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Identification and quantification of a new genotoxic product of degradation in a synthetic opioid partial agonist analgesic

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The Buprinal generic drug administered by injectable way is an analgesic manufactured by the Algerian company SAIDAL. The active ingredient which is Buprinorphine hydrochloride belongs to the class of the strong analgesics and more especially to level II bis which is reserved for the relief of the severe pains. Besides Buprinorphine, Buprinal is constituted by the following excipients: glucose, hydrochloric acid and water for injectable preparations.

The appearance during the study of stability of a unknown chromatographic peak (HPLC) ,and non-existent previously, having a time of retention about 2.55 minutes, required the release of a deep investigation. The increase of the area of the peak during the study of stability directed us to the track of a product of degradation which is due either to the degradation of Buprénorphine hydrochloride, or to the degradation of the glucose. Having eliminated the track of the active ingredient, the efforts were concentrated on the glucose which has the 5-Hydroxy Méthyl Furfural (5HMF) as main product of degradation according to the available literature. By injecting the reference substance (CRS) of 5HMF in the same chromatographic conditions as Buprinal, we deducted that the time of retention of the unknown peak corresponds perfectly to the reference substance 5HMF. Concerning the toxicity of 5 HMF, literature indicates that 5HMF is potentially genotoxic and carcinogenic and that the risk is higher when it is metabolized in Sulfoxy Méthyl Furfural (SMF) or ChloroMéthylFurfural (CMF). Also a study *in silico* with QSAR Toolbox software of the OECD has confirmed the genotoxic potential of 5 HMF because of his aldehyde group.

According to the mixed international committee EXPERTS' FAO/WHO on food additives (JECFA) the maximal quantity tolerated by day and by person should not exceed 540 µg. In the 2nd part of our work we looked to determine the concentration of 5HMF in the finished product Buprinal to compare it on one hand with the concentration of 5HMF in the reference drug product and on the other hand to prove the harmlessness by verifying that the limit of JECFA was not exceeded.

Biography

H Imoudache obtained a diploma of pharmacist in 2006 of the Faculty of Medicine of Algiers and medical specialized study (DEMS) in pharmaceutical chemistry in 2010. He has been working as the Assistant Professor from 2011 till date in Hospitalo-university and Assistant Professor to the Faculty of Medicine of Blida and consultant in the center of research and development of the company SAIDAL.

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