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TITLE

Gamma Irradiation of Ciprofloxacin in Solid State and in **Gel Formulations: Physico-Chemical** Characterization

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The present work was based on studying the effect of gamma irradiation on the physicochemical properties of Ciprofloxacin (CPX) in solid state as well as in different gel formulations. The radiation doses were 0, 15, 25, 50 and 100 kGy from Cobalt-60 source in a Gammacell-22) at a rate of l.15 Gray/s. The effect of radiation has been investigated using DSC, IR, spectropltotometric scanning, X-ray and SEM photomicrography. All irradiated samples in solid state showed chemical stability at the used doses. The DSC thermogram showed no change in the melting point (266°C) indicating that the CPX identity existed. These findings were also supported by the existence of principal absorption bands in the IR spectra at frequencies 1,616, 1,498 and 2,845 per cm for C=O stretching band of quinolone, C-N stretching band and N-C stretching band. The decrease in the enthalpy by increasing the dose ofirradiation attributed the change in crystalline ciprofloxacin to a more amorphous form. The X-ray diffraction patterns of irradiated solid showed a lesser degree of crystallinity as evidenced by fewer peaks of lower intensity compared with the non-irradiated sample. The characteristics of diffraction peaks relevant to crystalline CPX virtually disappeared by increasing the dose of radiation from I5 to 100 kGy. This was also clearly demonstrated by SEM photomicrography. In case of CPX gel using different concentration of Pluronic F-127, drug instability due to irradiation was less severe as concentration of pluronic was increased indicating more drug protection as the concentration of copolymer increased. At pluronic concentration of 25% w/v, low irradiation doses namely 15 and 20 kGy did not harm the drug and its concentration in the gel was kept within 98 \pm 1.59%. Sterility test on pluronic gel (25% w/v) revealed that irradiation dose at 20 kGy can give a definite sterile product. Release study of CPX from the pluronic gel (25% w/v) showed a significant decrease in drug release after 180 min from irradiated (20 kGy) pluronic gel.