



Toxics Link  
for a toxics-free world

# PHARMACEUTICAL POLLUTION IN INDIA

AN EMERGING  
CONCERN



## **ABOUT TOXICS LINK**

Set up in 1996, Toxics Link is an Indian environmental research and advocacy organization engaged in disseminating information to help strengthen the campaign against toxics pollution, provide cleaner alternatives and bring together groups and people affected by the problem. Toxics Link's Mission Statement: "Working together for environmental justice and freedom from toxics. We have taken upon ourselves to collect and share both information about the sources and the dangers of poisons in our environment and bodies, and information about clean and sustainable alternatives for India and the rest of the world."

The organisation's unique expertise lies in the areas of hazardous, medical and municipal waste, international waste trade, and the emerging issues of pesticides, Persistent Organic Pollutants (POPs), hazardous heavy metal contamination, etc. from the environment and public health point of view. We have successfully implemented various best practices and have brought in policy changes in the aforementioned areas apart from creating awareness among several stakeholder groups.

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## Table of

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# Contents

<b>Acknowledgements</b>	<b>v</b>
<b>Abbreviations</b>	<b>vi</b>
<b>Chapter I About Pharmaceutical Pollution</b>	<b>1</b>
<b>Chapter II Status of Pharmaceutical Industry</b>	<b>4</b>
Global Pharmaceutical Industry	4
Pharmaceutical Industry in India	5
The Growth Story of Indian Pharma Industry	6
India: An emerging production hub of pharmaceuticals	7
<b>Chapter III Pharmaceutical Pollution: A Global Challenge</b>	<b>8</b>
Impacts of Pharmaceutical Pollutants on Ecosystem	8
Impacts of Pharmaceutical Pollution on Human Health	10
<b>Chapter IV Global Regulatory Mechanisms Addressing Pharmaceutical Pollution</b>	<b>11</b>
European Union	11
United States Environmental Protection Agency	12
Strategic Approach to International Chemicals Management (SAICM)	12
<b>Chapter V Pharmaceutical Pollution: An Emerging Concern for India</b>	<b>14</b>
Patancheru: A Wake-up Call!!	15
Pharmaceutical Pollution in Other Parts of India	16
<b>Chapter VI Pharmaceutical Pollution in Baddi-Barotiwal-Nalagarh (BBN)</b>	<b>19</b>
Environmental Challenges in Baddi-Barotiwal-Nalagarh Cluster	20
Issue of Common Effluent Treatment Plant in Baddi	20
<b>Chapter VII Toxics Link's Assessment in Baddi-Nalagarh Industrial Area</b>	<b>23</b>
Indicative Research Study	23
Overall Observation	23
Sampling Locations	24
Results and Discussion	25

<b>Chapter VIII Conclusion and Recommendations</b>	<b>27</b>
Conclusion	27
Recommendations	28
<b>ANNEX 1</b>	<b>29</b>
Test Methodology	29
<b>List of Figures</b>	
Figure 1   Export and Import in Pharmaceutical Sector	6
Figure 2   State Wise Distribution of Pharmaceutical Manufacturers in India (Annual report 2010-2011)	7
Figure 3   Baddi Industrial Hub on the Banks of Sirsa River	21
Figure 4   Sampling Point 1	24
Figure 5   Sampling Point 2	24
<b>List of Tables</b>	
Table 1    Concentration of Pharmaceutical Compounds in Water	25

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We extend our gratitude to The Shriram Institute of Industrial Research and Spectro Laboratory from New Delhi for doing the analysis of collected water samples.

