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? |  |