Current Pharma Research
Vol. 1, Issue 1, October-December 2010

Dissolution Profile of Various (Three) Marketed Brands of Metformin Hydrochloride.

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Abstract
Sustained release dosage form is mainly designed for maintaining therapeutic blood or tissue levels of the drug for extended period of time with minimized local or systemic adverse effects. Economy and greater patient compliance are other advantages[1]. In recent years, clinical studies on Metformin hydrochloride (MET) have demonstrated that this drug is an effective agent for treatment of diabetes mellitus. It is a widely used antidiabetic from biguanide class. The need for present investigation is because of its availability as a single and combinational dosage form. In present study the comparative dissolution study of three marketed tablet formulations i.e. Dibeta-SR (D) [TORRENT], Glycophage (GF) [FRANCO- INDIAN], Gluformin (GF) [PIRAMAL HC] was being carried out. All the formulations showed excellent drug release profile. The present study gives an idea about its release so that it will be useful for further development concerned with the improvement of patient compliance.

Key Words
Metformin hydrochloride, Dissolution profile.

Materials and Methods

Materials
The pure drug MET was obtained from Zim laboratories, Nagpur whereas other chemicals used such as Hydrochloric acid, Phosphate buffer etc. of analytical grade were obtained from local supplier.

Equipments
The Shimadzu UV Spectrometer – 1700 & USP dissolution apparatus Type-II (VEEGO SCIENTIFIC) were used.

Methods[3, 4]
The study was done on six station USP dissolution apparatus Type-II (VEEGO SCIENTIFIC). The three marketed sustain release tablet formulations of MET were selected. All batches of tablets were evaluated using 900 ml of sequential gastrointestinal release medium, i.e. 0.1N hydrochloric acid (pH 1.2) for first two hours and then phosphate buffer of pH 6.8 for remaining 7 hours. Temperature was maintained at 37 ± 0.5°C throughout the study and stirring at 50 rpm was carried out. Samples were collected periodically, filtered through 0.45 micron filter and replaced with dissolution medium. After filtration through Whatman filter paper 41, concentration of MET was determined spectophotometrically at 233 nm (Shimadzu 1700 UV-Vis Spectrophotometer). Actual amount of released drug was determined from the calibration curve.

Results and Discussion
The comparative dissolution study of various marketed formulation is being carried out. All the formulation showed excellent drug release profile. The marketed formulations D, GP and GF showed 88.301+ 0.36%, 84.183+1.65% and 85.5312+ .55% drug release respectively as shown in Table No. I, and is represented graphically in Fig. No. I. The standard given in I.P. 1996 for drug content is 95.0% - 101.0%. It is useful to evaluate tablets potential for efficacy, amount of drug per tablet needed to be monitored from tablet to tablet & batch to batch. The results were as shown in Table No. II. All the necessary tablet evaluation tests were also performed on the three brands & the results were found to be within the acceptable limits as shown in Table No: III

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Time (Hours)	D Avg% release	GP Avg % release	GF Avg % release
0	0.0	0.0	0.0
0.5	17.324	13.268	16.103
1	18.706	17.557	18.878
1.5	23.646	19.295	23.945
2	26.998	22.257	27.404
3	45.870	24.838	40.527
4	56.497	42.626	46.550
5	64.401	49.769	55.512
6	69.963	59.201	62.864
8	85.438	78.418	81.771
9	88.301	84.183	85.312

Table I: Percentage Drug Release

Brand	Content of active ingredient
D	98.66 %
GP	101.46 %
GF	101.20 %

Table II: Drug Content

Sr No.	Parameter	D	GP	GF
1	Thickness(cm)	5.62-5.74	4.90-4.97	6.51-6.56
2	Weight variation	passes	passes	passes
3	Hardness(kg/cm2)	4-5	8-9	7-8
4	Friability (%)	0.88%	0.53%	0.25%
5	%DR(by calculation)	89.93%	85.75%	86.9%
6	%DR(by PCP Disso.)	88.30%	84.18%	85.31%

Table No III: Evaluation Test

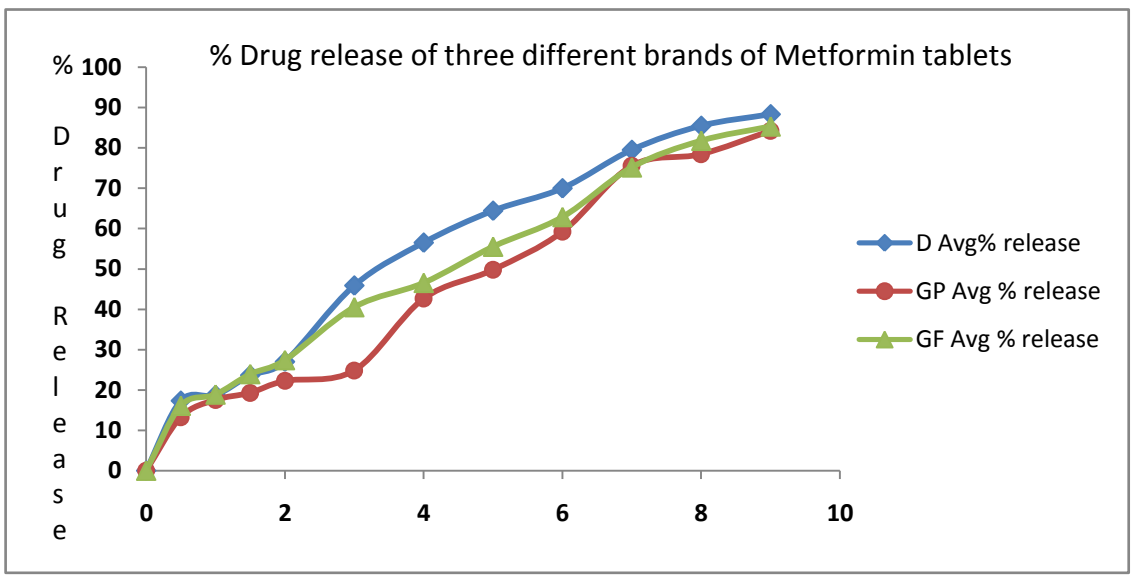

Figure I: % Drug Release

Conclusion

The marketed preparations of Metformin hydrochloride tablets showed good results in various tests for drug release studies and all brands showed values of parameters within acceptable limits (as per I.P.- 1996). From the above results it can be concluded that brand GP has possess zero order release which is an ideal release profile in order to achieve the pharmacological prolonged action.

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