# GOOD MANUFACTURING PRACTICES - AUDIT REPORT FORM (FRM-0211)
## Health Products and Food Branch Inspectorate

| HC USE ONLY | |
|---|---|
| File Number | Date/Time of Receipt |

**Please refer to the Instructions on how to complete this form.**

## GENERAL INFORMATION

### A. Submission Information

**1a. Date(s) of audit**

**1b. Purpose of audit:**

- New Establishment Licence Application ☐
- Amendment to Establishment Licence ☐
- Renewal of Establishment Licence ☐
- In Support of a Drug Submission ☐ (please specify)

**2a. Date of last inspection**

**2b. Type of last inspection:**

- Corporate Audit ☐
- Consultant Audit ☐
- Regulatory Agency ☐ (please specify)
- Qualified Authority ☐ (please specify)
- Other ☐ (please specify)

### B. Building Information

**3. Building Name**

**4. Address, Number/Street/Suite/Land Location/Plot**

| 5. City/Town | 6. Province/State | 7. Postal Code/Zip Code | 8. Country |
|---|---|---|---|
| | | | |

| 9. Telephone Number | 10. Fax Number | 11. Website |
|---|---|---|
| | | |

### C. Personnel

| 12a. Opening meeting attendees | 12b. Closing meeting attendees |
|---|---|
| | |

### D. Scope of Audit

**13. Operation(s):**

**14. Product(s)/Dosage Form(s):**

### E. Auditor Information

**15. Name(s):**

**16. Type:**
- Corporate ☐
- Consultant ☐

**17. Qualifications and experience:**

### F. Background Information:

**18.**

## Premises [C.02.004]

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|---|---|---|
| **The premises in which a lot or batch of a drug is fabricated or packaged/labelled shall be designed, constructed and maintained in a manner that** | | |
| **(a) permits the operations therein to be performed under clean, sanitary and orderly conditions;** | Yes ☐ | No ☐ |
| **(b) permits the effective cleaning of all surfaces therein; and** | Yes ☐ | No ☐ |
| **(c) prevents the contamination of the drug and the addition of extraneous material to the drug.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

### Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
|---|---|---|
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### Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

### Attachments

**Attach supporting documentation such as SOPs, action plans with timelines for each corrective action identified above.**

**List of attachments:**

| Equipment [C.02.005] | | |
|---|---|---|
| **The equipment with which a lot or batch of a drug is fabricated, packaged/labelled or tested shall be designed, constructed, maintained, operated and arranged in a manner that :** | | |
| **(a) permits the effective cleaning of its surfaces;** | Yes ☐ | No ☐ |
| **(b) prevents the contamination of the drug and the addition of extraneous material to the drug; and** | Yes ☐ | No ☐ |
| **(c) permits it to function in accordance with its intended use.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
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## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

## Attachments

**Attach supporting documentation such as SOPs, action plans with timelines for each corrective action identified above.**

**List of attachments:**

| Personnel [C.02.006] | | |
|---|---|---|
| **Every lot or batch of a drug shall be fabricated, packaged/labelled, tested and stored under the supervision of personnel who, having regard to the duties and responsibilities involved, have had such technical, academic and other training as the Director considers satisfactory in the interests of the health of the consumer or purchaser.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
|---|---|---|
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## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

## Attachments

**Attach supporting documentation such as SOPs, action plans with timelines for each corrective action identified above.**

**List of attachments:**

| Sanitation [C.02.007] | | |
|---|---|---|
| **(1) Every person who fabricates or packages/labels a drug shall have a written sanitation program that shall be implemented under the supervision of qualified personnel.** | Yes ☐ | No ☐ |
| **(2) The sanitation program referred to in subsection (1) shall include** | | |
| **(a) cleaning procedures for the premises where the drug is fabricated or packaged/labelled and for the equipment used in the fabrication or packaging/labelling; and** | Yes ☐ | No ☐ |
| **(b) instructions on the sanitary fabrication and packaging/labelling of drugs and the handling of materials used in the fabrication and packaging/labelling of drugs.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale.** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
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## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

## Attachments

**Attach supporting documentation such as SOPs, action plans with timelines for each corrective action identified above.**