# Abbreviations

<b>AIIMS</b>	All India Institute of Medical Sciences
<b>AMR</b>	Anti-microbial resistance
<b>APIs</b>	Active Pharmaceutical Ingredients
<b>APPCB</b>	Andhra Pradesh Pollution Control Board
<b>BBN</b>	Baddi Barotiwalu Nalagarh
<b>CAGR</b>	Compound Annual Growth Rate
<b>CETP</b>	Common Effluent Treatment Plant
<b>CETP</b>	Common Effluent Treatment Plant
<b>CPCB</b>	Central Pollution Control Board
<b>EPSPs</b>	Environmentally Persistent Pharmaceutical Pollutants
<b>ERA</b>	Environmental Risk Assessment
<b>EU</b>	European Union
<b>FDPs</b>	Finished Dosed Products
<b>GATT</b>	General Agreement on Tariffs and Trade
<b>GC-MS</b>	Gas chromatography–mass spectrometry
<b>GDP</b>	Gross-Domestic Product
<b>HIV</b>	Human immunodeficiency virus
<b>HPPCB</b>	Himachal Pradesh Pollution Control Board
<b>IBEF</b>	The India Equity Brand Foundation
<b>LC-MS</b>	Liquid chromatography–mass spectrometry
<b>MDR-TB</b>	Multi-drug resistant Tuberculosis
<b>MNCs</b>	Multi-national companies
<b>MOEFCC</b>	Ministry of Environment, Forest and Climate Change
<b>NEERI</b>	National Environmental Engineering Research Institute
<b>NEIPP</b>	North East Industrial and Investment Promotion Policy
<b>ng/l</b>	Nano-gram per litre
<b>NGO</b>	Non-governmental organizations
<b>NGT</b>	National Green Tribunal
<b>NPPA</b>	National Pharmaceutical Pricing Authority
<b>PETL</b>	Patancheru Enviro Tech Limited



<b>PFI</b> s	Pharmaceutical Formulation Intermediates
<b>SAICM</b>	Strategic Approach to International Chemicals Management
<b>SDWA</b>	Safe Drinking Water Act
<b>SPCB</b>	State Pollution Control Board
<b>STP</b>	Sewage Treatment Plant
<b>STWs</b>	Sewage Treatment Works
<b>TSDF</b>	Treatment Storage and Disposal Facility
<b>USA</b>	United States of America
<b>USEPA</b>	United States Environmental Protection Agency
<b>WHO</b>	World Health Organization
<b>WWTP</b>	Waste Water Treatment Plant
<b>ZLD</b>	Zero-liquid discharge



## Chapter I

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# About Pharmaceutical Pollution

