

(54) Title of the invention : A MODIFIED RELEASE CAPECITABINE TABLET AND PROCESS TO PREPARE THEREOF

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(57) Abstract :

The present invention relates to modified release capecitabine tablet preferably consist of effective concentration of hydroxyl propyl cellulose (HPC) range from 15 to 30 % w/w as a extended release matrix polymer and sodium alginate (SA) range from 20 to 30 % w/w as a release modifying polymer accurately weighed and passed through mesh # 60 sieve; mixed uniformly for 30 min further blended with additives; lactose for 10 min, granulated with non aqueous isopropyl alcohol (IPA) and to the end magnesium stearate in a concentration range from 1 to 2% w/w, compressed on a rotary tablet compression machine. Capecitabine, hydroxypropyl cellulose (HPC) and sodium alginate (SA) were assessed through one or more ways to determine melting point, solubility, loss on drying, quantitative analysis by UV spectroscopy, FTIR, DSC, X ray diffractometry, drug excipients compatibility studies and prepared modified release tablets were evaluated for thickness, hardness, friability, weight variation, content uniformity, swelling index and stability study ensures the purity, safety and stability of the preparation while in vitro drug release study reveals higher drug release percentage range from 84 to 99; sustained up to 24 hour and kinetic model study shown sustained release of drug up to 24 hours. The modified release tablet withstands to gastric pH and sustained with effective therapeutic concentration for 24 hours with reduced dose frequency and cost effective treatment in colon cancer.

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