

P5. AN APPROACH TO THE STERILIZATION OF β -ALANINE BY IONIZING RADIATION

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The amino acid β -alanine is the rate-limiting point for the endogenous synthesis of carnosine (beta-alanyl-L-histidine) in skeletal muscle. Carnosine has a wide range of biomedical applications, including improved exercise tolerance and athletic performance [1]. While some questions regarding the physiological roles of carnosine in humans remain to be clarified [2], the use of β -alanine for infusion in humans is one aspect to be considered for biomedical purposes at laboratorial level. Sterilization is mandatory when it comes to parenteral or intravenous routes of administration. The aim of this work was to evaluate the viability of the use of ionizing radiation for the sterilization of β -alanine, as radiation sterilization stands as a powerful technique for the sterilization in a single process inside the final package. For this purpose, β -alanine was transferred to sealed glass vials and then sterilized. Irradiation was performed in a ⁶⁰Co multipurpose irradiator, at a dose rate of 8.5 kGy.Hour⁻¹ totalizing the pre-established doses of 5, 10, 15, 20, 25 30, 40 and 50 kGy, as confirmed by Harwell Type 4034 dosimetry. The samples were characterized by X-ray diffraction in the seek for structural changes and β -alanine content was determined by UV-HPLC analysis. Sterility assurance was evaluated by inoculation assay as described in the US Pharmacopeia [3] and performed in accordance to the ISO 11737-2 [4]. All assays were performed before and after irradiation. Irradiation resulted in no significant changes in the crystal structure of β -alanine, although such effects were more pronounced as irradiation dose increased. No new peaks were identified bellow 40 kGy. In addition, no changes in β -alanine content were detected using up to 40 kGy. Sterility levels were already acceptable at 5 kGy. Our results indicate that irradiation may be performed at the standardized dose for sterilization [5] without causing relevant damage to its molecular structure or content. In summary, high energy irradiation was found to be suitable technique for the sterilization of β -alanine without any compromise to β -alanine structure or causing its degradation.

References

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