this powder through the sieve 120# to remove any large particles and to ensure the powder is uniformly fine and free-flowing. Sieving process as shown below in figure-1.



Figure 1: Sieving of Ingredients.

- ❖ **Final Mixing:** After sieving, mix the powder once more to ensure a homogeneous product. The final mixture should have a smooth texture, free of lumps, and should flow easily when applied.^[12]

Evaluation of dusting powder

Evaluation of formulation was carried out as follows:

- **Physical characteristics:** The color, odor and appearance of the powder is evaluated by simple visualization.
- **pH:** pH is a measure of the acidic or basic nature of the formulation. The pH of dusting powder is determined to avoid the irritation to the skin.
- **Particle size:** The particle size of prepared powder was determined by using microscope and sieve analysis.^[8]
- **Bulk density (BD) and tapped density (TD):** The powder was passed through a no. 18 sieve into a pre-weighed 25 ml graduated cylinder with 0.5ml markings. The bulk volume was measured after manually tapping the cylinder two times on a flat table top surface. The tapped volume was measured with the tap density tester after tapping in increments of 500, 750, and 1250 taps with 250 drops per minute.

$$\text{Bulk density} = \text{Bulk mass} / \text{Bulk volume}$$

$$\text{Tapped density} = \text{Mass of granules} / \text{volume of granules}$$

- **Angle of repose:** The flow properties of powders can be studied by measuring angle of repose. It was determined by the funnel method. The funnel was fixed in place, 4cm above the bench surface. After the cone from 5g of sample was built, height of the granules forming the cone (h) and the radius(r) of the base were measured as shown below in figure-2. The angle of repose was calculated as follows:

$$\text{Angle of repose} = \tan^{-1}(h/r)$$

Where,

h= height of the powder cone

r= radius of the powder cone

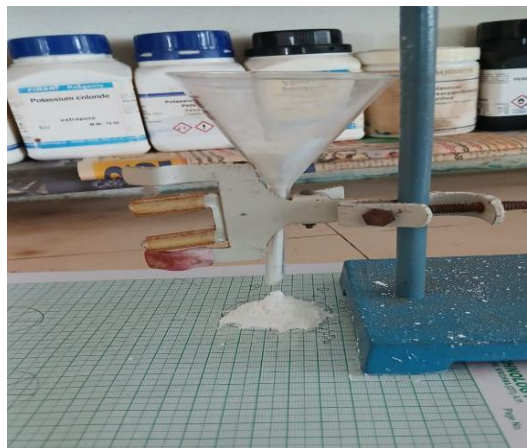


Figure-2: Angle of Repose.

- **Carr's index:** The bulk and tapped densities were used to calculate Carr's compressibility index to provide measure of the flow properties and compressibility of powders.

$$\text{Carr's index} = \frac{\text{Tap density} - \text{bulk density}}{\text{tap density}} * 100$$

- **Hausner ratio:** It is indicative of flow properties. It is derived property from bulk and tapped density. Lower the Hausner ratio is indicating better flow whereas higher ratio indicates poor flow of granules. Hausner ratio is calculated by the following formula:

$$\text{Hausner ratio} = \frac{\text{Tap density}}{\text{Bulk density}}$$

- **Moisture content:** Percentage of moisture content is calculated by using formula:

$$\% \text{ Moisture} = \frac{\text{Initial weight} - \text{final weight}}{\text{initial weight}} \times 100.^{[8]}$$

ASSAY

Redox Titration Assay Procedure^[13]

1. Sample preparation: Accurately weigh a quantity of Clotrimazole dusting powder equivalent to about 100 mg of Clotrimazole.
2. Extraction: Extract the Clotrimazole from the powder using 50 mL of acetone.
3. Titration: Transfer the extract to a 100 mL titration flask and add 2-3 drops of starch indicator.
4. Titration with potassium bromate: Titrate the solution with 0.1 M potassium bromate until the indicator changes colour.
5. Endpoint: The endpoint is determined by the colour change of the indicator.

- Calculate the percentage of Clotrimazole in the dusting powder using the following formula:

Percentage of Clotrimazole = (Volume of titrant × Molarity of titrant × Equivalent weight of Clotrimazole) / Weight of sample.

ANTIMICROBIAL ACTIVITY

Preparation of Agar Plate

1. Prepare Sabouraud dextrose agar (SDA) or any other suitable fungal growth medium.
2. Sterilize the medium by autoclaving at 121 °C for 15-20 minutes.
3. Cool the medium to around 45-50 °C.
4. Pour the medium into sterile petri dishes to a depth of about 4-5 mm.
6. Allow the medium to solidify.