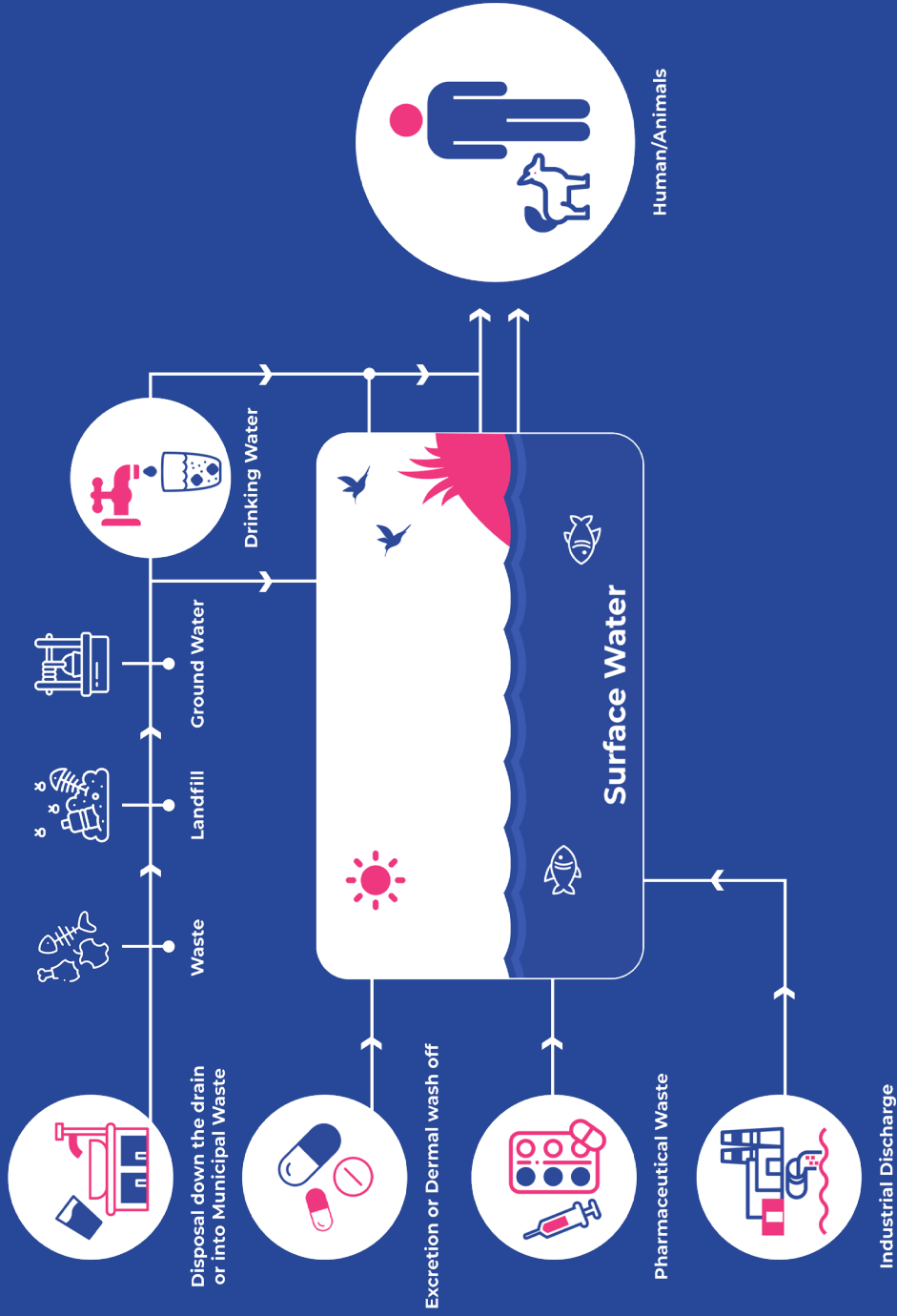
Pharmaceuticals, are synthetic chemicals used in different medicines or drugs essentially for the prevention and treatment of diseases. As per The World Health Organization<sup>1</sup>, the ubiquitous use of pharmaceuticals in human and veterinary medical practices, aquaculture and agricultural products have led to the continual release of a wide array of pharmaceutical chemicals into our environment.

APIs are biologically active non-biodegradable compounds present in the environment. They do not readily go under metabolization in human or animal body and are excreted as such. They are designed in a way to have a longer lifetime inside the human or the animal body to have maximum effect on the target organisms. Owing to this property, these compounds have high persistence once in the environment. However, some of the compounds are found to be excreted in their parent form with very little degradation or transformation, e.g. Amoxicillin (80–90% excretion in parent form) and some are degraded almost entirely and are excreted in their metabolic forms<sup>2</sup>. This raises an immediate need to trace the degradation rates, half-lives, persistence and mobility of pharmaceutical pollutants in the environment.

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1 Pharmaceuticals in Drinking Water, World Health Organization, 2012

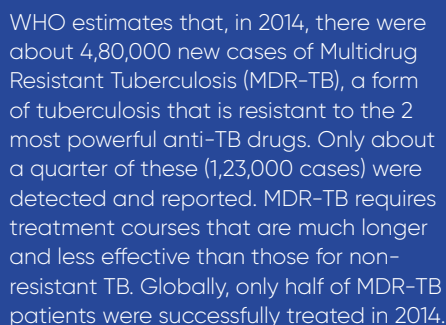
2 Dosed Without Prescription: Preventing Pharmaceutical Contamination of Our Nation's Drinking Water; NRDC White Paper, 2009



In the last two decades, more than 100 APIs have been detected globally in effluents discharges, surface waters, ground and drinking water and soil. A global study<sup>3</sup> has detected over 600 APIs and their metabolites in 71 countries. The major sources of these compounds are through effluent discharge of poorly controlled manufacturing or production facilities, primarily those associated with generic medicines. Other than that, discharge from the health care facilities and discharge through excretion are also contributing factors. Practice of discarding unused or expired drugs into the waste stream are also identified as sources of pharmaceutical presence in the environment.

