Understanding The Role Of In Vitro And In Vivo Evaluation Techniques In Determining The Performance Of Lipid Based Formulations

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OBJECTIVE
To understand the impact of In Vitro & In Vivo evaluation techniques on the performance of lipid based formulations

INTRODUCTION

Lipid Based Drug Delivery Systems

Accessibility of hydrophobic API

Assessment of solubility of hydrophobic molecules

In Vitro Lipid Digestion of life formulation

In Vitro Methods to evaluate Absorption Solubility

In Vivo Methods to evaluate Hepatic clearance/Degradation Process

Research & Development (Preclinical Studies)

Pre-Clinical Studies (Animal Studies)

In Vivo Pharmacokinetic Studies in Beagle Dogs

CONCLUSION

Although the In Vitro dissolution profiles for all the three prototypes matched with Market Reference in the three Biorelevant Medium and Distilled Water, the In Vitro Dissolution Test failed to discriminate solubilization capacity of the formulations.

In Vitro Lipolysis Test proved to be an excellent discriminatory tool to evaluate the solubilization capacity of LBDDS and to match the performance of the formulation with Market Reference.

Pharmaceutical Profiles for Curcumin formulations generated from Beagle Dog Studies were matching with the predictions in in vitro Lipolysis Test.

Beagle Dog Animal Model was found better than Wistar Rat Animal Model for evaluating the In Vivo performance of LBDDS.

This could be attributed to the larger Gut Volume of Wistar Rats in comparison to Beagle Dog rendering its digestive (in vitro Lipolysis Test) and Faecal Bacterial activity (animal studies).

Methods & Animals used for Evaluation

In Vivo Evaluation in Beagle Dogs

In Vivo Evaluation in Wistar Rats

Current Procedure

Matching of In Vivo Dissolution profiles with Market Ref

In Vivo Lipolysis Testing to understand Solubilization Capacity of Formulation

Expensive in Vivo evaluation (Preclinical Studies in Beagle Dogs)

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Current Procedure

Matching of In Vivo Dissolution profiles with Market Ref

In Vivo Lipolysis Testing to understand Solubilization Capacity of Formulation

Expensive in Vivo evaluation (Preclinical Studies in Beagle Dogs)

Table: In Vivo Pharmacokinetic Studies in Beagle Dogs

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Units</th>
<th>GPL1 (665 mg)</th>
<th>GPL2 (750 mg)</th>
<th>GPL3 (900 mg)</th>
<th>Market Reference (300 mg)</th>
<th>GPL</th>
<th>GPL2</th>
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| Parameter: PK parameters for Wistar Rat Studies

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RESULTS & DISCUSSIONS

In Vivo Lipolysis Studies

In Vivo Pharmacokinetic Studies in Beagle Dogs

In Vivo Pharmacokinetic Studies in Wistar Rats

REFERENCES
1. www.gattefosse.com