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Guardians of Purity: In-Process Quality Control in Herbal and Synthetic Antifungal Medicines

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Abstract

Fungal infections are a major global health concern, ranging from superficial to systemic conditions, and are especially common in immunocompromised patients. Synthetic drugs, particularly those of the azole class, are widely used but frequently cause adverse effects and face growing resistance issues. In contrast, herbal drugs are gaining attention for their comparable or potential efficacy against fungal pathogens and are valued for their more favourable safety profile. This study aimed to evaluate and compare the in-process quality control parameters of marketed herbal and synthetic formulations used in the management of fungal infections. Tablets, creams, soaps, and powders were procured from the local market. The synthetic formulations included Fluconazole tablets, Canesten creams, Ketostar soap, and Canesten powder. The herbal formulations included Arkaneem tablets, Trichoderm creams, Neo Neem soap, and Neem powder. Quality assessments were conducted in accordance with the Indian Pharmacopoeia and standard guidelines. The study assessed the following parameters: weight variation, hardness, friability, disintegration, viscosity, pH, foam stability, bulk density, tapped density, angle of repose, and moisture content. Results indicated that both tablet types complied with pharmacopeial limits for weight variation, hardness, and friability; however, the herbal tablets exhibited a prolonged disintegration time compared to the synthetic tablets. Both creams displayed acceptable viscosity and pH values within skin-friendly ranges. Herbal soap produced a more stable foam than its synthetic counterpart, while the herbal powder demonstrated superior flow properties but a higher moisture content. Overall, herbal formulations showed satisfactory quality control characteristics, suggesting they may be safer and more patient-friendly alternatives. However, optimization is required for the disintegration time and moisture content. Further pharmacological and clinical evaluations are recommended to validate therapeutic efficacy.

Keywords

Fungal infections, Herbal formulations, Synthetic formulations, Quality control, Antifungal agents

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1. INTRODUCTION:

Fungal diseases, commonly referred to as mycoses, are a significant public health concern. They result from various fungi, including yeasts and Molds, and can affect the skin, nails, respiratory tract, and other body systems. Globally, fungal infections contribute to high mortality rates, and their incidence is rapidly increasing, causing more than 1.5 million deaths annually. These infections pose the greatest burden among immunocompromised patients, including

individuals with HIV/AIDS, cancer, those who have undergone organ transplants, and patients receiving intensive care. Fungal infections typically occur through direct contact with an infected person or animal, contaminated objects such as clothing and hairbrushes, or exposure to moist environments.[1-2]

Current treatment options include azoles (e.g., itraconazole, fluconazole, voriconazole) and polyenes (e.g., amphotericin B, nystatin), which are effective against a broad spectrum of fungal infections. The widespread use of these agents has led to an increase in antifungal resistance. In addition, synthetic antifungal drugs are associated with adverse effects such as gastrointestinal disturbances (abdominal pain, nausea, diarrhea) and dermatological reactions. [3-5]

To overcome these limitations, herbal antifungal drugs are being explored as alternatives due to their lower risk of side effects and potential to combat resistant strains. Herbal antifungal agents, such as oregano oil (rich in carvacrol and thymol), turmeric (Curcuma longa, containing curcumin and ar-turmerone), and caprylic acid, have demonstrated strong antifungal activity, even against Candida species, including resistant strains. These natural products may also reduce drug resistance and lower the required dosage.[4-11]

Ensuring product quality during manufacturing is essential for therapeutic efficacy, safety, and patient compliance. In-process quality control (IPQC) tests- including weight variation, hardness, thickness, friability, disintegration, viscosity, pH, foam stability, bulk density, tapped density, moisture content, and angle of repose- provide critical insights into the quality and performance of pharmaceutical formulations.[12-15]

The present study evaluates the IPQC parameters of both synthetic (Fluconazole tablets, Canesten cream, Ketostar soap, and Canesten powder) and herbal (Arkaneem tablets, Trichoderm cream, Neo Neem soap, and Neem powder) formulations used in the treatment of fungal infections. The aim is to identify and compare the quality attributes of these formulations across different dosage forms (tablets, creams, powders, and soaps) and highlight the potential advantages of herbal formulations over synthetic ones. [16-18]

2. MATERIALS AND METHODS:

2.1 Materials:

Eight marketed pharmaceutical products were selected for evaluation of in-process quality control (IPQC) parameters. The formulations, which included both synthetic and herbal products, were procured from local pharmacies in Hanamkonda, Telangana, India. Products from the same batch were used for each dosage form to ensure consistency. The selected formulations are listed below:

1. **Tablets:** Fluconazole (synthetic), Arkaneem (herbal)
2. **Creams:** Canesten (synthetic), Trichoderm (herbal)
3. **Soaps:** Ketostar (synthetic), Neo Neem (herbal)
4. **Powders:** Canesten (synthetic), Neem (herbal)

All chemicals and reagents used in the study complied with analytical grade standards.