Across the globe, including India, APIs have emerged as the major concern and many factors including the poor treatment of the effluents by drug manufacturing facilities, high-consumption rate of medicines, over prescription and the tendency to self-medicate coupled with poor disposal facilities are contributing significantly to the APIs in the environment.

Further, many of the anti-microbials and antibiotics led to the development of resistant microbes leading to Anti-Microbial Resistance (AMR) which is also a threat to human health today. As a result, the medicines of even the most curable diseases are becoming ineffective and infections persist in the body, also increasing the risk of spread in others.



WHO estimates that, in 2014, there were about 4,80,000 new cases of Multidrug Resistant Tuberculosis (MDR-TB), a form of tuberculosis that is resistant to the 2 most powerful anti-TB drugs. Only about a quarter of these (1,23,000 cases) were detected and reported. MDR-TB requires treatment courses that are much longer and less effective than those for non-resistant TB. Globally, only half of MDR-TB patients were successfully treated in 2014.

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<sup>3</sup> Pharmaceuticals in the environment– the global perspective; Occurrence, effects, and potential cooperative action under SAICM, 2014

# Status of Pharmaceutical Industry



### Global Pharmaceutical Industry

Pharmaceutical industry is one of the largest industries in the world and has expanded globally. Incidentally in USA, pharma industries were found to be continually growing even when there was no growth observed in other top industries there. It is reported that the global pharmaceutical market is expected to be worth 1.57 trillion by 2023<sup>4</sup>. In 2019, the world's largest pharmaceutical exporters and importers are shown in graphic below.

#### World's Largest Pharmaceutical Exporters<sup>5</sup>

1. Germany: \$84.7 billion
2. Switzerland: \$71.7 billion
3. United States: \$49.7 billion
4. Belgium: \$45.7 billion
5. Ireland: \$40 billion

#### World's Largest Pharmaceutical Importers<sup>6</sup>

1. United States: \$99.7 billion
2. Germany: \$53.7 billion
3. Belgium: \$36.7 billion
4. United Kingdom: \$33.8 billion
5. Switzerland: \$29.3 billion

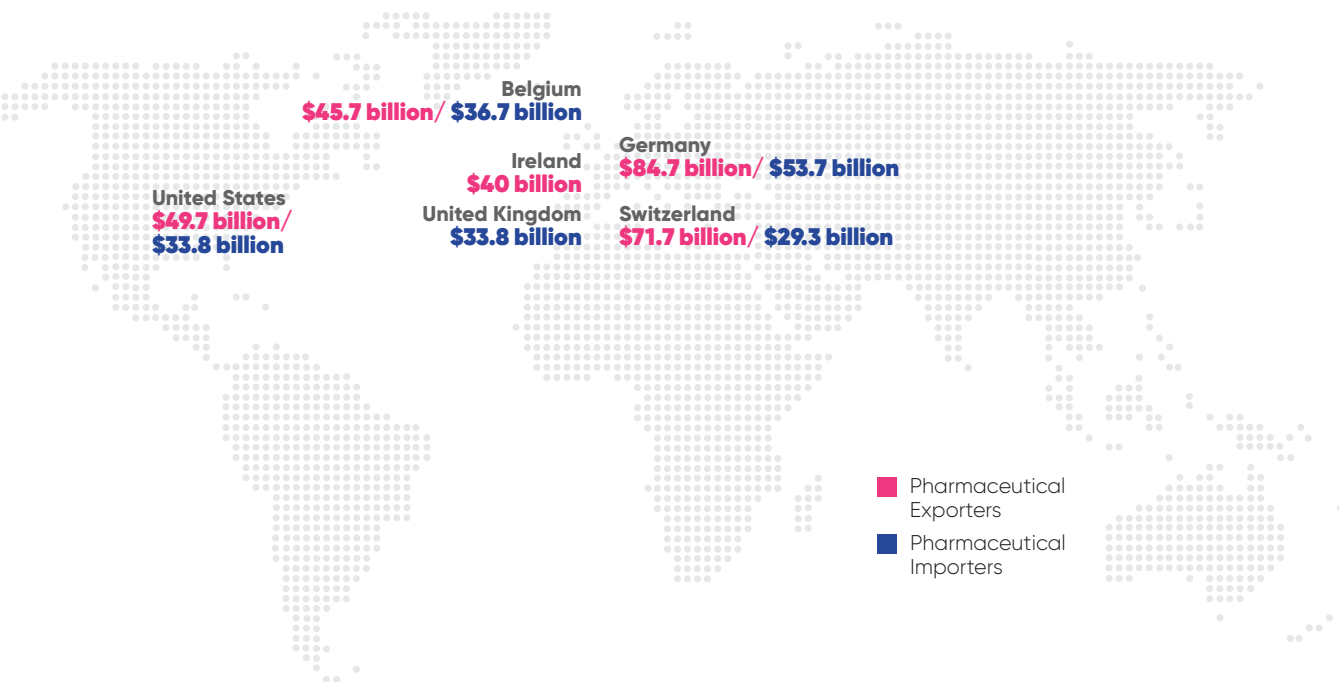
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4 <https://www.navadhi.com/publications/global-pharmaceuticals-industry-analysis-and-trends-2023>

