

## Research Compliance and Quality Assurance Program (RCQA): Audit Checklist – Investigational Product (Pharmacy)

<b>Protocol Title / Code:</b>	
<b>Sponsor:</b>	
<b>PI Name:</b>	
<b>Auditor Name:</b>	
<b>Audit Date(s):</b>	
<b>Investigational Product (IP) Name(s):</b>	

<b>Storage Conditions</b>					
<b>Verification of the following:</b>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	N/A	Not Reviewed	Comments
IP(s) is stored as per temperature conditions defined in protocol and/or the Investigator’s Brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Temperature logs are filed for applicable equipment. Temperature logs include 24/7 monitoring.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Temperature deviations have been filed as appropriate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IP(s) is stored separately by protocol and strength, with containers labeled as per requirement.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IP labels all contain Health Canada required elements.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Calibration and maintenance records for equipment have been filed as appropriate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IP(s) is stored in a secured place, with restricted access.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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<b>Receipt and Destruction</b>					
<b>Verification of the following:</b>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<b>N/A</b>	<b>Not Reviewed</b>	<b>Comments</b>
Shipping receipts for IP(s) from point of manufacture to delivery to site are filed (i.e., receipts match entries on the IP accountability log, and each receipt is documented on the accountability log).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Confirmation of receipt and/or temperature log data to the sponsor is filed. Any deviations / defects upon receipt were documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Documentation of destruction is filed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Accountability</b>					
<b>Verification of the following:</b>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<b>N/A</b>	<b>Not Reviewed</b>	<b>Comments</b>
A log for each IP and dose strength is filed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Balance on logs match physical inventory.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IP(s) study supply is adequate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Expiration dates are tracked, if applicable. No expired drug has been dispensed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IP dispensing dates/doses match with source documents.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Calculations within the IP accountability log were done correctly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Accountability					
Verification of the following:	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	N/A	Not Reviewed	Comments
IP bottles were dispensed correctly according to IVRS confirmations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IP(s) returned from participant(s) are documented. Those that have not been returned have been documented and accounted for in source documents.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IP orders for each participant are filed. No IP was dispensed prior to investigator signature.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Initials on the IP accountability log are consistent with those on the training /delegation log.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<u>Blinded studies</u> : Blind has been maintained throughout the study.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<u>Blinded studies</u> : Decoding procedures are available and filed; if unblinding occurred, decoding procedures were followed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Study Documents					
Verification of the following:	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	N/A	Not Reviewed	Comments
Most recent approved version of the protocol is filed in the Pharmacy binder.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
All versions of Investigator’s Brochure(s) (IB) are filed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
All versions of instructions for handling IP(s) and trial-related materials for each IP, or equivalent, are filed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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<b>Study Documents</b>					
<b>Verification of the following:</b>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<b>N/A</b>	<b>Not Reviewed</b>	<b>Comments</b>
Sample of label(s) attached to IP container(s) are filed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<u>Investigator Sponsored Studies</u> : Certificates of analysis of IP are filed for all doses and batches received.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pharmacy Binder is labeled as per requirement (may include, but not limited to: protocol number, internal pharmacy binder number, IP name, and disease site).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Log for visiting monitors / external auditors has been signed and filed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Current version of IP order templates are filed (or available within an established electronic system).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Delegation of study tasks is clearly documented (including at satellite pharmacies).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Staff training on the following has been done in a timely fashion, documented, and filed: <ul style="list-style-type: none"> <li>• Initial protocol</li> <li>• All protocol amendments, as applicable</li> <li>• Study Pharmacy manual (all versions), if available</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<u>Randomized studies</u> : A Master Randomization list is filed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Correspondence					
Verification of the following:	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	N/A	Not Reviewed	Comments
Pharmacy agreement was executed and filed prior to site/study activation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Correspondence regarding site/study activation is filed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Correspondence to the study team regarding different stages of study is filed (including, but not limited to: start-up, interim analysis, accrual on hold, accrual closed, study termination and close out).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Notification of each amendment to the study team upon approval is filed. Study team was notified in a timely manner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

General					
Verification of the following:	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	N/A	Not Reviewed	Comments
Pharmacy SOP is available for review: contains key procedures (e.g. handling temperature excursions) and has been routinely reviewed (2-3 years).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Good documentation practices (i.e. ALCOAC principles) were followed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Documents have been correctly paginated.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Worksheets/logs/forms do not contain blank spots. Signatures/initials/dates are completed where required.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
No loose (unbound) pages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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**Additional Notes:**