2.2 Quality Control Evaluation:[19]

All tests were performed in accordance with the Indian Pharmacopoeia (IP, 2020) and standard guidelines.

- **Tablets:**
  - Weight variation: Twenty tablets were weighed individually on a calibrated electronic balance, and the mean ± SD was calculated.
  - Hardness: Hardness was evaluated using a Monsanto hardness tester.
  - Thickness: measured with a vernier caliper.
  - Friability: Twenty tablets were tested in a Roche friabilator at 25 rpm for 4 minutes.
  - Disintegration: Six tablets were tested in distilled water at 37 ± 2 ºC using a USP disintegration apparatus.
- **Creams:**
  - Viscosity: Determined using a Brookfield viscometer with spindle no. 64 at 25 ± 1 ºC.
  - pH: Measured at 25 ºC using a calibrated digital pH meter.
  - Visual appearance: assessed for color, homogeneity, and consistency.
- **Soaps:**
  - Foam stability: Evaluated by the cylinder shake method; foam height was recorded at 1, 5, and 10 minutes.
  - pH: Determined by dissolving 1% w/v soap solution in distilled water and measuring with a pH meter.
  - Appearance: Examined for uniformity of color and shape.
- **Powders:**
  - Bulk density and tapped density: Using the graduated cylinder method, bulk density and tapped density were calculated.
  - Angle of repose: Measured using the fixed funnel method.
  - Moisture content: Determined by loss on drying at 105 °C until constant weight.
  - Visual assessment: Checked for color, texture, and clumping.

3. RESULTS AND DISCUSSION:

3.1 Tablets:

Both herbal (Arkaneem) and synthetic (fluconazole) tablets complied with Indian Pharmacopoeia (IP) standards for weight variation and friability. However, clear differences were observed in hardness, thickness and disintegration. Herbal tablets showed markedly higher hardness (10.0 kg/cm^2) compared to synthetic tablets (3.5 kg/cm^2). Although increased hardness improves mechanical strength, it often correlates with slower disintegration, which was confirmed in this study. The thickness of herbal tablets (5.4 mm) was greater than that of synthetic tablets (3.2 mm), possibly reflecting formulation difference. Herbal tablets failed to meet the IP disintegration limit (105 min vs ≤ 30 min), whereas synthetic tablets disintegration within 6 minutes, ensuring faster onset of action.

Parameters	Herbal tablet (Arkaneem)	Synthetic tablet (Fluconazole)	IP Limit
Hardness (kg/cm$^{2)}$	10.0	3.5	-
Thickness (mm)	5.4	3.2	-
Friability (%)	0.225	0.16	≤1.0
Disintegration (min)	105	6	≤30 (uncoated)

4.2 Creams:

Both creams demonstrated smooth texture and homogeneity with acceptable pH values (herbal: 6.5; synthetic: 5.2), which are within the skin-friendly range (4.5-7.0). The slightly acidic pH of the synthetic creams supports antifungal activity, while the herbal creams near- neutral pH may enhance tolerability. Viscosity values were within acceptable ranges, indicating good spreadability and ease of application.

4.3 Soaps:

Foam stability and pH are critical for consumer acceptability and skin compatibility. The herbal soap-maintained foam stability for more than 5 minutes, compared with 3 minutes for synthetic soap, suggesting better cleansing and longer-lasting lather. Both soaps had pH values within the acceptable range for skin use, minimizing irritation risk.

4.4 Powders:

Powder formulations were assessed for flow properties and moisture content. The herbal powder demonstrated superior flowability, with a lower angle of repose (34.7) compared to the synthetic powder (41.2). However, it also showed higher moisture content (7.52%), which may predispose to microbial growth and reduce shelf stability. Synthetic powder, with lower moisture (2.50%) offers better long-term stability.

Parameters	Herbal (Neem)	Synthetic (Canesten)
Bulk density (g/ml)	0.41	0.53
Tapped density (g/ml)	0.56	0.81
Angle of repose (º)	34.7	41.2
Moisture content (%)	7.52	2.50

4. CONCLUSION:

Both herbal and synthetic antifungal formulations met most of the evaluated quality control parameters. Herbal products demonstrated advantages in terms of foam stability, flow properties, and potential safety profile, while synthetic tablets showed superior disintegration times, ensuring faster onset of action. Overall, herbal formulations exhibited satisfactory quality characteristics; however, improvements are required in tablet disintegration and moisture control of the powder to enhance stability and therapeutic performance.

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