Appendix I

Pharmacy Audit Report Form

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:

NCI Protocol 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. FDA Form 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 Outdated drugs are not stored together with the active drug supply.				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:

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Prepared by: Date:

(Signature)