Please fill out the answers below regarding your stability study request. It is best if a separate questionnaire is completed for each formulation. If you have any questions, please contact ARL at 405-271-1144. These answers will assist ARL in providing a quote. Thank you.

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| --- | --- |
| **QUESTIONS** | **ANSWERS** |
| 1. Please provide contact information: Name, Business Name, Address, Phone, Email, etc.
 |  |
| 1. What is the purpose of the study? (BUD, IND filing, etc.)
 |  |
| 1. What is the regulatory status needed for this study? (cGMP, non-GMP)
 |  |
| 1. Is your facility registered or does your facility plan to register with the FDA as 503B Outsourcing Facility?
 |  |
| 1. What is the active(s) and its concentration in the formulation?
 |  |
| 1. What other ingredients are included in the formulation? (Excipients, buffers, other – please specify)
 |  |
| 1. Does this product have a preservative?

If so, at what concentration? If yes, is this a new formulation? Is this a different container than the manufactured product? |  |
| 1. What is the route of administration?
 |  |
| 1. Provide description of the container and device. (Size, volume, and other details)
 |  |
| 1. Is this a single or multi-dose container?

 |  |
| 1. Provide typical and maximum batch size.
 |  |
| 1. Provide intended storage condition. (Ambient, Protected from Light, Accelerated Storage, etc.)
 |  |
| 1. Provide target expiration (12 months, etc).
 |  |
| 1. Provide a list of the tests you would like performed and the frequency.
 |  |
| 1. Provide the # of lots to be tested.
 |  |
| 1. Do you have any special requests (i.e. duplicate HPLC analysis)?
 |  |
| 1. Do you have an existing stability method to transfer?
 |  |
| 1. Are you providing a study protocol?
 |  |
| 1. Do you plan to use this test method for future release testing?
 |  |