**List of attachments:**

| Sanitation [C.02.008] | | |
|---|---|---|
| **(1) Every person who fabricates or packages/labels a drug shall have, in writing, minimum requirements for the health and the hygienic behaviour and clothing of personnel to ensure the clean and sanitary fabrication and packaging/labelling of the drug.** | Yes ☐ | No ☐ |
| **(2) No person shall have access to any area where a drug is exposed during its fabrication or packaging/labelling if the person** | | |
| **(a) is affected with or is a carrier of a disease in a communicable form; or** | Yes ☐ | No ☐ |
| **(b) has an open lesion on any exposed surface of the body.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
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## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

## Attachments

**Attach supporting documentation such as SOPs, action plans with timelines for each corrective action identified above.**

**List of attachments:**

## Raw Material Testing [C.02.009]

| | | |
|---|---|---|
| **(1) Each lot or batch of raw material shall be tested against the specifications for that raw material prior to its use in the fabrication of a drug.** | Yes ☐ | No ☐ |
| **(2) No lot or batch of raw material shall be used in the fabrication of a drug unless that lot or batch of raw material complies with the specifications for that raw material.** | Yes ☐ | No ☐ |
| **(3) Notwithstanding subsection (1), water may, prior to the completion of its tests under that subsection, be used in the fabrication of a drug.** | Yes ☐ | No ☐ |
| **(4) Where any property of a raw material is subject to change on storage, no lot or batch of that raw material shall be used in the fabrication of a drug after its storage unless the raw material is retested after an appropriate interval and complies with its specifications for that property.** | Yes ☐ | No ☐ |
| **(5) Where the specifications referred to in subsections (1), (2) and (4) are not prescribed, they shall** | | |
| **(a) be in writing;** | Yes ☐ | No ☐ |
| **(b) be acceptable to the Director who shall take into account the specifications contained in any publication mentioned in Schedule B to the Act; and** | Yes ☐ | No ☐ |
| **(c) be approved by the person in charge of the quality control department.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
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| Corrective actions |
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| **Detail the corrective action(s) taken and/or to be taken.** |

| Attachments |
| --- |
| **Attach supporting documentation such as SOPs, action plans with timelines for each corrective action identified above.**<br>**List of attachments:** |

| Raw Material Testing [C.02.010] | | |
|---|---|---|
| **(1) The testing referred to in section C.02.009 shall be performed on a sample taken** | | |
| **(a) after receipt of each lot or batch of raw material on the premises of the fabricator; or** | Yes ☐ | No ☐ |
| **(b) subject to subsection (2), before receipt of each lot or batch of raw material on the premises of the fabricator, if** | Yes ☐ | No ☐ |
| **(i) the fabricator** | | |
| **(A) has evidence satisfactory to the Director to demonstrate that raw materials sold to him by the vendor of that lot or batch of raw material are consistently manufactured in accordance with and consistently comply with the specifications for those raw materials, and** | | |
| **(B) undertakes periodic complete confirmatory testing with a frequency satisfactory to the Director, and** | | |
| **(ii) the raw material has not been transported or stored under conditions that may affect its compliance with the specifications for that raw material.** | | |
| **(2) After a lot or batch of raw material is received on the premises of the fabricator, the lot or batch of raw material shall be tested for identity.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
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## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

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| Manufacturing Control [C.02.011] | | |
|---|---|---|
| **(1) Every fabricator, packager/labeller, distributor referred to in paragraph C.01A.003(*b*) and importer of a drug shall have written procedures prepared by qualified personnel in respect of the drug to ensure that the drug meets the specifications for that drug.** | Yes ☐ | No ☐ |
| **(2) Every person required to have written procedures referred to in subsection (1) shall ensure that each lot or batch of the drug is fabricated, packaged/labelled and tested in compliance with those procedures.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
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## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

