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# Inspection tracker: Drug manufacturing establishments

As part of Health Canada's ongoing commitment to openness and transparency, the Department is publishing information regarding emerging issues identified through our drug inspection program.

This tracker provides a snapshot of the potential health and safety issues Health Canada is tracking with companies that fabricate, package/label, test, wholesale, distribute or import drugs for sale in Canada. The information in the chart will expand to eventually include details about affected Canadian companies and products.

## How the inspection tracker works

- Health Canada responds to potential risks as soon as we hear about them whether from our own inspections, the companies themselves, adverse reaction reports or from our regulatory partners.
- The tracker highlights actions Health Canada is taking such as: requests for voluntary quarantine, stop sales, import restrictions, or product recalls. It also indicates those circumstances where no action has been warranted.
- Even if a company is listed on the tracker, it doesn't necessarily mean there is an immediate risk to the health of Canadians. It means Health

Canada is looking into a potential issue.

- Health Canada will continue to take action to manage risks identified to the health of Canadians using the most appropriate level of intervention, proportional to the risk to health.
- This tracker currently doesn't list specific drugs and health products affected but links to [Recalls and Safety Alerts](#) if a risk has been linked to specific products on the Canadian market.
- This tracker is updated regularly.
- Once an item is listed in the closed section, it indicates that there is no further action being taken by Health Canada at this time and there will be no more updates regarding this item.
- Last update: **September 21, 2022**

## Open items

| Establishment   | Status of issue  | Source of information under review | Primary reason for action |
|---|--|------------------------------------|---------------------------|
| <b>Accu Bio-Chem Laboratories</b><br>1755 Victory Boulevard, Glendale, CA, 91201, United States | <ul style="list-style-type: none"> <li>• Canadian importer(s) contacted by Health Canada for information</li> <li>• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)</li> <li>• No further action required by Health Canada at this time</li> </ul> | Regulatory Partner(s)              | General GMP observations  |

| <b>Establishment</b>  | <b>Status of issue</b>   | <b>Source of information under review</b> | <b>Primary reason for action</b> |
|---|--|---|----------------------------------|
| <p><b>Advanced Accelerator Applications USA, Inc.</b><br/>57 East Willow Street, Millburn, NJ, 07041, United States</p>           | <ul style="list-style-type: none"> <li>• Canadian importer(s) contacted by Health Canada for information</li> <li>• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)</li> </ul> | Regulatory Partner(s)                     | General GMP observations         |
| <p><b>Bharat Biotech International Limited</b><br/>Sy. No. 230, 231 and 235, Turkapally, Telangana, India, 00078</p>              | <ul style="list-style-type: none"> <li>• Canadian importer(s) contacted by Health Canada for information</li> <li>• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)</li> </ul> | Regulatory Partner(s)                     | General GMP observations         |
| <p><b>CTX Lifesciences Private Ltd.</b><br/>Block No. 251-252 Sachin-Magdalla Road, GIDC, Sachin, Surat 394230 Gujarat, India</p> | <ul style="list-style-type: none"> <li>• Canadian importer(s) contacted by Health Canada for information</li> <li>• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)</li> </ul> | Regulatory Partner(s)                     | General GMP observations         |









| Establishment  | Status of issue  | Source of information under review | Primary reason for action |
|--|--|------------------------------------|---------------------------|
| <b>Jost Chemicals Co.</b><br>8150 Lackland Rd.<br>Saint Louis,<br>Missouri, US<br><b>NEW</b>   | <ul style="list-style-type: none"> <li>• Canadian importer(s) contacted by Health Canada for information</li> <li>• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)</li> </ul> | Regulatory Partner(s)              | General GMP observations  |
| <b>Lupin Limited Unit 1</b><br>Unit 1, 198-202 New Ind Area No 2,<br>Mandideep<br>Madhya Pradesh,<br>India                             | <ul style="list-style-type: none"> <li>• Canadian importer(s) contacted by Health Canada for information</li> <li>• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)</li> </ul> | Regulatory Partner(s)              | General GMP observations  |
| <b>Pharmactive ilac San. ve Tic. A.S.</b><br>Karaagag Mahallesi<br>Fatih Bulvari,<br>Kapakli, Tekirdag,<br>59510, Turkey<br><b>NEW</b> | <ul style="list-style-type: none"> <li>• Canadian importer(s) contacted by Health Canada for information</li> <li>• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)</li> </ul> | Regulatory Partner(s)              | General GMP observations  |









Filter items









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Closed items









| <b>Establishment</b>   | <b>Status of issue</b>    | <b>Source of information under review</b>   | <b>Primary reason for action</b>   |
|--|---|---|--|
| <p><b>Acharya Chemicals</b><br/>W41 &amp;W42, MIDC<br/>Industrial estate -<br/>Morivali Village, 421501<br/>AMBARNATH (W) (Dist<br/>Thane), 42150, India</p>                             | <ul style="list-style-type: none"> <li>• Canadian importer contacted by Health Canada for information</li> <li>• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)</li> <li>• No further action required by Health Canada at this time</li> </ul> | <p>Regulatory Partner(s)</p>  | <p>General GMP observations</p>  |









