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COMPARATIVE ANALYSIS OF ARTEMETHER WITH LUMEFANTRINE TABLETS: A STUDY OF THREE PHARMACEUTICAL BRANDS

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ABSTRACT

Purpose: This study aims to assess the physicochemical equivalence of eight brands of Artemether with Lumefantrine Tablets, an antimalarial drug combination, sourced from various retail pharmacy outlets in international markets. **Method**: Eight different brands of Artemether with Lumefantrine Tablets were evaluated for quality and physicochemical equivalence. The assessment included tests for uniformity of weight, friability, thickness, crushing strength, disintegration, and chemical assay of the tablets. **Results**: All brands of tablets met the standards set by the Indian Pharmacopoeia (IP) for uniformity of weight, disintegration, and crushing strength. Three brands also passed the friability test. The amounts of Artemether with Lumefantrine released from the different brands showed no significant difference ($P > 0.05$). **Conclusion**: Out of the eight brands analysed, only three (not registered by NAFDAC) met all the British Pharmacopoeia (BP) quality specifications and demonstrated physical and chemical equivalence. This study underscores the importance of continuous market surveillance to verify the equivalence of new products with the innovator product.

Keywords: Chemical equivalence, comparative study, Artemether with Lumefantrine Tablets.

INTRODUCTION

Malaria has deep roots in Indian history, spanning millennia. Ancient texts like the Atharva Veda, dating back to around 1000 BCE, describe malaria as "Vishama Jwara," indicating intermittent fever. This disease has long posed a significant public health challenge in India, especially in tropical regions where mosquito breeding thrives[1].

During the British colonial era, malaria became particularly problematic due to infrastructure projects like railways and irrigation systems, which created ideal breeding habitats for mosquitoes. The disease notably affected British troops and administrators, prompting efforts to control it through methods such as swamp drainage and the use of quinine for treatment[2].

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Post-independence in 1947, India continued its fight against malaria. The National Malaria Control Programme launched in 1953 and was succeeded by the Malaria Eradication Programme in 1958. These initiatives emphasized insecticides, mosquito nets, and antimalarial medications to curb transmission[3].

Despite these efforts, malaria persisted in many rural and remote areas of India. In recent decades, renewed efforts have focused on malaria control and elimination, introducing new strategies like insecticide-treated bed nets, indoor spraying, and artemisinin-based combination therapies (ACTs) for treatment[4].

India's government has set ambitious goals for malaria elimination, aiming to achieve zero indigenous cases by 2030. These efforts reflect ongoing commitments to public health and underscore the importance of sustained vigilance and innovative approaches in combating malaria[5].

Methodology

Materials:

Three brands of Artemether with Lumefantrine Tablets (A to C) were procured from various retail outlets in other countries. The manufacturing and expiry dates are detailed in Table 1[6].

- **Brand A:** FM Plus
- **Brand B:** Lumerax – 80
- **Brand C:** Rezatrin Forte

Table 1: Country of origin, manufacture and expiry dates ofThree brands of Artemether with Lumefantrine Tablets

Brand	Date of Manufacture	Expiry Date	Country of Origin	NAFDAC* Registration
A	Feb, 2023	Jan, 2025	India	No
B	Jul, 2023	May, 2025	India	No
C	Sep, 2023	Aug, 2025	India	No

IP Standard for tablets for tablets Dosage form :-

SR NO.	Average weight of tablet (Mg)	Maximum % difference allowed
1	80 or Less	10%
2	80 – 250	7.5%
3	More than 250	5%

Instrument Method Image :-

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1) Weight machine for weight variation.

2) Vernier caliper for Thickness.

3) Disintegration tester.

4) Friability tester.

5) Hardness tester

The Brands product image A, B , C :-

Differences of all brand

Brand name	Weight uniformity	Thickness	Hardness test	Friability test	Disintegration test
Brand A	± 41.26	3.140	e.g. 2.67 , 2.38 etc	1%	7.63 min.
Brand B	± 48.99	1.760	e.g. 3.97 , 3.12 etc	1%	7.60 min.
Brand C	± 56.95	2.26	e.g. 3.23 , 3.76 etc	1%	8.36 min.

Results & Discussion

All samples used in the study were within their shelf life at the time of investigation. Three out of the eight brands analyzed in the "Comparative Analysis of Three Brands of Artemether with Lumefantrine Tablets" were not registered by NAFDAC. The physicochemical properties of the various brands of Artemether with Lumefantrine are summarized in Table 1. All brands exhibited acceptable uniformity of weight [7], as none showed a percent deviation in weight greater than 5%, as per the Indian Pharmacopoeia 1986. This test ensures that tablets within each batch are of appropriate size [8]. The crushing strength, an essential criterion for tablet durability against chipping and breakage during storage and handling, ranged from 7.8 to 15 kgF across the brands tested. Friability, which assesses tablet resistance to abrasion, showed acceptable results for brands A, B, and C, but brands D and E did not meet the standard. This discrepancy could be due to inadequate binding agent amounts, moisture content, or compression pressure during formulation. The disintegration test, crucial for assessing tablet dissolution into particles, met the BP 1998 requirement of not more than 15 minutes for all brands tested. Chemical assays to determine Artemether with Lumefantrine content showed that all brands contained between 90% and 110% of the labeled amount specified for Lumefantrine [9]. However, brand A's Artemether content was 141.2%, significantly deviating from the innovator product ($p < 0.05$)[10]. This could stem from poor preparation techniques during formulation, potentially leading to segregation of particles, especially considering the small amount of Artemether (25 mg) in the combination tablet.

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