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Extended Abstract
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Pharma Europe 2016 : Identification and quantification of a new genotoxic product of degradation in a synthetic opioid partial agonist analgesic - H Imoudache- Blida University of Medicine

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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. A conventional medication is a pharmaceutical medication that contains a similar concoction substance as a medication that was initially ensured by synthetic licenses. Nonexclusive medications are took into consideration deal after the licenses on the first medications terminate. Since the dynamic concoction substance is the equivalent, the clinical profile of generics is accepted to be identical in performance. A conventional medication has a similar dynamic pharmaceutical fixing (API) as the first, yet it might vary in certain qualities, for example, the assembling procedure, plan, excipients, shading, taste, and packaging. In spite of the fact that they may not be related with a specific organization, nonexclusive medications are normally dependent upon government guidelines in the nations in which they are administered. They are named with the name of the producer and a conventional non-exclusive name, for example, the United States Adopted Name (USAN) or International Non-restrictive Name (INN) of the medication. A nonexclusive medication must contain indistinguishable dynamic fixings from the first brand-name detailing. The U.S. Food and Drug Administration (FDA) expects generics to be indistinguishable from or inside a worthy bioequivalent scope of their image name partners, as for pharmacokinetic and pharmacodynamic properties. (The FDA's utilization of "indistinguishable" is a lawful understanding, not exacting.) Biopharmaceuticals, for example, monoclonal antibodies, vary naturally from little particle drugs. Biosimilars have dynamic pharmaceutical fixings that are practically indistinguishable from the first item and are regularly directed under an all-inclusive arrangement of rules, however they are not equivalent to conventional medications as the dynamic fixings are not equivalent to those of their reference products. By and large, conventional items become accessible after the patent assurances, stood to a medication's unique engineer, lapse. When conventional medications enter the market, rivalry frequently prompts generously lower costs for both the first brand-name item and its nonexclusive reciprocals. In many nations, licenses give 20 years of assurance. In any case, numerous nations and areas, for example, the European Union and the United States, may give as long as five years of extra assurance ("patent term rebuilding") if makers meet explicit objectives, for example, directing clinical preliminaries for pediatric patients. Makers, wholesalers, safety net providers, and drugstores would all be able to expand costs at different phases of creation and distribution. In 2014, as per an examination by the Generic Pharmaceutical Association, conventional medications represented 88% of the 4.3 billion solutions filled in the United States. "Marked generics" then again are characterized by the FDA and NHS as "items that are (an) either novel measurement types of off-patent items created by a producer that isn't the originator of the particle, or (b) an atom duplicate of an off-patent item with an exchange name." Since the organization causing marked generics to can spend little on innovative work, it can spend on promoting alone, accordingly procuring higher benefits and driving expenses down. For instance, the biggest incomes of Ranbaxy, presently claimed by Sun Pharma, originated from marked generics. The genotoxic substances incite harm to the hereditary material in the cells through cooperations with the DNA succession and structure. For instance, the progress metal chromium interfaces with DNA in its high-valent oxidation state so to cause DNA injuries prompting carcinogenesis. The metastable oxidation state Cr(V) is accomplished through reductive initiation.

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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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