

ABSTRACT:

Allergic rhinitis is the most common allergic disease worldwide and affects about 18% to 40% of the general population. Anti-allergic medicines (eg, some antihistamines) can cause adverse events such as somnolence and can have an additional negative impact on quality of life. Combining Montelukast with Levocetirizine gives additional benefits in comparison with either drug alone and could be considered for patients whose quality of life is impaired by persistent allergic rhinitis. Montelukast sodium is alkaline, stable and Levocetirizine is acid stable, if we prepare a matrix tablet, both the drugs would be in contact and make it unstable during the shelf life of the formulation. Hence it is recommended to prepare bi-layer tablet, as it improves and increases the stability of both the drugs in combination. Bi-layer tablet of Montelukast with Levocetirizine is more stable with respect to stability studies, in comparison to matrix tablet.

Montelukast conventional form and Levocetirizine immediate release bi-layered tablet formulations were prepared with different compositions. The basic approach followed in this study was to incorporate a combination of superdisintegrants in optimum concentrations which can minimize disintegration time. Various batches of bi-layer tablets were prepared by direct compression method. The formulated bi-layer tablets were evaluated for various physicochemical parameters, disintegration time and for *in vitro* drug release. All the batches of the formulations possessed required physicochemical parameters. The manufacturing procedure was found to be reproducible and formulations were stable after two month of accelerated stability studies.

Keywords: Bi-layered tablet, Levocetirizine, Montelukast, formulation, evaluation, physical parameters, *in vitro* disintegration test, *in vitro* drug release, stability studies.