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FORMULATION OF A NATURAL INTRAORAL DISPERSIBLE FILM (IDF) FOR INTRAORAL DELIVERY OF VARIOUS NATURAL DRUGS USING EDIBLE RICE PAPER FILM AS THE CARRIER VEHICLE

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Aim & Background: At present, pharmaceutical researchers are focusing on instantaneous intraoral dispersible technologies as novel drug delivery systems, because they have outstanding advantages over the traditional oral and parenteral routes of drug administration. Some essential natural drugs have low oral bioavailability due to extensive first pass metabolism and pre-systemic degradation in the gastrointestinal tract. Currently, a cheap rice paper intraoral dispersible film (IDF) has been developed

Objectives: In this study, formulation was optimized using the experimental factorial design. The IDFs were loaded with model, natural, anti-cancer drugs, resveratrol and curcumin with low oral bioavailability.

Methods: They were evaluated for thickness, folding endurance, swelling behaviour, among others. These related to their drug release properties. Permeation was evaluated using the pig mucosal membrane mounted on a Franz diffu sion cell. Taste testing was done to determine acceptability using a taste panel.

Results & Discussions: 16 formulations showed variations in their profiles. Formulation 16 proved optimal. The dissolution rate at steady state concentrations of resveratrol was 29mg per second and the permeability coefficient was 389 mg/sec.cm2. Curcumin dissolution rate at steady state concentrations was 0.25mg per second and the permeability coefficient was 42.71 mg/sec.cm2. Resveratrol permeability rate was 0.42 mg/sec. and that of curcumin was 0.14 mg/sec. Resveratrol flux was 0.21 mg/sec./cm^2. Curcumin flux was 0.14 mg/sec./cm^2. Drug entrapment was 80% for both molecules. The 20 mg of resveratrol and curcumin dissolved in 47.6 sec. and 71.4 sec. respectively. In this study, after permeation, a concentration of 6.73mg/ml of resveratrol and 0.061mg/ml of curcumin were detected after two hours of the experiment on administering only 20 mg of each of the drugs suggesting that curcumin is 100 times less permeable than resveratrol. The release profile was a burst release. On contrast, curcumin oral dose of 2 g/kg to rats yielded 1.35±0.23 µg/ml in 0.83 hours and in humans, given the same dose yielded either undetectable or extremely low (0.006±0.005 µg/ml after one hour in blood. Two separate mono-glucuronide metabolites yielded a Cmax of ~7.5 µM following a single 5.0 g oral dosage of Resveratrol.

Conclusion: The key finding was, ex vivo release profiles of the optimized formulation revealed first order release and later zero order. Therefore, it is evident that rice paper IDF could efficiently deliver natural drugs into the systemic circulation intraorally. However, further studies need to be performed to prove increased bioavailability in human subjects

BIOGRAPHY

Eliphaz Mukasa has worked at Medipharm Industries EA Ltd., Uganda factory for five years. He is specialized in cGMP and ORS manufacture. He has studied at Mulago Hospital School of Dispensing for a Higher Diploma in Pharmacy in 1988. He taught at Mulago Paramedical School for two years. He has attended a clinical instructor's course at Mbale Health Manpower Development Centre in 1999 and worked as an Assistant Drugs Inspector at Uganda National Drug Authority for seven years. He has also attended NIPER Chandigarh India for assessment of quality of pharmaceuticals. He did his BPharm in 2012 at Nelson Mandela Metropolitan University, former University of Port Elizabeth (NMMU) Port Elizabeth South Africa. He has worked at Johannesburg General Hospital Charlotte Maxeke for his pharmacist internship in 2013. Presently he is an M Pharm student at the University of the Witwatersrand, SA 2013 to 2016. He served as a Community Service Pharmacist at Nessie Knight Hospital Sulenkama Qumbu, Eastern Cape, South Africa.

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