CAN SOLUBILIZING EXCIPIENTS BE USED WITH THE RAT BATA MODEL TO ASSESS THE TASTE OF POORLY WATER-SOLUBLE DRUGS?

J Soto[a], A Mohamed Ahmed[a], R Turner[b], S Desset-Brethes[b], G Winzenburg[b], M Orlu Gul[a] and C Tuleu[a]

[a]UCL School of Pharmacy, 29/39 Brunswick Square, WC1N 1AX, London, United Kingdom

[b]Novartis Pharma AG, Basel, Switzerland

Introduction

Taste assessment is an important element of pharmaceutical drug development, especially for the paediatric population. The rat brief-access taste aversion (BATA) model has shown great promises in assessing the taste of aversive APIs (Rudnitskaya et al. 2013; Soto et al. 2015). However, numerous APIs are poorly soluble yet elicit an aversive taste such as hydrocortisone. Thus, there is a need to find out inherent taste characteristics of solubilizing excipients in order to solubilise poorly water-soluble APIs for taste assessment with the BATA model.

Purpose

This pilot study aims at assessing the palatability of Dimethyl sulfoxide (DMSO), a well established co-solvent not necessarily used in paediatric formulations but used at early development and screening stages.

Materials and Methods

The BATA model used ten mildly water-deprived male Sprague-Dawley rats with the lickometer "Davis Rig MS-160" which electronically records the number of licks that rats do to different DMSO concentrations (0.25-5% v/v in water) randomly presented.

Results

The data showed that DMSO could be used undetected up to 1% (49 average licks, not significantly different from water 50 licks), however even at the highest concentrations the % of lick inhibition (even if significant) was only of around 20%. No variability was observed between the two testing sessions, which confirmed the robustness of the model.

Conclusions

It was feasible to select the maximum tasteless concentration of DMSO with the rat BATA model. Further studies are planned to screen more solubilizing excipients used in Oral Formulations.

References

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