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BII-40

NOVEL MUCOADHESIVE TABLETS FOR TREATMENT OF ORAL CANDIDOSIS: ''IN VIVO'' EVALUATION OF THE BIOPHARMACEUTICAL PERFORMANCE.

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Mucoadhesive tablets containing nystatin (10 mg), were evaluated in vivo. The assays were carried out with 12 healthy volunteer and the concentration of nystatin in saliva was determined at different times. Tablets remained attached to the buccal mucosa during 270 min. No evidence of ulceration or bleeding was observed. Typical appearance of intact buccal mucosa was seen before and after contact with the tablet. The tablets were well accepted by the volunteers. Concentration of nystatin in saliva was several times higher than MIC over a period of approximately 4.5 hours, which was in agreement with the behavior observed in vitro. These results permit to infer that the administration of this mucoadhesive tablets could be advantageous compared to conventional formulations and mucoadhesive extended release tablets might produce better therapeutic performance than conventional formulations in the treatment of oral candidosis.

BII-41

IVERMECTIN AND NITROXYNIL CO-ADMINISTRATION IN SHEEP: EFFECT OF BODY CONDITION ON THEIR KINETIC DISPOSITION

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Ivermectin (IVM) is an endectocide compound from the avermectin family. Nitroxynil (NTX) is a trematodicidal compound. Combination of different drug molecules is a modern and challenging approach in parasite control. The aim of the present work was to study the plasma disposition of both IVM and NTX after subcutaneous (SC) co-administration to sheep with different body conditions. Two groups (n= 8) of sheep with statistical different body weight (fat and thin) were treated with *Nitromectin*® (IVM 200 µg/kg and NTX 10 mg/kg) by the SC route. Blood samples were collected up to 60 days post-treatment and plasma concentrations of IVM and NTX were determined by HPLC. IVM and NTX were well absorbed after its co-administration. Higher IVM plasma concentrations were measured in "thin" sheep compared to the "fat" group. However, NTX plasma concentrations in the thin were lower than these measured in fat group. A large volume of distribution (IVM) and high plasma protein binding (NTX) help to explain the observed pharmacokinetic differences for these drugs in animals with different body condition.

BII-42

COMPARATIVE ALBENDAZOLE SULPHOXIDE PHARMACOKINETICS AFTER SINGLE ORAL ADMINISTRATION OF THREE DIFFERENT FORMULATIONS IN DOGS.

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New therapeutics alternatives using Benzimidazole compounds are being studied to improve posology and antiparasite efficacy. The aim of this work was to compare plasma pharmacokinetics (PK) profiles of three different oral Albendazole (ABZ)-based formulations in dogs. Nine animals were randomly divided into three groups and two phases (incomplete block design). Phase I (n=9): *Group I (formulation A):* received 25 mg/kg of ABZ conventionally formulated. *Group II (formulation B)* received 25mg/kg of a modified ABZ formulation (poloxamer solid dispersion)). *Group III (Formulation C),* received Albendazole Sulfoxide (ABZSO) (equimolar dose). After 21 days of wash-out period the experiment was repeatead as Phase II. Blood samples were taken over 24h and subsequently analyzed by HPLC. ABZSO and $ABZSO_2$ were the analytes recovered in plasma. Significant *(P<0.001)* AUC values (+500%) and Cmax (+487%) for ABZSO, were obtained for the formulation C when statiscally compared with A and B. However, no statistical differences on PK parameters were found between A and B formulations. In conclusion formulation C, showed the best trend as potential antiparasite activity.

BII-43

EVALUATION OF PHARMACEUTICAL BIOEQUIVALENCE AND ANTHELMINTIC EFFICACY FOR DIFFERENT ALBENDAZOLE GENERIC FORMULATIONS IN PARASITIZED SHEEP

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Albendazole (ABZ) is a broad-spectrum anthelmintic drug widely used in human and veterinary medicine. The aim of this work was to evaluate the bioequivalence and anthelmintic efficacy of four different generic formulations of ABZ in sheep parasitized with resistant nematodes. Fifty parasitized lambs were divided into five groups (n=10): Untreated control and treated groups A (reference), B, C and D. Treated animals received different ABZ formulations (5 mg/kg). Plasma samples were collected over 3 days post-treatment and drug concentrations measured by HPLC. The efficacy of the different treatments was estimated by the faecal egg counts reduction test (FECRT). No bioequivalence was observed between the reference and either B or D generic formulations. The FECRT ranged between 36 and 59%. The study demonstrated a lack of bioequivalence for some of the generic ABZ formulations under study, which are commercially available for use in sheep.