ORODISPERSIBLE FILM FABRICATION BY HOT MELT EXTRUSION FOR DENTAL PAIN AMELIORATION BY QUALITY BY DESIGN APPROACH

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ABSTRACT

Surgical dental procedures cause pain and inflammation leading to temporary restriction of the movement of the oral cavity. Consumption of analgesic medications in the form of tablets or dispersible tablets causes compliance issues due to the compromised movability of the mandibular joint. An Orally Disintegrating Film (ODF), due to its pliability and compact size, can be a patient compliant tool for management of postoperative dental pain over parenterally administered opioids, conventional as well as orodispersible tablets of steroids or NSAIDS. Due to the inadequacies involved in solvent-casting, an unmet need exists for a continuous, eco-friendly and patient compliant process of manufacturing. The present research work addresses the unmet need of a patient compliant delivery system containing ketorolac tromethamine by Hot Melt Extrusion. The ODF optimized by Quality by Design was found to be stable with excellent mechanical properties and provided superior release profile as compared to the equivalent marketed formulation.