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Dissolution, HSPM, PXRD, DSC Studies on Gastro Retentive Multi-Particulates of Metformin Hydrochloride for the Treatment of Diabetes using Gelucire

Prashant UPADHYAY 1* and Jayanta K. PANDIT 2

¹ Department of Pharmaceutics, College of Pharmacy I.F.T.M, Delhi Road, Moradabad-244001 and Gautam Buddh Technical University, Lucknow (Uttar Pradesh, INDIA) ² Department of Pharmaceutics, Institute of Technology, Banaras Hindu University, Varanasi-221005, (Uttar Pradesh, INDIA)

SUMMARY. Metformin hydrochloride (MH), an important drug in the treatment of type II diabetes mellitus, requires multiple administration in 500-1500 mg doses/day. Sustained release gastro retentive multiparticulates of MH were prepared by dispersing drug in melted gelucire 39/01 and 43/01 using the melt granulation technique. Hot stage polarized microscopy, powder X-ray diffraction and differential scanning calorimetry thermograms were conducted to test crystallinity of MH and significant decrease in crystallinity was found. The percent drug entrapment in matrices was around 99.8 %. The multi-particulates demonstrated favorable in vitro floating ability for 11 h. Evaluation for in vitro drug release data analysis was performed using PCP-Disso software. Prepared formulations followed zero order kinetics and drug release mechanism was anomalous diffusion controlled. The combination of ethylcellulose, methylcellulose and microcrystalline cellulose with gelucire were noted for release of drug, floatability and consistency for optimized formulation. It was concluded that matrices of gelucire 39/01 and 43/01 may serve as effective carriers for highly water-soluble drugs for controlled delivery as compared to release profile with marketed sustained release product.

KEY WORDS: Differential scanning calorimetry, Gastro retentive multi-particulates, Gelucire, Hot stage polarized microscopy, Melt granulation method, Metformin hydrochloride, X-ray diffraction.

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^{*} Author to whom correspondence should be addressed. E-mail: p23upadhyay@yahoo.com