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|---|--|--|---|
| <p><b>Actavis Laboratories, FL. Inc.,</b><br/>4955 Orange Drive,<br/>Davie, Fort Lauderdale,<br/>Florida, USA, 33314</p>  | <ul style="list-style-type: none"> <li>• Canadian importer contacted by Health Canada for information</li> <li>• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)</li> <li>• Medically necessary products identified.</li> <li>• Issued terms and conditions to Canadian importer(s)</li> <li>• No further action required by Health Canada at this time</li> </ul> | <p>Regulatory Partner(s)</p>   | <p>General GMP observations</p>   |





| Establishment   | Status of issue    | Source of information under review   | Primary reason for action   |
|---|--|--|---|
| <p><b>Agila Onco Therapies Ltd.</b><br/>Plot No. 284/B<br/>Bommasandra Jigani<br/>Link Road, Industrial<br/>Area, Bangalore,<br/>Karnataka, India</p>                             | <ul style="list-style-type: none"> <li>• Non-compliant rating issued</li> <li>• No further action required by Health Canada at this time</li> </ul> <p>Related recalls and alerts:</p> <ul style="list-style-type: none"> <li>• <u>Methotrexate Injection USP 50 mg/2 mL - Voluntary Recall Due to the Potential Presence of Foreign Particulate Matter</u></li> </ul> | <ul style="list-style-type: none"> <li>• Regulatory Partner(s)</li> <li>• Canadian importer(s)</li> </ul>  | <p>General GMP observations</p>   |
| <p><b>AGILA SPECIALTIES PRIVATE LTD.</b><br/>Opp II M, Bilekahalli,<br/>Bannerghatta Road,<br/>Bangalore, Karnataka,<br/>India - 560 076</p>                                      | <ul style="list-style-type: none"> <li>• Canadian importer(s) contacted by Health Canada for information</li> <li>• No critical risks identified to date</li> <li>• No further action required by Health Canada at this time</li> </ul>  | <p>Regulatory Partner(s)</p>   | <p>General GMP observations</p>   |
|   |  |  |   |









| <b>AGILA SPECIALTIES PRIVATE LTD., SPECIALTY FORMULATION</b><br>Establishment   | <b>Status of issue</b>    | <b>Source of information under review</b>   | <b>General GMP observations Primary reason for action</b>   |
|---|---|---|---|
| <b>FACILITY (SFF)</b><br>19A, Plot No. 284-B/1<br>Bommasandra Jigani<br>Link Road, Anekal<br>Taluk, Bangalore India<br>- 560 105  | <ul style="list-style-type: none"> <li>• Canadian importer(s) contacted by Health Canada for information</li> <li>• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)</li> <li>• Medically necessary products identified</li> <li>• Requested voluntary quarantine of non-medically necessary products</li> <li>• Voluntary quarantine in place</li> <li>• Issued terms and conditions to Canadian importer(s)</li> <li>• No further action required by Health Canada at this time</li> </ul> |   |   |











| Establishment   | Status of issue     | Source of information under review   | Primary reason for action   |
|---|---|--|---|
| <p><b>Akorn Inc.</b><br/>1222 West Grand Ave<br/>Decatur, IL<br/>USA, 62522-1412</p>  | <ul style="list-style-type: none"> <li>• Canadian importer contacted by Health Canada for information</li> <li>• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)</li> <li>• No further action required by Health Canada at this time</li> </ul> | <p>Regulatory Partner(s)</p>   | <p>General GMP observations</p>   |

| Establishment   | Status of issue     | Source of information under review   | Primary reason for action   |
|---|---|--|---|
| <p><b>Akorn Inc.</b><br/>72 Veronica Ave,<br/>Somerset NJ, 08873,<br/>USA</p>   | <ul style="list-style-type: none"> <li>• Canadian importer contacted by Health Canada for information</li> <li>• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)</li> <li>• No further action required by Health Canada at this time</li> </ul> | <p>Regulatory Partner(s)</p>   | <p>General GMP observations</p>   |

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|--|--|--|---|
| <p><b>AllerQuest LLC</b><br/>           10 Farmington Valley Drive, Suite 106<br/>           Plainville, Connecticut 06062-1182, United States</p> | <ul style="list-style-type: none"> <li>• Canadian importer contacted by Health Canada for information</li> <li>• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)</li> <li>• Medically necessary products identified</li> <li>• Terms and Conditions applied</li> </ul> | <p>Regulatory Partner(s)</p>   | <p>General GMP observations</p>   |

| Establishment   | Status of issue    | Source of information under review   | Primary reason for action   |
|---|--|--|---|
| <p><b>Amanta Healthcare Ltd.</b><br/>Plot No 876 NH No 8,<br/>Hariyala Matar Kheda,<br/>Gujarat, 387411, India</p>  | <ul style="list-style-type: none"> <li>• Canadian importer(s) contacted by Health Canada for information</li> <li>• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)</li> <li>• Medically necessary products identified</li> <li>• Issued terms and conditions to Canadian importer(s)</li> <li>• No further action required by Health Canada at this time</li> </ul> | <p>Regulatory Partner(s)</p>   | <p>General GMP observations</p>   |

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|---|--|--|---|
| <p><b>Antibioticos do Brasil</b><br/>                     Rod. Professor Zeferino Vaz, Km135-SP332, Cosmopolis, Sao Paulo, Brazil<br/>                     13150-000</p>          | <ul style="list-style-type: none"> <li>• Canadian importer(s) contacted by Health Canada for information</li> <li>• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)</li> <li>• Medically necessary products identified</li> <li>• Issued terms and conditions to Canadian importer(s)</li> </ul> | <p>Regulatory Partner(s)</p>   | <p>General GMP observations</p>   |

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**Date modified:**

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