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NOTE

Comparative X-Ray Diffraction Studies of Indomethacin Solid Dispersions

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This study focuses on comparative investigation of solid dispersion system consisting of drug and carrier in fresh as well as after storage at elevated temperature. Solid dispersions of a water-insoluble indomethacin with different water soluble carriers namely urea, mannitol, sucrose and dextrose were prepared. The samples were stored at a temperature of 40 ± 1 ºC for 2 months and results of X-ray diffractograms of fresh samples as well stored samples were compared. Samples of solid dispersion of mannitol-sucrose-indomethacin and mannitol-dextrose-indomethacin showed increased crystallinity.

Key Words: Indomethacin, Urea, Mannitol, Sucrose, Dextrose, X-ray diffraction, Solid dispersions.

Indomethacin is a common NSAIDS and a potent drug with usual dose of 50-100 mg/day, practically insoluble in water. Among numerous ways of enhancing drug dissolution, solid dispersion of drug in a water-soluble polymer is one of the promising techniques[1,2] using all physical methods like eutectic mixtures[3], solid solution, glass solution[4] and dispersions[5].

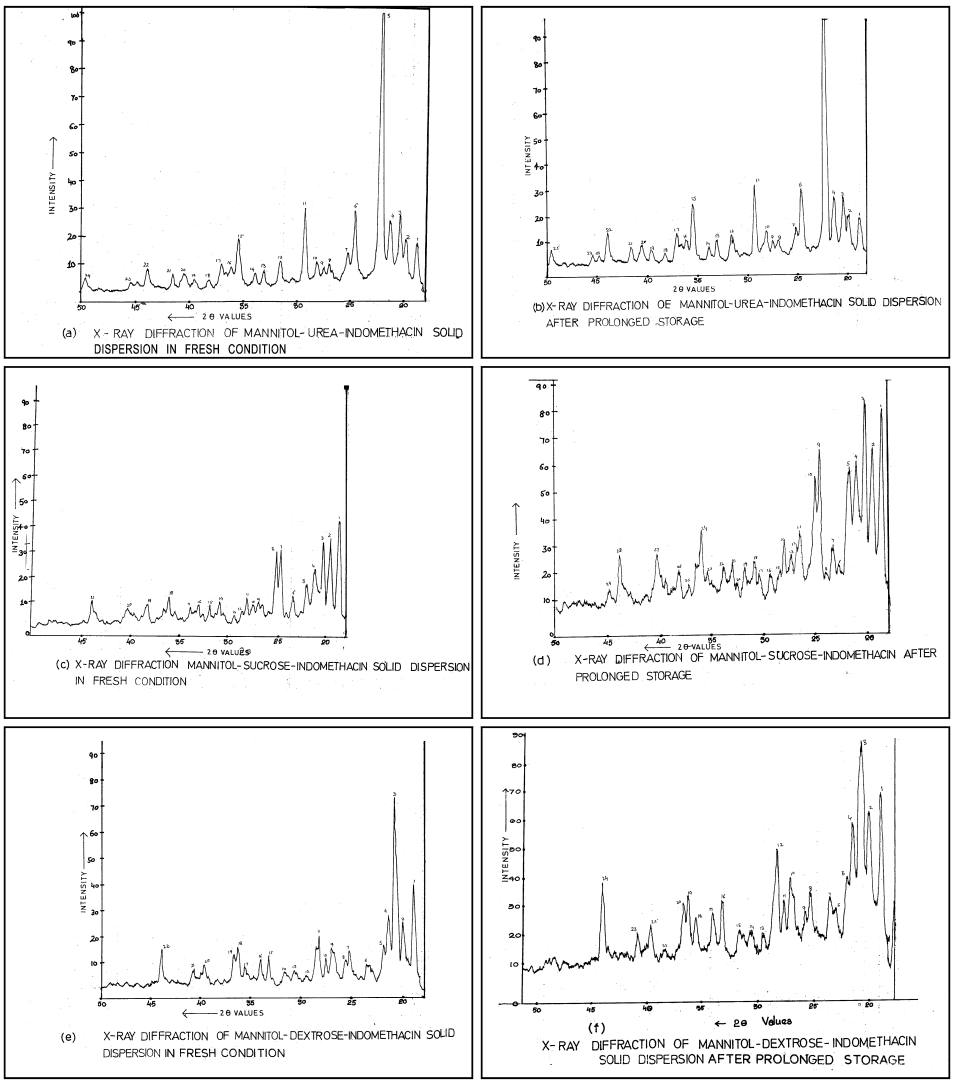
Solid dispersion preparation: Weighed quantities of indomethacin and carriers mixture (50:50) in ratio of (20:80) were melted using hot liquid paraffin bath. The melt was allowed to cool immediately on the ice bath. The hardened mass was pulverized and passed through sieve no. 100 and stored in an air closed container in a desiccators.

Aging studies: Aging studies of solid dispersions have become important to observe physico-chemical changes occurring during storage. Samples of solid dispersion of mannitol-urea-indomethacin, mannitol-sucrose-indomethacin and mannitol-dextrose-indomethacin were stored for two months at 40 ± 1 ºC temperature in closed containers. After 2 months, X-ray diffraction study was performed to observe changes in crystallinity.

X-ray diffraction study: To carry out X-ray diffraction study powdered samples of indomethacin solid dispersions were analyzed using Phillips Holland X-ray diffractometer. The powder was fixed on to X-ray diffraction[6] slide and fitted into a sample holder on X-ray diffraction machine. X-ray diffraction spectra were obtained

between 2θ range of 18-50 ºC (Figs. 1-6) and corresponding intensities were compared using model no. P.W.1310/01 with CuK_α radiations and a nickel filter having scanning speed of 1 ºC/min on a moving chart rate of 10 mm/min.

The result of X-ray diffraction study of solid dispersion of mannitol-urea-indomethacin, mannitol-sucrose-indomethacin and mannitol-dextrose-indomethacin in fresh as well as after storage were compared (Figs. 1-6). It showed there are differences in intensities and sharpness in peaks of mannitol-sucrose-indomethacin and mannitol-dextrose-indomethacin. In case of solid dispersion of mannitol-urea-indomethacin however showed very little changes in the intensity and sharpness of peaks after storage as compared to fresh condition.



The result of present investigation have projected that the intensity of crystalline peaks of solid dispersions mannitol-sucrose-indomethacin and mannitol-dextrose-indomethacin was significantly less in fresh condition than that after prolonged storage. It indicates lower crystallinity in fresh sample due to amorphous state which got converted into crystalline state during storage at accelerated temperature. This is probably a major obstacle of solid dispersion technology in that the number of market products arising from this approach has been less than expected.

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