

APPENDIX I. PHARMACY AUDIT REPORT

**DCP PROJECT
PHARMACY AUDIT REPORT**

I. SITE INFORMATION

Instructions: Please provide the requested information for each of the items listed below.
Provide comments whenever necessary or helpful.

Name of Clinical Site:

Protocol Name:

Document Number:

Name and Address of Pharmacy:

Date of Audit:

Conducted by:

Investigational Pharmacy Personnel:

| NAME | TITLE | MET WITH MONITOR (Y/N) |
|-------------|----------------------|-------------------------------|
| | Pharmacist of Record | |
| | Other Staff / Title | |

Additional Comments:

II. MAINTENANCE OF RECORDS

Instructions: Please provide the requested information for each of the items listed below (“Y” = Yes, “N” = No). Please provide comments whenever necessary or helpful.

| ITEMS VERIFIED and/or DISCUSSED | Y | N | *NA | COMMENTS |
|---|---|---|-----|----------|
| A. Are the following protocol-specific documents present? | | | | |
| 1. Form FDA 1572 | | | | |
| 2. Prescriber signature list | | | | |
| 3. Most recent version of the protocol for which the site has IRB approval | | | | |
| 4. Participant study assignment list | | | | |
| 5. Drug ordering instructions | | | | |
| B. Are the following records accessible only to the site pharmacist or his/her designee? | | | | |
| 1. Study assignment lists | | | | |
| 2. Investigational agent accountability/inventory records | | | | |
| 3. Order forms/shipping receipts | | | | |
| 4. Participant-specific profiles, if used | | | | |

III. SECURITY AND STORAGE OF THE INVESTIGATIONAL DRUGS

| ITEMS VERIFIED and/or DISCUSSED | Y | N | *NA | COMMENTS |
|---|---|---|-----|----------|
| A. Inspect the investigational drug storage area. | | | | |
| 1. Are the investigational drugs stored according to the manufacturer’s specifications? | | | | |
| 2. Are supplies sufficient? | | | | |
| 3. Outdated drugs are not stored together with the active drug supply. | | | | |
| 4. Is refrigerator and/or freezer storage available? | | | | |
| a. If yes, describe location of refrigerator and/or freezer and method of monitoring temperature. | | | | |
| 5. Is study drug stored in a secure, limited access area? | | | | |

IV. DRUG ACCOUNTABILITY, PREPARATION AND DISPENSATION

| ITEMS VERIFIED and/or DISCUSSED | Y | N | *NA | COMMENTS |
|--|------------------------------|---|-------------------------|----------|
| A. Accountability | | | | |
| 1. Do the increases in drug inventory on the investigational accountability records agree with the shipment receipts? | | | | |
| 2. Are the accountability records legible and complete with each entry initialed by the pharmacists of record or other authorized personnel? | | | | |
| 3. Are there any entries in the accountability records that indicate dispensing of investigational agents to persons other than participants enrolled in this/these studies? | | | | |
| 4. If study drug is commercially available, are procedures in place to assure that study drug is not stored together with the general supply? | | | | |
| 5. Does the inventory balance documented on the accountability record correspond precisely with the actual physical inventory? | | | | |
| a. If No, provide actual numbers of the agent counted as well as the amount recorded on the accountability record for each discrepancy noted | | | | |
| Drug | Accountability Record | | Inventory Amount | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| Explanation/Discussion | | | | |
| 6. Is the amount of drug supply on hand reasonable based on current enrollment and accrual rate? | | | | |

IV. DRUG ACCOUNTABILITY, PREPARATION AND DISPENSATION (continued)

| ITEMS VERIFIED and/or DISCUSSED | Y | N | *NA | COMMENTS |
|---|---|---|-----|----------|
| B. Drug Preparation and Dispensing | | | | |
| 1. Describe the routine procedure for dispensing study drugs. | | | | |
| a. When, in relation to the participant study visit, is the study drug prepared? Describe: | | | | |
| b. How does the investigational pharmacist usually receive study drug prescriptions? Describe: | | | | |
| c. To whom does the investigational pharmacist dispense study drugs? Describe: | | | | |

Additional Comments:

Prepared by:

(Signature)

Date:
