

APPLICATION OF DSC METHOD TO ANALYSIS SOME DRUGS γ , β -STERILIZED

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Increasing use of ionising radiation for sterilization of drugs instigated a study of the radiochemical stability of drugs, auxiliaries and casings if sterilization is performed of ready made products. The radiation (γ , β , X) has ionising properties and depending on the sensitivity of the sterilized compound, auxiliary or casing, can induce some undesirable changes manifested as discoloration, appearance of smell, etc.

This communication presents results of a study on the influence of γ and β - irradiation on physical and chemical properties of some drugs *in substantia*. The compounds studied were 17 drugs from different chemical and pharmacological groups, including β -lactam antibiotics, imidazole derivatives of antimycotic activity and dihydropyridine derivatives affecting circulation. The initial compounds and their irradiated counterparts (25-100 kGy) were subjected to thermal studies by DSC technique, using a 200 Netzsch made instrument. Measurements were carried out in the argon atmosphere at the rate of temperature changes 5 K/min and samples of 7 mg \pm 5%. The DSC spectra of the irradiated compounds revealed a broadening and shift of the endothermic peaks towards lower temperatures, which means that the processes of melting decomposition were not uniform. Also for the irradiated compounds, the melting points were by 0,3-3,7 K lower than those for non-irradiated drugs, the reduction of enthalpy varied in the range 0,15-3,36 J/g and the energy of activation was somewhat reduced.

The changes observed, more pronounced for greater irradiation doses, suggest a kind of destruction of the irradiated compounds or free radicals in them. This supposition was verified spectrophotometric and chromatographic methods (TLC, IR, UV, GC-MS). The results did not evidence a statistically significant mass loss, but the fact that EPR signal was observed for all the compounds testified to the presence of free radicals.

References:

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2. H.B. Ambroz, E.M. Kornacka, B. Marciniak, M. Ogradowczyk and G.K. Przybytniak, *Radiation Physics and Chemistry*, accepted for publication in 2000.