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**List of attachments:**

| Manufacturing Control [C.02.012] | | |
|---|---|---|
| **(1) Every fabricator, packager/labeller, distributor referred to in section C.01A.003, importer and wholesaler of a drug shall maintain** | | |
| **(a) a system of control that permits complete and rapid recall of any lot or batch of the drug that is on the market; and** | Yes ☐ | No ☐ |
| **(b) a program of self-inspection.** | Yes ☐ | No ☐ |
| **(2) Every fabricator and packager/labeller and, subject to subsections (3) and (4), every distributor referred to in paragraph C.01A.003(*b*) and importer of a drug shall maintain a system designed to ensure that any lot or batch of the drug fabricated and packaged/labelled on premises other than their own is fabricated and packaged/labelled in accordance with the requirements of this Division.** | Yes ☐ | No ☐ |
| **(3) The distributor referred to in paragraph C.01A.003(*b*) of a drug that is fabricated, packaged/labelled and tested in Canada by a person who holds an establishment licence that authorizes those activities is not required to comply with the requirements of subsection (2) in respect of that drug.** | Yes ☐ | No ☐ |
| **(4) If a drug is fabricated or packaged/labelled in an MRA country at a recognized building, the distributor referred to in paragraph C.01A.003(*b*) or importer of the drug is not required to comply with the requirements of subsection (2) in respect of that activity for that drug if** | | |
| **(a) the address of the building is set out in that person's establishment licence; and** | Yes ☐ | No ☐ |
| **(b) that person retains a copy of the batch certificate for each lot or batch of the drug received by that person.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
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| Corrective actions |
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| **Detail the corrective action(s) taken and/or to be taken.** |
| **Attachments** |
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| Quality Control Department [C.02.013] | | |
|---|---|---|
| **(1) Every fabricator, packager/labeller, distributor referred to in paragraph C.01A.003(*b*) and importer shall have on their premises in Canada a quality control department that is supervised by personnel described in section C.02.006.** | Yes ☐ | No ☐ |
| **(2) The quality control department referred to in subsection (1) shall be a distinct organizational unit that functions and reports to management independently of any other functional unit, including the manufacturing, processing, packaging or sales unit.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
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## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

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| Quality Control Department [C.02.014] | | |
|---|---|---|
| **(1) No lot or batch of drug shall be made available for sale unless the sale of that lot or batch is approved by the person in charge of the quality control department.** | Yes ☐ | No ☐ |
| **(2) A drug that is returned to the fabricator, packager/labeller, distributor referred to in paragraph C.01A.003(*b*) or importer thereof shall not be made available for further sale unless the sale of that drug is approved by the person in charge of the quality control department.** | Yes ☐ | No ☐ |
| **(3) No lot or batch of raw material or of packaging/labelling material shall be used in the fabrication or packaging/labelling of a drug unless the material is approved for that use by the person in charge of the quality control department.** | Yes ☐ | No ☐ |
| **(4) No lot or batch of a drug shall be reprocessed without the approval of the person in charge of the quality control department.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
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## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

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**List of attachments:**

| Quality Control Department [C.02.015] | | |
|---|---|---|
| **(1) All fabrication, packaging/labelling, testing, storage and transportation methods and procedures that may affect the quality of a drug shall be examined and approved by the person in charge of the quality control department before their implementation.** | Yes ☐ | No ☐ |
| **(2) The person in charge of the control department shall cause to be investigated every complaint on quality that is received and cause corrective action to be taken where necessary.** | Yes ☐ | No ☐ |
| **(3) The person in charge of the quality control department shall cause all tests or examinations required pursuant to this Division to be performed by a competent laboratory.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
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## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

| Attachments |
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| **Attach supporting documentation such as SOPs, action plans with timelines for each corrective action identified above.**<br><br>**List of attachments:** |

| Packaging Material Testing [C.02.016] | | |
|---|---|---|
| **(1) Each lot or batch of packaging material shall, prior to its use in the packaging of a drug, be examined or tested against the specifications for that packaging material.** | Yes ☐ | No ☐ |
| **(2) No lot or batch of packaging material shall be used in the packaging of a drug unless the lot or batch of packaging material complies with the specifications for that packaging material.** | Yes ☐ | No ☐ |
| **(3) The specifications referred to in subsections (1) and (2) shall** | | |
| **(*a*) be in writing;** | Yes ☐ | No ☐ |
| **(*b*) be acceptable to the Director who shall take into account the specifications contained in any publication mentioned in Schedule B to the Act; and** | Yes ☐ | No ☐ |
| **(c) be approved by the person in charge of the quality control department.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

