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Evaluation of a pediatric liquid formulation to improve 6-mercaptopurine therapy in children

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6-mercaptopurine has until recently had no adequate formulation for pediatric patients with acute lymphoblastic leukemia (ALL). The only oral paraben-free 6-MP liquid formulation named Loulla was developed and evaluated in the target population. Preclinical and clinical evaluation was performed according to a Pediatric Investigation Plan, in order to apply for a Pediatric Use Marketing Authorization. The pre-clinical study assessed the maximum tolerated dosage-volume and evaluated local mucosal toxicity of 28 daily administrations in treated compared to controls gold hamsters. The multi-centre clinical study was single-dose, open-label, crossover trial, conducted in 15 ALL children during maintenance therapy. Bioavailability and palatability of a single 50 mg fixed dose of Loulla compared to 50 mg registered tablets were evaluated in a random order on two consecutive days. Seven blood samples over 9 hours were obtained each day at to determine pharmacokinetic parameters, including Tmax, Cmax, AUC_{0-9} and $AU_{C0-\infty}$. A questionnaire adapted to children testing Loulla palatability and preference for either Loulla or the usual 6-MP tablet was completed. Occurrence of adverse events was determined at study visits by vital sign measurements, patient's spontaneous reporting, investigator's questioning and clinical examination. The dosage-volume of 75 mg/kg/day was well tolerated in gold hamster. The relative bioavailability of liquid Loulla formulation compared to the reference presentation is 76% for AUCs and 80% for Cmax. The taste of Loulla and the mouth feeling after ingestion compare favorably to the tablet. No adverse event occurred. Pharmacokinetic, palatability and safety data support the use of Loulla in children.

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Increase and effectiveness in the activity of audits of quality in the Center of Genetic Engineering and Biotechnology

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This poster presentation aims at sharing the experiences of a study carried out by a group of researchers who audited the quality at the Center of Genetic Engineering and Biotechnology in Havana, Cuba, by means of its correct planning and control. For this purpose, bibliographical review as well as methods such as interviews, brainstorming, group decision-making and causes-effect diagrams was necessary. The application of the methods made it possible to carry out the diagnosis and analysis of the situation and to give a solution to the problem. The diagnosis showed that the activity does not guarantee a continuous improvement of the processes and quality of the system. Some actions were implemented, such as: Upgrading the procedures and forms of the activity, creating an organizational structure and making audit programs to accomplish different activities and processes. These actions rendered remarkable results for audits, since they included the evaluation by suppliers, the internal audits and the protocols, final reports and critical phases of the preclinical and clinical tests.

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