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(57) Abstract :

The present invention relates to a pullulan-based oral thin film of promethazine for improved bioavailability and patient compliance. The composition comprises promethazine or a pharmaceutically acceptable salt thereof in 2% to 10% by weight, pullulan as film-forming polymer in 40% to 70% by weight, a plasticizer in 5% to 20% by weight, a sweetener in 2% to 10% by weight, and a flavoring agent in 0.5% to 5% by weight, with optional secondary polymers, stabilizers or surfactants, and citric acid. The film is prepared by dissolving polymers and excipients, incorporating promethazine, degassing, casting, and drying. The resulting strip disintegrates rapidly in the oral cavity, bypasses first-pass metabolism, masks bitterness, and offers convenient administration for adult, pediatric, and geriatric patients.

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