Novel Oral Amphotericin B Formulation (iCo-010) Remains Highly Effective against Murine Systemic Candidiasis following Exposure to Tropical Temperature

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**Purpose**
To evaluate the antifungal activity of amphotericin B (AmB) following administration of a novel oral AmB formulation (iCo-010) that has been pre-exposed to tropical temperatures, in a mouse model of systemic candidiasis.

**Methods**
Amphotericin B (AmB) was prepared as a 5 mg/ml suspension in a mixture of Pecol, Gelucire 44/14 and VitE-TPGS 2,3 (iCo-010). The formulation was protected from light and incubated in a sealed container at 43°C for 60 days. Mice infected with Candida albicans were treated with either iCo-010 formulation pre-incubated at 430C for 60 days or freshly prepared iCo-010 formulation at doses of 5, 10 and 20 mg/kg once daily for 5 consecutive days. Seven days following the last dose the liver, spleen, lung, heart and brain were removed and the number of Colony forming units (CFUs) was determined as a measure of tissue fungal load. In addition, the concentration of AmB within each tissue was determined using HPLC.

**Results**
There were no significant differences in the reduction of CFUs and the concentration of AmB recovered in all organs at all iCo-010 doses tested between the freshly prepared iCo-010 formulation compared to the formulation pre-incubated at 430C for 60 days.

**Conclusion**
A novel oral Amphotericin B formulation, iCo-010, incubated at 43°C for 60 days to simulate the exposure of the formulation to tropical temperatures remained highly effective against murine systemic candidiasis.

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