5 <https://howmuch.net/articles/pharmaceutical-trade-around-the-world>

6 <https://howmuch.net/articles/pharmaceutical-trade-around-the-world>





## Pharmaceutical Industry in India

Indian pharmaceutical sector is currently the third largest in terms of volume and tenth largest in terms of value and contributes 1.72% to the GDP (as per the Annual report 2019-2020 of the Department of Pharmaceuticals). The country is the largest provider of generic drugs globally; it accounts for 20%<sup>7</sup> of the global exports. It is the source of 60,000 generic brands across 60 therapeutic categories and manufactures more than 500 different APIs. Pharma Vision 2020, launched by the Government of India in 2016, aimed to make India a major hub for end-to-end drug discovery.

**India's  
Pharmaceutical  
Sector: Third  
Largest Industry  
in the World - By  
Volume**

The Indian Pharmaceutical sector was valued at USD 33 billion in 2017. The India Equity Brand Foundation (IBEF), a body set up by the country's Ministry of Commerce and Industry has predicted that the pharmaceutical industry is expected to grow at a CAGR of 22.4% in the future. It is expected to grow to USD 100 billion by 2025<sup>8</sup>.

India is also amongst the top 20 pharmaceutical markets exporting to more than 200 countries with its major destinations being USA, Russia, Germany, Austria, UK, West Europe, Japan and

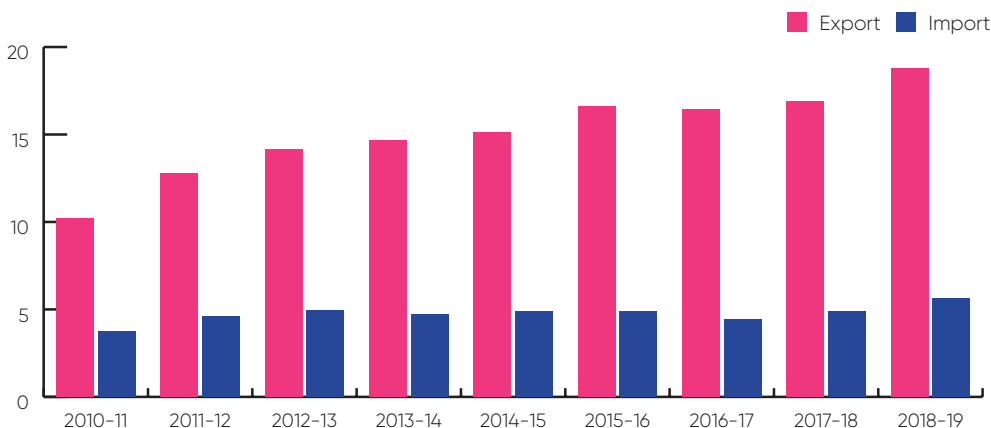
<sup>7</sup> Pharmaceuticals, IBEF, 2019

