

5th International Conference and Exhibition on

Pharmaceutics & Novel Drug Delivery Systems

March 16-18, 2015 Crowne Plaza, Dubai, UAE

Oral formulations of Metformin in semi-solid matrices: Design, characterization & *in vitro* evaluations

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Purpose. To formulate and evaluate oral dosage forms of Metformin hydrochloride (MH) having sustained-release properties that would also increase MH bioavailability and address the shortcomings in the currently marketed sustained-release tablets. Methods. MH micronized powder was dispersed in molten polymeric matrices composed of Gelucire® 50/13 and various proportions of high molecular weight hydrophilic polymers, hydrophobic oily semisolid excipients, and muco-adhesive polymeric materials. The MH loaded matrices were filled in hard gelatin capsules (HGC) each containing 500 mg MH and were subsequently characterized using Differential Scanning Calorimetry (DSC) and X-Ray Diffraction Analysis (XRD). The prepared HGC were subjected to content uniformity and *in vitro* dissolution testing according to the USP-35 compendial requirements. The dissolution data were compared to instant and sustained-release marketed tablets. The effect of incorporating various proportions of the semisolid excipients on MH dissolution release rate, were also investigated. Results. MH content of the prepared HGC ranged between 96 to 103%. All the prepared semisolid filled HGC resulted in extended-release profiles of MH that lasted between 5 to 11 hours and demonstrated a release pattern which typically follows the release from mixes of triglycerides with polyethylene glycol esters of fatty acids. The incorporation of muco-adhesive excipients like Carbomer to the Gelucire® 50/13-MH semisolid matrices extended the release of MH from 5 hours initially to 9 hours as a result of the formation of a gel layer around the matrix. However, the incorporation of different hydrophilic excipients like PEG35000 and Gelucire® 44/14 along with the muco-adhesive excipients sustained the release of MH up to 11 hours. XRD analysis of the MH prepared matrices demonstrated minor changes in the crystalline nature of MH. Depending on the loading ratios and the nature of the semisolid matrices used, DSC analysis revealed the changes in MH crystallinity to be from 100 to 23 %. Conclusion. HGC formulated using semisolid matrices showed promising results in extending the release of MH. However, bioavailability studies to test the ability of such Gelucire based HGC of MH to improve its bioavailability and *in vivo* residence times are future plans. Acknowledgements: This work was made possible by a NPRP award [NPRP 09-795-3-215] to HM Younes from the Qatar National Research Fund (a member of The Qatar Foundation). The statements made herein are solely the responsibility of the authors.

Biography

Husam Younes is a graduate of the Faculty of Pharmaceutical Sciences at the University of Alberta (UA) in Edmonton, Alberta, Canada. He received his BSc (Pharm) in 1992 followed by MSc (Pharmaceutical Technology) in 1995. He worked as a Technical Manager in the Pharmaceutical Industry in Palestine and Jordan then completed his PhD from UA in 2002. In August 2007, Younes moved to Qatar to start his new career as the Founding Chair of Pharmaceutical Sciences department in the new Pharmacy Program at Qatar University. He is currently an Associate Professor of Biopharmaceutics at the College of Pharmacy and the founder of the new Pharmaceutics and Polymeric Drug Delivery Research Laboratory. He previously worked in the pharmaceutical industry and also as a senior consultant to Newfoundland Health Department in Canada. His main research is in the areas of controlled drug release, biomaterials, tissue engineering and synthesis of novel biodegradable polymers designed for localized and targeted delivery of therapeutic proteins in cancer therapy. Younes supervised graduate students and postdoctoral fellows in his lab and acted as an editorial board member and a reviewer for many pharmaceutical and drug delivery journals.

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