Project ID: _____

GCC CENTER FOR COMPREHENSIVE
PK/PD & FORMULATION

GCC Center for Comprehensive PK/PD & Formulation (CCPF)

General Product Information Form

This information will be kept confidential

Please be as complete and succinct as possible; indicate if the information is not available or not applicable to your request. References may be cited. Indicate in the check boxes any information you do not wish to share with our contractors.

INFORMATION
Project Name:
Candidate Name:
Structure (if available to share):
Is this candidate a ☐ vaccine ☐ adjuvant ☐ biologic or ☐ therapeutic
To what drug class does this compound belong?
Target indication (Disease and host population, e.g. Systemic candidiasis in neutropenic hosts):
Target of drug (if known):
Mechanism of Action:
Has a stable formulation been developed? ☐ Yes ☐ No If yes, please provide information on the formulation (storage buffer, pH, salt conditions, etc.):
Is the manufacturing process appreciably developed? ☐ Yes ☐ No Please describe the current status of the manufacturing process:

Is GMP material required for requested studies? ☐ Yes ☐ No

Material grade available: ☐ cGMP ☐ Research

If Research grade:

1. Which route should be used to administer the investigational agent to animals?	☐ Oral ☐ Intravenous ☐ Subcutaneous ☐ Intramuscular ☐ Intraperitoneal ☐ Other
2. Describe any way the investigational agent may need to be prepared, reconstituted, or manipulated by the contractor prior to administration to the animals (e.g., what diluents/excipients to use, what concentrations should be achieved, should the reconstituted formulation be vortexed or sonicated, etc).	
3. If the agent is to be administered intravenously, subcutaneously, intramuscularly, or by intraperitoneal injection, should it be sterile filtered prior to administration? If so, please describe which filter to use.	
4. Does the investigational agent need to be prepared/reconstituted prior to each dose, or can it be prepared less frequently (e.g., daily, weekly)? Please provide information regarding storage conditions (e.g. frozen, refrigerated, room temperature, protected from light).	
5. Please provide the following information regarding the investigational agent once prepared for administration to animals.	pH Osmolality Pyrogenicity

Amount of candidate product available for requested studies:

Solubility (skip if this service was requested) :

Stability of candidate (skip if this service was requested) ; storage and handling conditions, MSDS, if possible (please include any product warnings, cautions and preparation instructions, e.g. filtration):

Do you have IP rights for this product? ☐ Yes ☐ No

Please provide your nondisclosure agreement if applicable.

Have you filed a patent request? ☐ Yes ☐ No

If so, please provide all key patent numbers:

DEVELOPMENT PLAN

Provide a concise scientific justification for use of this candidate. Focus specifically on:

- Purported public health impact
- Improvements in health benefits offered beyond current measure(s)
- Significance of the proposed work in the context of the overall project

Describe the overall Product Development Plan. Specifically, please describe the strategy for advancing the product and how the requested service(s) will help fill the gaps in your product development plan.

REFERENCES

Please list critical references providing relevant background information on your product.