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(57) Abstract :

The present invention relates to a standardized phytochemical-based oral formulation derived from Moringa oleifera, developed for the chemoprevention and management of oral squamous cell carcinoma (OSCC) and the mitigation of chemotherapy-induced fatigue. The formulation is enriched with 17 bioactive compounds including quercetin, kaempferol, chlorogenic acid, β -sitosterol, eugenol, niiazimicin, and isothiocyanates, integrated in optimized ratios to exert synergistic antioxidant, anti-inflammatory, and anticancer effects. Using network pharmacology and molecular docking, the formulation demonstrated strong interactions with key cancer-related targets including AKT1, EGFR, TP53, TNF- α , JUN, IL-6, and MAPK, indicating broad multi-pathway activity. Preclinical evaluation in a DMBA-induced OSCC rat model revealed significant reduction in tumor progression, restoration of epithelial architecture, and suppression of inflammatory cytokines. The formulation markedly enhanced antioxidant defenses by increasing glutathione (GSH) and superoxide dismutase (SOD) levels while reducing malondialdehyde (MDA), an indicator of oxidative stress. In addition, the formulation demonstrated notable efficacy in alleviating chemotherapy-associated fatigue, as evidenced by improved neuromuscular coordination and endurance in rotarod performance tests. When co-administered with 5-fluorouracil (5-FU), the formulation exhibited synergistic anticancer benefits while minimizing chemotherapy-induced oxidative damage and fatigue. The formulation is safe, biocompatible, and suitable for scalable manufacturing into oral dosage forms such as capsules, tablets, suspensions, or nutraceutical preparations. This invention offers a natural, cost-effective, and scientifically validated phytopharmaceutical for integrative oncology, addressing both tumor suppression and supportive care needs during chemotherapy.

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