

## Government of Canada

## Gouvernement du Canada

<u>Canada.ca</u> ➤ <u>Departments and agencies</u> ➤ <u>Health Canada</u> ➤ <u>Drugs and health products</u>

> Reports and Publications - Drugs and Health Products > Compliance and Enforcement

# 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 <u>Recalls and Safety Alerts</u> 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 <u>closed section</u>, 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: May 29, 2024

#### **Open items**

Establishment	Status of issue	Source of information under review	Primary reason for action
Bell International Laboratories, Inc. 2950 Lexington Avenue South, Eagan, MN, 55121, United States	<ul> <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
Everest Organics Limited Sadasivpet Mandal, Aroor Village, Telangana, 502291, India New	<ul> <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
Natco Pharma Limited Kothur Village, Kothur Mandal, Rangareddy District, Telangana, 509228, India	<ul> <li>Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner</li> <li>Canadian importer(s) contacted by Health Canada for information</li> </ul>	Regulatory Partner(s)	General GMP observations

Establishment	Status of issue	Source of information under review	Primary reason for action
Sri Krishna Pharmaceuticals Ltd. Unit II, A-34 & A-35, IDA, Nacharam, Medchal- Malkajgiri District, Hyderabad, Telangana, India, 500076	<ul> <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
Westwood Laboratories Inc. 710 South Ayon Avenue, Azusa, CA, 91702, United States New	<ul> <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	Show 10 > entries
	Snow 10 $\checkmark$ entries

#### **Closed items**

		Source of information	Primary
	Status of	under	reason for
Establishment 🕇 🖶	issue ↑↓	review 1	action <b>↑</b> ↓

/30/24, 1:27 PM	Inspection tracker: Drug mani	ufacturing establishments - Canada ı	a.ca
1	<b>↑</b>	1	<b>1</b>
Abraxis Bioscience LLC 620 N. 51st Avenue, Phoenix, AZ, 85043, United States	<ul> <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

		-	
1	<b>+</b>	1	1
Accra Pac Inc. dba Voyant Beauty 1919 Superior Street, Elkhart, IN, 46516-4707, United States	<ul> <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

30/24, 1.27 PW		diacturing establishments - Canada	
<b>1</b>	1	<b>1</b>	<b>↑</b>
Accu Bio-Chem Laboratories 1755 Victory Boulevard, Glendale, CA, 91201, United States	<ul> <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

mapocalon tracker. Drug manufacturing establishments Canada.ca			
1	<b>↑</b>	1	1
Acharya Chemicals W41 &W42, MIDC Industrial estate - Morivali Village, 421501 AMBARNATH (W) (Dist Thane), 42150, India	<ul> <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>	Regulatory Partner(s)	General GMP observations

