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Study the quality of metformin hydrochloride sustained release tablets available in Sri Lanka

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Type 2 diabetes mellitus (T2DM) is a non-insulin dependent diabetes mellitus, where high blood glucose level is due to comparatively less amount of insulin secretion or insulin resistance or decreased insulin action on target tissues. Highly water soluble Metformin Hydrochloride (MH) is used in the treatment of T2DM as first line drug choice. The sustained release dosage form is needed for better therapeutic effect due to low bio availability and short half-life of MH. The quality of drug is a very important parameter in success of treatment.

Top seven MH sustained release tablet brands in Sri Lanka were selected for this study. Samples were collected from local market and quality was evaluated. Assay of tablets from each brand was studied in High Performance Liquid Chromatography (HPLC) system according to United State Pharmacopeia (USP). Drug releasing pattern of tablets from each brands were studied in the medium of potassium dihydrogen phosphate (pH- 6.8) at 37 ^{0}C in dissolution tester according to United States Pharmacopoeia (USP), using Apparatus 2 (paddle). The aliquot was withdrawn from the vessel at the end of first, third and tenth hour and amount of MH released from the tablet was calculated through measurement of absorbance at 232 nm in a uv-visible spectrophotometer. Twenty tablets were randomly selected from each brand and tested for weight variation according to the British Pharmacopeia. The thickness, diameter and hardness were tested for ten tablets from each brand. Ten tablets from each brand tested for friability according to USP.

Tablet assay of all brands was between ± 6.0 % of label claim. It satisfied the USP standard. In terms of drug release, at the end of the first hour (USP limit – 20 to 40%) and the tenth hour (USP limit – greater than 85%) the USP standard limits were obeyed, but drug release at the end of the third hour (USP limit – 45 to 65%) was a little above the upper limit for three brands out of seven. The tablet weight of all seven brands was within 5% of average weight. It fulfills the BP standard limits. The friability of six brands out of seven was less than 1% for 100 rotations as USP standard. The tablet diameter, hardness and thickness of all brands were in acceptable limits.

Even though, tablet assay of all brands were within USP limits, three brands failed in sustained drug releasing properties due to unsuccessful combination of drug releasing polymers in the formulation. The friability of one brand out of seven failed due to low hardness. It can be concluded that friability of tablets do not affect drug releasing property.

References

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