ABSTRACT

Ambroxol hydrochloride has relatively short plasma half life. The need for the administration of the drug for two to three times a day can decrease patient compliance. Sustained release formulations that would maintain plasma level for 8-12 h might be sufficient for daily dosing of Ambroxol Hydrochloride. The overall objective of the present work was to develop an oral sustained release Ambroxol Hydrochloride tablet prepared by direct compression method using hydrophilic Eudragit RSPO and RLPO alone or in combination with hydrophobic ethylcellulose polymer as rate controlling factor. All the batches were evaluated for thickness, weight variation, hardness, friability and drug content and *in vitro* drug release for 12 h. The *in vitro* drug release study revealed that when Eudragit RSPO, RLPO and Ethylcellulose were used alone as the only retarding polymer, a sustained drug release pattern was not observed while, combining Eudragit with ethylcellulose, the drug release pattern was observed in a sustained manner for 12 h. F7 formulation sustained the drug release for longer period of time as compared to other formulations. So F7 was selected as the best formulation. Kinetic modeling of *in vitro* dissolution profiles revealed that the drug release mechanism ranges from diffusion controlled to anomalous type. Fitting the data to Korsmeyer equation indicated that diffusion along with erosion could be the mechanism of drug release.

Keywords: Eudragit RSPO, Eudragit RLPO, Ethylcellulose, sustained release, Release kinetics.