

ABSTRACT

The present study was focused on the evaluation of quality and standardization of montelukast sodium used in the treatment of asthma and allergic conditions. Ten brands of Montelukast sodium (Montelair, MNTK, Irmax, Indokast, Respicare, Montaza, Ventek, Montair, Monokast, Montika) were collected from the local market for the studies. Different physical and chemical tests were performed for the purpose. UV-Vis spectrophotometric and HPLC techniques were used for quantitative analyses and the results showed that the hardness of all the brands lie within the limits (4-10kg) except Indokast (1.7kg) and Respicare (10.8 kg). The disintegration of all the brands lie within the official limit (not more than 30 min). While the results of quantitative assay by HPLC and UV showed that assay results of all brands by HPLC and UV lie within the official limit (90-110%) except Indokast which shown higher concentration by UV assay (112.25%) and by HPLC its assay was (111.57%).

The UV method was verified by performing linearity, precision and accuracy and stability of method and this method can be used for standardization of montelukast.