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Proposal for Formulation Development Study – *Sample*

CLIENT
COMPANY: *ABCD Therapeutics*
REPRESENTED BY: Mr. Ab Cd

CARBOHYDE
COMPILED BY: Balázs Kondoros
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1. OBJECTIVE:

The main objective is to investigate the efficiency and the solubilizing effect of preparing complexes with various cyclodextrins and the active pharmaceutical ingredient (API) requested by the CLIENT. Based on the preliminary studies a cyclodextrin will be selected and solid or liquid formulation(s) will be prepared. Forced stability studies will also be included.

2. TASK OF CARBOHYDE:

Develop a well-defined work plan and a timeline after consulting the CLIENT and reviewing the relevant literature.

An analytical method will be developed or adopted to measure the concentration of the API.

A feasibility study needs to be performed to test which pharmaceutically approved cyclodextrin is optimal for solubilizing the API. The solubility of the API will be determined in the absence as well as the presence of the following cyclodextrins:

- Alpha-cyclodextrin (10 % (w/V)) pH ranges (3-4, 5-6, 7-8)
- Beta-cyclodextrin (1.5 % (w/V)) pH ranges (3-4, 5-6, 7-8)
- Gamma-cyclodextrin (20 % (w/V)) pH ranges (3-4, 5-6, 7-8)
- Sulfobutylether-beta-cyclodextrin (20% (w/v)) pH ranges (3-4, 5-6, 7-8)
- Hydroxypropyl-beta-cyclodextrin (20% (w/v)) pH ranges (3-4, 5-6, 7-8)

In summary: 5 different cyclodextrin at 1 concentration and 3 different pH ranges with 3 parallel measurements, which adds up to 45 samples altogether. Prior to measurement, the samples will be filtered through a 0.22 µm pore-size filter.

The solubilizing potency of the cyclodextrins will be compared and 1 cyclodextrin will be selected for a comprehensive phase-solubility study after discussion with the CLIENT. Solubility isotherms of the API will be recorded at 25 °C applying the selected cyclodextrin and pH (buffered) and the complexation efficiency will be calculated.

Solid or liquid formulation(s) will be prepared with the selected cyclodextrin after discussing with the CLIENT. Prepared formulations will be stressed in a controlled environment, and various analytical tests will be performed based on the requirements of the CLIENT.

3. SECTION - DELIVERABLES

- Informal weekly status report via email
- A final report in English with the obtained experimental data (including raw data)
- 1-hour concluding videoconference to discuss and evaluate results and proposed next steps.

4. COMMERCIAL TERMS:

Fee and payment: 15,000 EUR (fifteen thousand Euros) are due to CarboHyde for activities listed under Tasks of CarboHyde, including analytical and documentation costs.[i]

[i] Disclaimer: This Sample proposal is provided for illustrative purposes only and does not constitute professional advice or a guaranteed solution. The final proposal will be customized based on information from the CLIENT, the API as well as know-how of CarboHyde.