Application of Clotrimazole Dusting Powder

1. Prepare a suspension of clotrimazole dusting powder in sterile distilled water (e.g., 1-2 % w/v).
2. Use a sterile pipette or spreader to apply 1-2 mL of the suspension onto the agar plate.
3. Spread the suspension evenly over the surface of the agar plate using a sterile spreader or glass rod.
4. Use a sterile loop or swab to create 3-4 wells or depressions in the agar plate.
5. Fill each well with 10-20 µL of the clotrimazole dusting powder suspension.

Inoculation and Incubation

1. Inoculate the agar plate with a fungal suspension (e.g., *Candida albicans*) using a sterile swab or spreader.
2. Incubate the agar plate at 25 °C ± 2 °C for 24-48 h.
3. Observe the agar plate for growth inhibition zones around the wells or depressions containing the clotrimazole dusting powder suspension.

Evaluation

1. Measure the diameter of the growth inhibition zones.
2. Calculate the percentage of fungal growth inhibition.
3. Compare the results with a positive control (e.g., fluconazole) and a negative control (e.g., sterile distilled water).

RESULTS AND DISCUSSION

Table 2: Results Interpretation for clotrimazole dusting powder.

PARAMETERS	OBSERVATION
Colour	White
Odour	Characteristics
Appearance	Smooth
pH	5
Particle size	0.125 mm
Bulk density	0.31 g/cm ³
Tapped density	0.35 g/cm ³
Angle of repose	21 ⁰
Carr's index	17 %
Hausner ratio	1.20
Moisture content	3.09 % w/w
Percentage of clotrimazole	90 %

- Physical characteristics-** The physical characteristics of the powder was evaluated. The color of powder was white with characteristics odour and smooth appearance.
- pH of the formulation-** The pH of dusting powder was determined by digital pH meter. 1gm of powder was dissolved in 100 ml of distilled water and the pH was measured. The pH was found to be acidic.
- Particle size-** The particle size of the powder was found in the range was found to be 0.125 mm.
- Bulk density-**The bulk density of the powder was found to be 0.31 g/cm³.
- Tap density -** The Tap density of the powder was found to be 0.35 g/cm³.
- Angle of repose -** The Angle of repose of the powder was found to be 21⁰.
- Carr's index-** The Carr's index of the powder was found to be 17 %.
- Hausner index-** The Hausner ratio of the powder was found to be 1.20.
- Moisture content-** The Moisture content was found to be 3.09 % w/w.
- Redox Titration Assay Procedure:**

Table 3: Redox Titration calculation.

Trial No	Contents in flask	Burette Reading		Final Burette Reading	Indicator
		Initial	Final		
1.	1 g of powder sample + 50 ml of acetone+ 2 drop of starch indicator	0 ml	28 ml	28 ml	Starch
2.		28 ml	54 ml	26 ml	
3.		0 ml	25 ml	25 ml	

Average of volume of burette reading = $28 + 26 + 25 / 3 = 26.3$ ml

Calculate the percentage of Clotrimazole in the dusting powder using the following formula:

Percentage of Clotrimazole = (Volume of titrant × Molarity of titrant × Equivalent weight of Clotrimazole) / Weight of sample.

Percentage of Clotrimazole = $26.3 \times 0.1 \times 0.034484 / 1$ g

= $0.0906 / 1 = 0.09$ g

= 9 mg

Percentage of Clotrimazole present in the prepared formula

= $9/10 \times 100 = 90\%$

CONCLUSION

It was concluded that clotrimazole dusting powder is an effective anti-fungal treatment that offers a reliable solution for various dermatological conditions. Its broad-spectrum activity against fungal infections. Clotrimazole dusting powder is a valuable option in the therapeutic arsenal for treating superficial fungal infections, promoting skin health, and improving patient's quality of life. Clotrimazole dusting powder was successfully prepared with ingredients viz., Talc, Starch, Salicylic acid, Benzoic acid and Menthol. The prepared powder was evaluated for its physical characteristics like (colour, odour, Appearance), particle size (0.125 mm), bulk density (0.31 g/cm³), flowability and antimicrobial test (sample collected from garden soil). The results showed that the powder had a uniform particle size (0.215 mm), good flow ability, suitable bulk density (0.31 g/cm³) and good antimicrobial activity. The percentage of clotrimazole present in the prepared dusting powder is estimated to be 90%. The prepared dusting powder lies within the acceptance range of given in Indian Pharmacopoeia.

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