



GUJARAT TECHNOLOGICAL UNIVERSITY

(Established by Government of Gujarat under Gujarat Act No. : 20 of 2007)

ગુજરાત ટેકનોલોજીકલ યુનિવર્સિટી
(ગુજરાત સરકારના ગુજરાત અધિનિયમ ક્રમાંક : ૨૦/૨૦૦૭ દ્વારા સ્થાપિત)

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Abstract of the Thesis



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Enrollment No: 229999901024

Faculty: Pharmacy

Discipline: Pharmaceutical Sciences

Title: Formulation, Evaluation and Standardization of
Phytopharmaceutical Dosage Form with Anti-Infective
Activity

Abstract

The current global health landscape is increasingly defined by the escalation of antimicrobial resistance, necessitating the transition from empirical traditional medicine to evidence-based, regulated phytopharmaceuticals. This research investigates the therapeutic potential of *Kigelia africana* fruit extract, addressing the critical gap between ethnobotanical utility and modern pharmaceutical standardization.

The study's methodological rigor is anchored in the development of validated High-Performance Thin-Layer Chromatography (HPTLC) methods for the simultaneous and precise quantification of four key markers: verbascoside, caffeic acid, ferulic acid, and coumaric acid. To optimize extraction efficiency, a 3² full factorial Design of Experiments (DOE) was implemented to analyze the synergistic effects of solvent composition and duration. The optimized extract, was rigorously screened via Headspace-Gas Chromatography (HS-GC) to ensure residual ethanol remained well below the minimum inhibitory concentration (MIC) for relevant pathogens. This ensures that the observed antimicrobial efficacy is intrinsic to the phytochemical profile rather than the solvent. This systematic approach transforms extraction from a simple preparation step into a strategic determinant of therapeutic quality.

The subsequent development of a topical gel utilized a Quality by Design (QbD) framework, systematically linking material attributes to Critical Quality Attributes (CQAs). The resulting dosage form demonstrated significant *in-vitro* activity against *Staphylococcus aureus* and

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Escherichia coli. Accelerated stability studies conducted under ICH Q1A(R2) guidelines confirmed the formulation's physical and chemical integrity, supporting a projected shelf life of three years.

This thesis offers a sophisticated scientific framework for the translational development of plant-derived anti-infective. By integrating advanced analytical validation with engineering-driven optimization, it provides a scalable, standardized pathway for botanical medicines to address the therapeutic void left by failing synthetic alternatives.

This research stands out because it directly addresses two intersecting gaps: the global rise of fungal and bacterial resistance, and the underutilization of phytopharmaceuticals within regulated drug frameworks. While antifungal resistance has been identified as a growing global health threat, few research initiatives explore topical phytopharmaceuticals as credible therapeutic options. Most plant-based formulations remain confined to traditional or alternative medicine, without systematic validation against modern regulatory standards. This moves beyond ethnobotanical claims by subjecting a topical gel to rigorous physical, chemical, and pharmacological evaluation aligned with the Drugs and Cosmetics Act. That combination of traditional knowledge, pharmaceutical development, and regulatory compliance gives the study a distinctive edge.

List of Publication(s):

- 1) Bodiwala Kunjan, Banker Nancy, **Lalwani Rahul**, Shah Mamta, Gajjar Anuradha. Quality control methods for fruit extracts of *Kigelia africana* using high performance thin layer chromatography. Natural Product Research, 39(15), 4409–4417.
- 2) **Lalwani Rahul**, Bodiwala Kunjan, Gajjar Anuradha. High-performance thin-layer chromatography method for the quantitative assessment of caffeic acid, coumaric acid, and ferulic acid in ethanol extracts of *Kigelia africana* fruits. Journal of Planar Chromatography 38, 147–154 (2025).