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DICLOFENAC ORODISPERSIBLE FILMS BY HOT MELT RAM EXTRUSION 3D PRINTING

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Background: Hot melt ram extrusion 3D printing was recently proposed to prepare small batches of orodispersible films (ODF), but the feasibility of loading thermosensitive drugs with low palatability has not been investigated. Among the possible candidates, diclofenac sodium (DNa) at a dose of 25 mg could be loaded in ODF, despite the limited formulative space, when an immediate release is required. However, the addition of taste masking agents (TMA) should be carefully evaluated as they can compromise the ODF processability and handling.

Purpose: This study aims to design ODF loaded by DNa and TMA by hot melt ram extrusion 3D printing and to study their influence on the mechanical and physico-chemical properties of ODF.

Methods: ODF made of maltodextrins with a dextrose equivalent of 6 containing DNa and TMA (i.e. mint, licorice-mint and sucralose) or a combination thereof were characterized in terms of drug content, disintegration time, *in vitro* dissolution test and tensile properties.

Results: All ODF disintegrated within 2 min complying the compendial specification. Impurity A of DNa was detected below the Ph. Eur. limits (< 0.2%). The *in vitro* dissolution profiles of DNa from ODF with and without TMA were superimposable ($t_{80\%}$~3 min) in deionized water; $t_{80\%}$decreased about 1-fold for ODF containing TMA in artificial saliva at pH=5.7 ($t_{80\%}$~2 min). Independently of the presence of TMA, drug loaded ODF were flexible and easy to handle without fracture, even if the presence of DNa significantly increased the tensile strength (placebo ODF=0.17±0.03 MPa vs DNa loaded ODF=2.21±0.54 MPa).

Conclusion: Hot melt ram extrusion 3D printing can be also proposed to prepare palatable ODF loaded by a thermosensitive drug.