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| No. | Observations | Risk Classification |
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| Packaging Material Testing [C.02.017] | | |
|---|---|---|
| **(1) The examination or testing referred to in section C.02.016 shall be performed on a sample taken** | | |
| **(*a*) after receipt of each lot or batch of packaging material on the premises of the person who packages a drug; or** | Yes ☐ | No ☐ |
| **(*b*) subject to subsection (2), before receipt of each lot or batch of packaging material on the premises of the person who packages a drug, if** | Yes ☐ | No ☐ |
| **(i) that person** | | |
| **(A) has evidence satisfactory to the Director to demonstrate that packaging materials sold to him by the vendor of that lot or batch of packaging material are consistently manufactured in accordance with and consistently comply with the specifications for those packaging materials, and** | | |
| **(B) undertakes periodic complete confirmatory examination or testing with a frequency satisfactory to the Director,** | | |
| **(ii) the packaging material has not been transported or stored under conditions that may affect its compliance with the specifications for that packaging material.** | | |
| **(2) After a lot or batch of packaging material is received on the premises of the person who packages a drug,** | | |
| **(*a*) the lot or batch of the packaging material shall be examined or tested for identity; and** | Yes ☐ | No ☐ |
| **(*b*) the labels shall be examined or tested in order to ensure that they comply with the specifications for those labels** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
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| Corrective actions |
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| **Detail the corrective action(s) taken and/or to be taken.** |
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| **<u>Attach</u> supporting documentation such as SOPs, action plans with timelines for each corrective action identified above.**<br>**List of attachments:** |

| Finished Product Testing [C.02.018] | | |
|---|---|---|
| **(1) Each lot or batch of a drug shall, prior to its availability for sale, be tested against the specifications for that drug.** | Yes ☐ | No ☐ |
| **(2) No lot or batch of a drug shall be available for sale unless it complies with the specifications for that drug.** | Yes ☐ | No ☐ |
| **(3) The specifications referred to in subsections (1) and (2) shall** | | |
| **(*a*) be in writing;** | Yes ☐ | No ☐ |
| **(*b*) be approved by the person in charge of the quality control department; and** | Yes ☐ | No ☐ |
| **(c) comply with the Act and these Regulations.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
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## Corrective actions

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## Attachments

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**List of attachments:**

| Finished Product Testing [C.02.019] | | |
|---|---|---|
| **(1) Subject to subsections (3) and (4), in the case of a packager/labeller, distributor referred to in paragraph C.01A.003(*b*) or importer, the testing referred to in section C.02.018 shall be performed on a sample taken** | | |
| **(*a*) after receipt of each lot or batch of the drug on the premises in Canada of the packager/labeller, distributor referred to in paragraph C.01A.003(*b*) or importer of the drug; or** | Yes ☐ | No ☐ |
| **(*b*) subject to subsection (2), before receipt of each lot or batch of the drug on the premises described in paragraph (*a*), if** | Yes ☐ | No ☐ |
| **(i) the packager/labeller, distributor referred to in paragraph C.01A.003(*b*) or importer** | | |
| **(A) has evidence satisfactory to the Director to demonstrate that drugs sold to him by the vendor of that lot or batch of the drug are consistently manufactured in accordance with and consistently comply with the specifications for those drugs, and** | | |
| **(B) undertakes periodic complete confirmatory testing with a frequency satisfactory to the Director, and** | | |
| **(ii) the drug has not been transported or stored under conditions that may affect its compliance with the specifications for that drug.** | | |
| **(2) Where the packager/labeller, distributor referred to in paragraph C.01A.003(*b*) or importer of a drug receives a lot or batch of the drug on their premises in Canada, and the useful life of the drug is more than 30 days, the lot or batch shall be tested for identity, and the packager/labeller shall confirm the identity after the lot or batch is packaged/labelled.** | Yes ☐ | No ☐ |
| **(3) The distributor referred to in paragraph C.01A.003(*b*) of a drug that is fabricated, packaged/labelled and tested in Canada by a person who holds an establishment licence that authorizes those activities is not required to comply with the requirements of subsections (1) and (2) in respect of that drug.** | Yes ☐ | No ☐ |
| **(4) If a drug is fabricated, packaged/labelled and tested in an MRA country at a recognized building, the distributor referred to in paragraph C.01A.003(*b*) or importer of that drug is not required to comply with the requirements of subsections (1) and (2) in respect of that drug if** | | |
| **(*a*) the address of the building is set out in that person's establishment licence; and** | Yes ☐ | No ☐ |
| **(*b*) that person retains a copy of the batch certificate for each lot or batch of the drug received by that person.** | Yes ☐ | No ☐ |
| **If yes, describe.**<br>**If no, provide a rationale** (e.g. Not applicable because…) | | |

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
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## Attachments