<sup>8</sup> Impacts of Pharmaceutical Pollution on Communities and Environment in India - Nordea Asset Management, 2016

Australia<sup>9</sup>. It ranked 11 in the top exporting countries in the year 2019. Despite being a major exporting country, it still relies on China for its APIs and it imports around \$3.5 billion worth of APIs (produced at a very low-cost) every year, mostly from China<sup>10</sup>.

The following figure demonstrates an increasing trend of both exports and imports to/from the country over the last few years:

**Figure 1 Export and Import in Pharmaceutical Sector**



(Source: Annual Report, Department of Pharmaceuticals)

## The Growth Story of Indian Pharma Industry

Until 1970s, the majority of India's medicines were supplied by international corporations with limited manufacturing facilities in India. The GATT agreement and the new patent regime adopted by the country to make medicines affordable to the poor, combined with the growth in contract manufacturing and outsourcing by multinational companies (MNCs) to low-cost Indian suppliers, led to the rapid development of India's generic drugs sector, often described as the 'backbone' of the country's pharmaceutical industry<sup>11</sup>. The industry has been growing ever since not only meeting the domestic but also the global demands. The primary reason for India being one of the major countries producing most of the drugs is because of:

- **Low-cost of production:** It is estimated that India's cost of production is 33% lower than that of the US<sup>12</sup>.
- **Cost efficiency:** The country has the ability to produce high quality, low-cost drugs for the domestic and the global market.

<sup>9</sup> Pharma 2020: The Vision by Government of India

<sup>10</sup> Impacts of Pharmaceutical Pollution on Communities and Environment in India - Nordea Asset Management, 2016

<sup>11</sup> Impacts of Pharmaceutical Pollution on Communities and Environment in India - Nordea Asset Management, 2016

<sup>12</sup> Pharmaceutical Report, 2019, IBEF



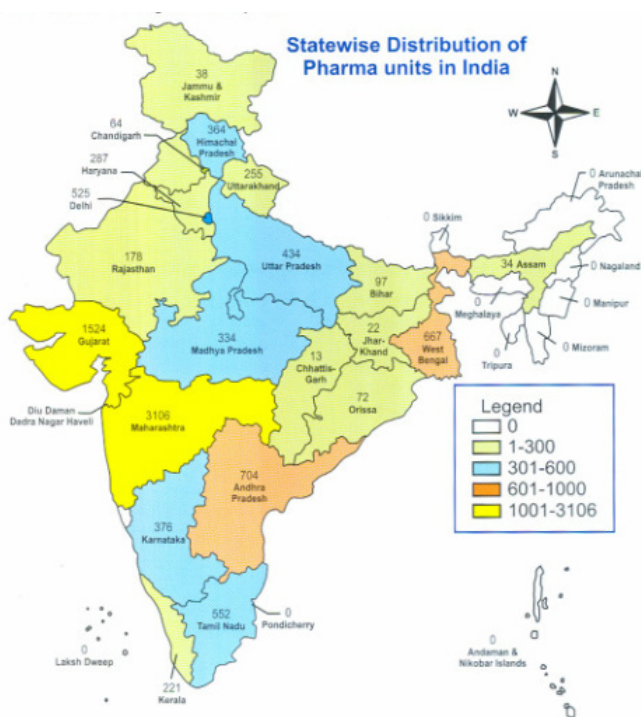
- **Increased private sector investment:** The investments have been increasing specially in the R and D sector.
- **Policy support:** The government has been extending economic and other benefits to the industry to expand and increase the production capacity by allocating funds, land, and reduction in the project approval time, provide tax benefits, etc.

