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ABSTRACT BOOK

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The development of a universal polymer matrix for immediate-release buccal films suitable for small-batch manufacturing

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Background: Buccal films are an innovative mucosal dosage form providing rapid onset of action, bypass of hepatic first-pass metabolism, and improved patient compliance [1]. The global market for oral polymeric films is steadily growing due to increasing demand for fast-acting antiemetic, analgesic, and neurological therapies. However, the development of a universal polymer platform with reproducible mechanical and biopharmaceutical properties, compatible with water-soluble active pharmaceutical ingredients (APIs), remains a significant challenge, particularly under small-batch manufacturing conditions.

Aim: To develop and experimentally validate a universal polymer matrix for immediate-release buccal films using ondansetron hydrochloride as a model drug.

Methods: A combined PVA/HPC system was formulated using polyvinyl alcohol (5.6% w/v) and hydroxypropyl cellulose (2.4% w/v) with glycerol (2% w/v) as a plasticizer. An aqueous solution of ondansetron hydrochloride (2 mg/mL, expressed as ondansetron) was incorporated into the polymer base at a 3:2 volume ratio (base:API solution) to produce 20 films. Films were prepared by solvent casting with controlled volumetric dosing (5 mL per mold) and dried at 37–38 °C for 20 h to constant weight. pH, weight uniformity, disintegration time, and dissolution were evaluated.

Results: The films showed a mean weight of 0.423 g with variability below 5%, confirming reproducible dosing. The pH (5.0–5.5) corresponded to physiological oral conditions. No pronounced bitterness or irritation was observed. Rapid disintegration (1–3 min) and immediate drug release were achieved: 75% within 3 min and 100% within 5 min, consistent with immediate-release mucosal dosage forms [2].

Conclusion: The results confirm the technological reproducibility of film formation based on the developed PVA/HPC matrix, its pharmaco-technological relevance, and the feasibility of technology transfer for fast-acting mucosal dosage forms under small-batch manufacturing conditions.

References:

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