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**List of attachments:**

| Records [C.02.020] | | |
|---|---|---|
| **(1) Every fabricator, packager/labeller, distributor referred to in paragraph C.01A.003(*b*) and importer shall maintain on their premises in Canada, for each drug sold,** | | |
| **(*a*) master production documents for the drug;** | Yes ☐ | No ☐ |
| **(*b*) evidence that each lot or batch of the drug has been fabricated, packaged/labelled, tested and stored in accordance with the procedures described in the master production documents;** | Yes ☐ | No ☐ |
| **(*c*) evidence that the conditions under which the drug was fabricated, packaged/labelled, tested and stored are in compliance with the requirements of this Division;** | Yes ☐ | No ☐ |
| **(*d*) evidence establishing the period of time during which the drug in the container in which it is sold will meet the specifications for that drug; and** | Yes ☐ | No ☐ |
| **(*e*) adequate evidence of the testing referred to in section C.02.018.** | Yes ☐ | No ☐ |
| **(2) Every distributor referred to in paragraph C.01A.003(*b*) and importer shall make available to the Director, on request, the results of testing performed on raw materials and packaging/labelling material for each lot or batch of a drug sold.** | Yes ☐ | No ☐ |
| **(3) Every fabricator shall maintain on his premises** | | |
| **(*a*) the written specifications for the raw material; and** | Yes ☐ | No ☐ |
| **(*b*) adequate evidence of the testing of the raw materials referred to in section C.02.009.** | Yes ☐ | No ☐ |
| **(4) Every person who packages a drug shall maintain on his premises**<br>**(*a*) the written specifications for the packaging material; and**<br>**(*b*) adequate evidence of the packaging material examination or testing referred to in section C.02.016.** | Yes ☐ | No ☐ |
| **(5) Every fabricator shall maintain on their premises in Canada** | | |
| **(*a*) detailed plans and specifications of each building in Canada at which they fabricate, package/label or test; and** | Yes ☐ | No ☐ |
| **(*b*) a description of the design and construction of those buildings.** | Yes ☐ | No ☐ |
| **(6) Every fabricator, packager/labeller and tester shall maintain on their premises in Canada details of the personnel employed to supervise the fabrication, packaging/labelling and testing, including each person's title, responsibilities, qualifications, experience and training.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

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| No. | Observations | Risk Classification |
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## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

## Attachments

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**List of attachments:**

| Records [C.02.021] | | |
|---|---|---|
| **(1) Subject to subsection (2), all records and evidence on the fabrication, packaging/labelling, testing and storage of a drug that are required to be maintained under this Division shall be retained for a period of at least one year after the expiration date on the label of the drug, unless otherwise specified in the person's establishment licence.** | Yes ☐ | No ☐ |
| **(2) All records and evidence on the testing of raw materials and packaging/labelling materials that are required to be maintained under this Division shall be retained for a period of at least five years after the materials were last used in the fabrication or packaging/labelling of a drug, unless otherwise specified in the person's establishment licence.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
|---|---|---|
| | | |
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| | | |

## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

| Attachments |
| --- |
| **Attach supporting documentation such as SOPs, action plans with timelines for each corrective action identified above.**<br><br>**List of attachments:** |

| Records [C.02.022] | | |
|---|---|---|
| **Every distributor referred to in section C.01A.003, wholesaler and importer of a drug shall retain records of the sale of each lot or batch of the drug, which enable them to recall the lot or batch from the market, for a period of at least one year after the expiration date of that lot or batch, unless otherwise specified in their establishment licence.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
|---|---|---|
| | | |
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## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

## Attachments

**<u>Attach</u> supporting documentation such as SOPs, action plans with timelines for each corrective action identified above.**

**List of attachments:**

| Records [C.02.023] | | |
|---|---|---|
| **(1) On receipt of a complaint respecting the quality of a drug, every distributor referred to in paragraph C.01A.003(*b*) and importer of the drug shall make a record of the complaint and of its investigation and retain the record for a period of at least one year after the expiration date of the lot or batch of that drug, unless otherwise specified in their establishment licence.** | Yes ☐ | No ☐ |
| **(2) On receipt of any information respecting the quality or hazards of a drug, every distributor referred to in paragraph C.01A.003(*b*) and importer of the drug shall make a record of the information and retain it for a period of at least one year after the expiration date of the lot or batch of that drug, unless otherwise specified in their establishment licence.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
|---|---|---|
| | | |
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## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

| Attachments |
| --- |
| **Attach supporting documentation such as SOPs, action plans with timelines for each corrective action identified above.**<br><br>**List of attachments:** |

