1.0 **PURPOSE**

The purpose of this protocol is to monitor the stability of _____ API (Active Pharmaceutical Ingredient) at _____San Diego.

2.0 **SCOPE**

This protocol outlines the sample storage conditions and test time points required for the stability study. It also describes the testing requirements and specifications for the drug substance at each time point. In addition, this protocol includes the packaging information of _____ used in this stability study.

The _____ final product is packaged in 0.5 oz, 4 oz, and 8 oz amber glass containers. All containers are identical in material and closure system the only difference is in size. However, only 0.5 oz containers were used for the stability study. This concept is defined in ICH Q7 (section 11.52); "*Stability samples should be stored in containers that simulate the market container. For example if the API is marketed in bags with fiber drums, stability samples can be packaged in bags of the same material and in small-scale drums of similar or identical material composition to the marked drums*".

3.0 **RESPONSIBILITIES**

3.1 ____Quality Control (QC) is responsible for:

3.1.1 Preparing and executing this stability protocol;

3.1.2 Performing testing of the stability samples according to stability Protocol;

3.1.3 Reviewing test results and notifying Quality Assurance of any discrepancies or OOS results;

3.1.4 Preparing and executing summaries and Stability Reports once testing is completed.

3.2 Quality Assurance (QA) is responsible for:

3.2.1 Providing storage of stability Samples at ____ for all storage conditions;

3.2.2 Reviewing the results at each time point;

3.2.3 Reviewing and approving the stability protocol, summaries, and Final Stability Report.

4.0 MANUFACTURING AND PACKAGING INFORMATION

Code No.	_____	**Item No.**	_____	**Manufacturing Date**	_____
PPL-SD Code	_____	**Batch No.**	_____	**Packaging Date**	_____
Manufacturer and Packager	_____	**Batch Size**	_____	**Fill Weight**	_____

4.1 **Primary Packaging Container:** Depyrogenated 0.5 oz (15 mL) Amber Wide Mouth Glass Packer with Polypropylene Lid with Foam Backed Teflon™ Liner Manufactured by EP Scientific LLC (Item No. ____, Batch No. ____)

4.2 **Total Study Requirements:** __ total containers, __ stability containers and __ contingency containers. Each stability sample is dedicated for single time point use. Store samples in the freezer after removal from the stability chambers and until data review, release and all investigations are completed.

5.0 STORAGE CONDITIONS AND TESTING

5.1 Stability samples packaging and labeling is performed per _____

5.2 Follow _____ for testing. · stability samples storage, pulling and____

5.3 Table 1 describes the storage conditions and testing requirements for each time point.

5.4 Report results for each time point on the "Stability Sample Analytical Reporting Form".

5.5 If any of the specified tests fail to meet the acceptance criteria at the recommended storage condition, report result per_____, *Investigation of Out of Specification (OOS) and Out of Trend (OOT) Results*. An OOS result under accelerated storage condition (e.g. 5 ±°C or 25 ± 2°C) is not an OOS result since this is not the recommended storage condition for the Drug Substance. However, all data shall be reviewed and verified for test failure.

5.6 Report delay, omissions of time point and any other discrepancy per SOP ____.

5.7 Resolve, investigate, and close all OOS/OOT and Deviation prior to approving data for each time point.

8.4 Spreadsheet Validation:

8.4.1 All functions supplied by the applications programs (arithmetic operators, log, linear regression, sine, logical operators, etc.) do not require validation testing under the scope of this procedure.

8.4.2 Spreadsheet validation shall be documented in Laboratory Notebook – follow SOP QA-010, *Laboratory Notebooks Requirements*.

8.4.3 Formulas Printout

8.4.3.1 Create a copy of the original in the workbook.

8.4.3.2 Choose the Formulas tab and select Show Formulas. Adjust the width of the columns in order to make all formulas completely visible.