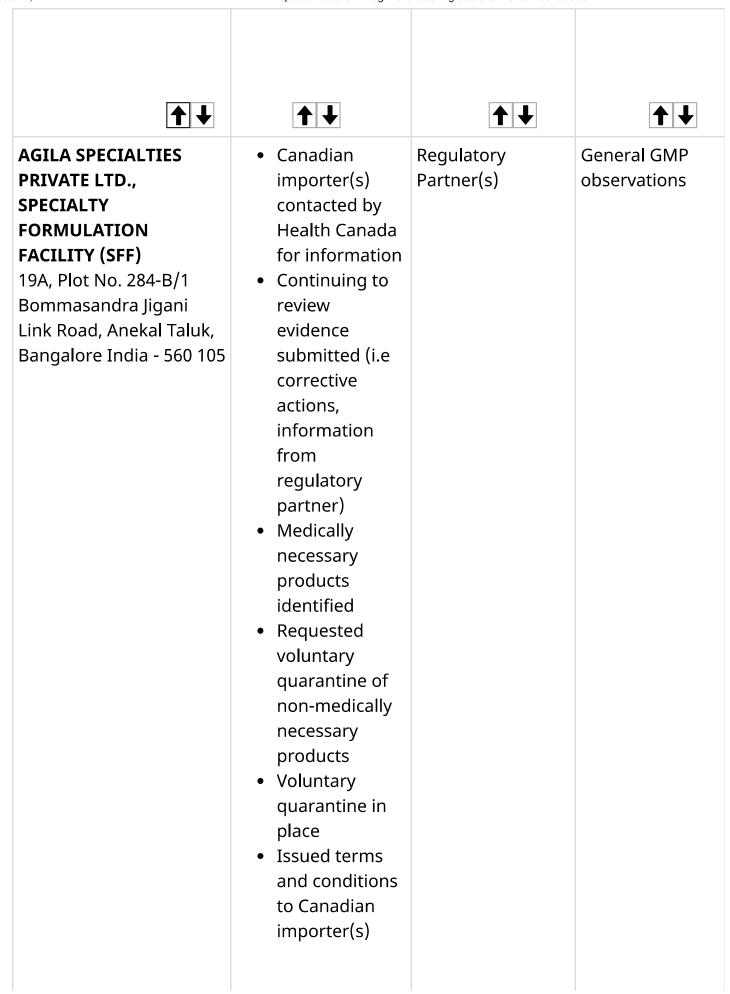
	, ,	diactaring establishments Canada	
Actavis Laboratories, FL. Inc., 4955 Orange Drive, Davie, Fort Lauderdale, Florida, USA, 33314	• Canadian importer contacted by Health Canada for information	Regulatory Partner(s)	General GMP observations
Fiorida, USA, 33314	<ul> <li>Continuing to review evidence 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</li> </ul>		
	Canada at this time		

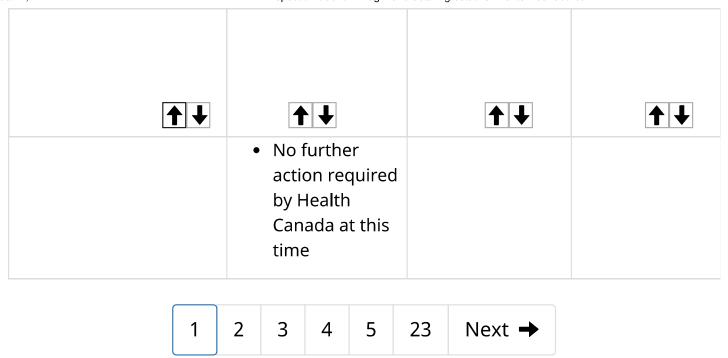
inspection tracker. Drug manufacturing establishments Canada.ca			
<b>1</b>	1	<b>↑</b>	1
Advanced Accelerator Applications USA, Inc. 57 East Willow Street, Millburn, NJ, 07041, United States	<ul> <li>Canadian importer(s) contacted by Health Canada for information</li> <li>Continuing to review evidence 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

50/24, 1.27 PW	mapeedon tracker. Drug man	Tracturing establishments - Canada	1.00
1	<b>↑</b>	1	<b>↑</b>
Advanced Cosmetic Research Laboratories Inc 20550 Prairie St, Chatsworth, CA, 91311, United States	<ul> <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>1</b>	1	1	1
Agila Onco Therapies Ltd. Plot No. 284/B Bommasandra Jigani Link Road, Industrial Area, Bangalore, Kamataka, India	<ul> <li>Non-compliant rating issued</li> <li>No further action required by Health Canada at this time</li> <li>Related recalls and alerts:</li> <li>Methotrexate Injection USP 50 mg/2 mL - Voluntary Recall Due to the Potential Presence of Foreign Particulate Matter</li> </ul>	<ul> <li>Regulatory Partner(s)</li> <li>Canadian importer(s)</li> </ul>	General GMP observations

	Inspection tracker. Drug mane		
AGILA SPECIALTIES PRIVATE LTD. Opp II M, Bilekahalli, Bannerghatta Road, Bangalore, Karnataka, India - 560 076	<ul> <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>	Regulatory Partner(s)	General GMP observations





#### **Date modified:**

2024-05-29