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Designing of a Novel Biomimicking *In-vitro* Dissolution Test Apparatus for Floating Drug Delivery Systems

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ABSTRACT

In the present study, a novel *In-vitro* dissolution apparatus was designed wherein the gastric acid secretion rate (2 mL/min), gastric volume (75 mL, 0.1N HCl dissolution medium) and gastric emptying were mimicked. Provision for agitation was made with the help of magnetic stirring bar to get uniform turbulent condition by making the magnetic bead to stir at certain height from the bottom. Sampling size five mL was sufficient in the proposed design.

Key words: Biomimicking, Dissolution, Floating Drug Delivery system.

Introduction

In-vitro dissolution testing generally carried out for quality control purposes and to establish an *In-Vitro In-Vivo* Correlation (IVIVC). Novel *In-vitro* dissolution apparatus for Floating Drug Delivery System (FDDS) was designed to overcome the various drawbacks associated with conventional dissolution apparatus such as, the floatable system tends to consistently sticking to and detach itself from the rotating shaft and to constantly rotate around the shaft during the entire dissolution period, sticking to sampling probes (pipette), lack of suitable sampling techniques, require large volume (900 mL) of biorelevant dissolution media which can be cost intensive & large drug sample size that is typically not available in the early stage development.

All above demerits leads to have impact on dissolution profile of drug that is because of unnecessary huge exposure of formulation to the medium. Due to vortex, there may be chances of air entrapment in the medium; this may leads to oxidation of some oxygen sensitive drugs. All currently used *in-vitro* dissolution methods do not mimic the *in-vivo* conditions present in the stomach. Hence, a modified*in-vitro* dissolution method was evaluated.

Experimental Method

In the proposed method, a gastric emptying phenomenon is mimicked by providing a side arm at the bottom of the apparatus. The test also tries to simulate the conditions of a flow-through cell with respect to availability of fresh dissolution medium around the dosage form. Various floating drug delivery system were fabricated according to published work on FDDS. The Drug release study from all fabricated formulation was performed with the USP paddle and the proposed design. The proposed design is based on the USP apparatus setup but scaled down with respect to the dimensions. Experiments were run at 37 ± 0.5 °C applying stirring speeds of 100 rpm.

Statistical analysis of the data was performed by comparing the $t_{30\%}$, $t_{50\%}$, and $t_{80\%}$ and by similarity factor f_2

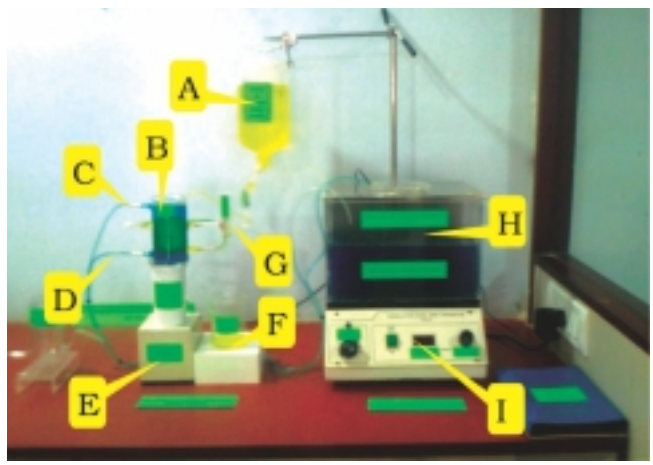

Fig.1: Fabricated glass assembly, (A) entry of dissolution medium from reservoir, (B) Biomimicking glass assembly, (C) outlet for warm water, (D) inlet for warm water, (E) DC motor with tachometer, (F) sample collecting beaker, (G) sample comes out from side arm attached at bottom, (H) warm water bath kept at 37 ± 0.5°C, (I) RPM display.

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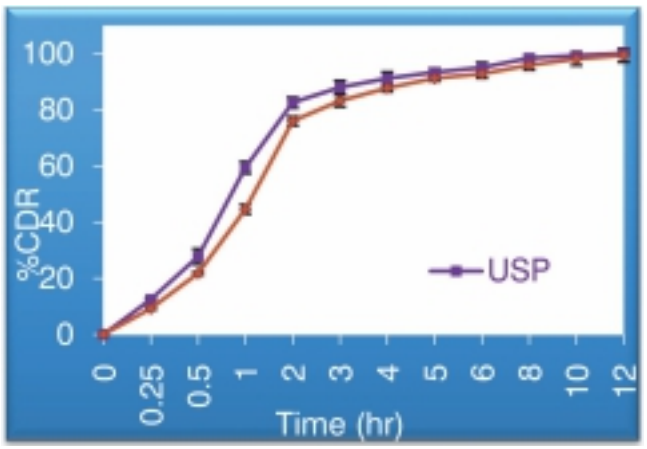

Fig.2: *In-vitro* dissolution profile of cifran OD obtained from USP type 2 & proposed dissolution test apparatus.

Table 1
In-vitro* dissolution profile of cifran OD tablet

Time (min)	USP type 2	Designed apparatus
	%CDR ± SD	%CDR ± SD
00	0.00 ± 0.00	0.00 ± 0.00
15	12.45 ± 0.61	9.21 ± 0.45
30	27.73 ± 1.73	21.77 ± 0.57
60	59.41 ± 1.06	44.57 ± 1.64
120	82.57 ± 1.93	75.99 ± 1.60
180	87.99 ± 1.30	83.20 ± 1.09
240	91.17 ± 1.29	87.75 ± 1.28

*each sample was analyzed in triplicate (n = 3).

assessment as a tool for dissolution data interpretation for dissolution behavior of floating drug delivery system.

Results and Discussion

The overall results show that the modified method provides a more reproducible dissolution profile, eliminates the risk of floating dosage forms sticking to the paddles, to the apparatus walls, agitation device, and sampling probes (pipette). It simplifies the sampling procedure by producing a smaller volume of dissolution medium. The proposed test may show good in-vitro in-vivo correlation since an attempt is made to mimic the in-vivo conditions.

Conclusion

Overall, this study concludes that, for the floating drug delivery system, the modified dissolution apparatus can be more rationally accepted as a substitute for the in-vivo dissolution assessment of the floating dosage form as it more closely simulates most of the in-vivo conditions. There is no need to have costly equipment to study dissolution profile. With this cheapest way there may be opportunity of success. In future, proposed design may stand alone to study dissolution profile for any kind of floating dosage form. Academicians and researchers may adopt this method due to its simplicity.

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