| Records [C.02.024] | | |
|---|---|---|
| **(1) Every fabricator, packager/labeller, distributor referred to in section C.01A.003, importer and wholesaler shall** | | |
| **(*a*) maintain records of the results of the self-inspection program required by section C.02.012 and of any action taken in connection with that program; and** | Yes ☐ | No ☐ |
| **(*b*) retain those records for a period of at least three years.** | Yes ☐ | No ☐ |
| **(2) Every person who fabricates or packages/labels a drug shall** | | |
| **(*a*) maintain records on the operation of the sanitation program required to be implemented under section C.02.007; and** | Yes ☐ | No ☐ |
| **(*b*) retain those records for a period of at least three years.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
|---|---|---|
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## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

| Attachments |
| --- |
| **Attach supporting documentation such as SOPs, action plans with timelines for each corrective action identified above.**<br><br>**List of attachments:** |

| Samples [C.02.025] | | |
|---|---|---|
| **(1) Every distributor referred to in paragraph C.01A.003(*b*) and importer of a drug shall retain in Canada a sample of each lot or batch of the packaged/labelled drug for a period of at least one year after the expiration date on the label of the drug, unless otherwise specified in the distributor's or importer's establishment licence.** | Yes ☐ | No ☐ |
| **(2) The fabricator shall retain a sample of each lot or batch of raw materials used in the fabrication of a drug for a period of at least two years after the materials were last used in the fabrication of the drug, unless otherwise specified in the fabricator's establishment licence.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
|---|---|---|
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| | | |
| | | |

## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

## Attachments

**Attach supporting documentation such as SOPs, action plans with timelines for each corrective action identified above.**

**List of attachments:**

| Samples [C.02.026] | | |
|---|---|---|
| **The samples referred to in section C.02.025 shall be in an amount that is sufficient to determine whether the drug or raw material complies with the specifications for that drug or raw material.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
|---|---|---|
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| | | |

## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

## Attachments

**Attach supporting documentation such as SOPs, action plans with timelines for each corrective action identified above.**

**List of attachments:**

## Stability [C.02.027]

| Every distributor referred to in paragraph C.01A.003(*b*) and importer shall establish the period of time during which each drug in the package in which it is sold will comply with the specifications. | Yes ☐ | No ☐ |
|---|---|---|

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
|---|---|---|
| | | |
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| | | |

## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

## Attachments

**Attach supporting documentation such as SOPs, action plans with timelines for each corrective action identified above.**

**List of attachments:**

| Stability [C.02.028] | | |
|---|---|---|
| **Every distributor referred to in paragraph C.01A.003(*b*) and importer shall monitor, by means of a continuing program, the stability of the drug in the package in which it is sold.** | Yes ☐ | No ☐ |

**If yes, describe.**

**If no, provide a rationale** (e.g. Not applicable because…)

## Deviations

**Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable.**

| No. | Observations | Risk Classification |
|---|---|---|
| | | |
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| | | |

## Corrective actions

**Detail the corrective action(s) taken and/or to be taken.**

## Attachments

**Attach supporting documentation such as SOPs, action plans with timelines for each corrective action identified above.**

**List of attachments:**

| Overall Rating | | |
|---|---|---|
| **This audit has demonstrated that the building(s), practice(s), procedure(s) used for conducting activities at this facility comply with the Good Manufacturing Practices set out in Division 2 of the *Food and Drug Regulations*.** | Yes ☐ | No ☐ |
| **If yes, describe**. (e.g., The establishment has responded adequately to the deficiencies noted during this audit.)<br>**If no, provide a rationale** (e.g. Not applicable because…) | | |

| ATTESTATION | | |
|---|---|---|
| **I hereby certify that all information contained in, or referenced by, this report is true, accurate and complete. No information is false or misleading; no omissions have knowingly been made that may affect its accuracy and completeness.** | | |
| Name(s) of Auditor<br>(Please print) | Signature(s) of Auditor | Date yyyy-mm-dd |

| ATTESTATION (if applicable) | | |
|---|---|---|
| **I hereby confirm that the facility referenced in Section B of this report is committed to implementing the appropriate changes, in order to comply with Division 2 of the *Food and Drug Regulations*.** | | |
| Name of Authorized Signing Official<br>(Please print) | Signature of Authorized Signing Official | Date yyyy-mm-dd |