

# *Siris Pharmaceutical Services, LLC*

## **Return Reconciliation Instructions for Protocol #123-45-6789 Version 1**

### **Overview:**

**Description:** Protocol #123-45-6789 is an ongoing study involving approximately 3200 patients at 100 sites.

**Storage Condition:** Monitored, NOT controlled, Ambient. (Note – All returns for this study will subsequently be destroyed. Under no circumstance will returns be reissued to a clinical site).

**Length of Study:** 4 Years

**Length of Storage:** 4 Years, or until further notice from Client.

**Destruction:** Return Drug will not be destroyed until written authorization is obtained from Client.

**Original packaging configurations (prior to use):** Kits (kit = 1 bottle) containing 24 tablets.

**Reconciliation Level:** Tablet

### **Reconciliation:**

Kits will be shipped to Siris in corrugated shippers from investigational sites in the US. A corrugated shipper will contain used or unused kit bottles. A Return of Investigational Product/ Reconciliation Form (RIPRF) for every 10 kits returned will be enclosed in shipment to Siris.

1. When a corrugated shipper arrives at Siris, it will be issued a receiving number and logged into the CTM (Clinical Trial Material) returns receiving log. If there is any evidence of damage, the return will be placed on hold and the Client Study Project Manager will be notified immediately. If there is no RIPRF accompanying the return, the return will be placed on hold and the Client Study Project Manager will be notified.
2. Working with one receiving number at a time, open the first corrugated shipper and remove contents, including the RIPRF.
3. Reconcile the return:
  - Verify that the correct form (Return of Investigational Product/Reconciliation Form) for this protocol (Protocol # 123-45-6789) is being used.

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- Verify that the Site #, Date, Site Rep's name and signature, and Monitor's name and signature have been filled in.
  - Verify that "All kits returned have been counted on-site" is circled "yes".
  - If any discrepancies are found with the paperwork, document it in the "Siris comments" section on the RIPRF.
  - Compare information on kit labels to information on RIPRF and document subject ID# on the RIPRF.
  - Count # of tablets in each kit. Verify Siris count against Site count of returned tablets.
  - Verify that the "reason for missing materials" is filled out if kit or unused tablets are missing.
  - If any discrepancies are found with a kit, document the discrepancy in the "Discrepancies Found" column on the RIPRF with a "D:" before the discrepancy.
  - If any comments are necessary for a particular kit, document the comment in the "Discrepancies Found" column on the RIPRF with a "C:" before the comment. All general comments may be entered in the "Siris comments" section.
  - Enter the Siris RR# and date received, then initial and date the RIPRF.
4. Enter all data in the Protocol #123-45-6789 data log and email it to the Client Study Project Manager as needed. All discrepancies will be noted in the data log as "D:" then the reason for discrepancy. All comments will be noted in the data log as "C:" then the comment.
5. Store the return and record the storage location on the RIPRF. File the RIPRF and all additional paperwork in the study specific file.

Prepared by: \_\_\_\_\_  
Siris Pharmaceutical Services

\_\_\_\_\_  
Date

Approved by: \_\_\_\_\_  
Client Project Manager

\_\_\_\_\_  
Date