## India: An emerging production hub of pharmaceuticals

Over the last few decades, India has emerged as an important pharmaceutical production hub of the world. The Indian pharmaceutical manufacturing companies are present at each stage of the production process: APIs; Pharmaceutical Formulation Intermediates (PFIs); and Finished Dose Products (FDPs, the end product). Though the country relies on China for most of its APIs needs and uses them to produce the FDPs, the government policy shifting towards producing APIs is leading to more and more companies producing them in-house.

As per the Directory of Pharmaceutical Manufacturing Units in India – National Pharmaceutical Pricing Authority (NPPA), 2007, the country has 10563 pharmaceutical manufacturers<sup>13</sup> with the maximum of them concentrated in 5 states namely, Maharashtra (29.7%), Gujarat (14.4%), West Bengal (7.2%), Andhra Pradesh (6.9%) and Tamil Nadu (5.4%). The following map shows the state wise distribution of pharmaceutical manufacturers in India:

**Figure 2 State Wise Distribution of Pharmaceutical Manufacturers in India (Annual report 2010-2011)**



However, recently Baddi of Himachal Pradesh and Sikkim have emerged as the new pharmaceutical production hub of the country.

<sup>13</sup> Directory of Pharmaceutical Manufacturing Units in India - National Pharmaceutical Pricing Authority, 2007

# Pharmaceutical Pollution: A Global Challenge

In the last few decades studies have confirmed the Pharmaceutical ingredients are being increasingly detected in all the environmental matrices including surface water, ground water, drinking water, soil, biota, etc. across the globe. This can lead to adverse impacts on the human health and environment.

## Impacts of Pharmaceutical Pollutants on Ecosystem

The scientific bodies, regulatory agencies, institutions and civil society organizations have published research studies on the impact of pharma pollution on the ecosystem. Incidentally this kind of pollution is not just a local problem as the contaminants travel through multiple sources and can thus reach a completely different location than its point of production, use or disposal. For instance, a 2010 study by Swedish researchers showed that seven out of eight travellers to India returned to Sweden carrying drug-resistant bacteria in their gut<sup>14</sup>.

The impacts of the presence of drugs in the environment and its affects are being observed since a few years now. Globally the issue of fish feminization was the first indicative study on how the presence of

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<sup>14</sup> Hyderabad's Pharmaceutical Pollution Crisis: Heavy Metal and Solvent Contamination at Factories in a Major Indian Drug Manufacturing Hub

a particular drug Estrogen, like Ethinyl estradiol, a component of the contraceptive pill was responsible for disappearance of a particular fish species<sup>15</sup>. This phenomenon was though reported first in the UK, but later found to be widespread in many countries.

A study conducted by IWW<sup>16</sup> in the year 2014 reviewed existing studies and found that more than 600 APIs or their metabolites have been detected in 71 countries with Diclofenac having the highest range of being present in 50 countries. A number of compounds like Ibuprofen, Propranolol, Erythromycin, Ofloxacin, Oxytetracycline, and Fluoxetine have also been reported in sludge from STWs in UK<sup>17</sup>. When this sludge is used as manure, it will lead to contaminated soil and thus contaminated crops.

Studies have also reported compounds like 17 $\beta$ -estradiol and 17 $\alpha$ -ethinyl estradiol (causing reproductive disorders) and other antibiotics in both surface and drinking water but these are found in very low concentrations<sup>18</sup> (ng/l) and thus what effects they are causing or they will be causing is still debatable but the indication of their presence is in itself a cause of concern. The World Health Organization, in 2012, reported 25 different pharmaceutical compounds in drinking water across the globe<sup>19</sup>.

It is difficult to ascertain the detrimental impacts of the wildlife from pharmaceutical pollutants however laboratory studies have confirmed the impact from pharmaceutical pollution. In a laboratory study, Fong & Ford, 2014, presence of certain antidepressants in the water altered spawning and larval release in bivalves (molluscs) and disrupted locomotion and reduced fertility in snails. Also, in a laboratory experiment conducted by Foster et al., 2010, Fluoxetine was found to cause delayed tadpole development in Leopard frog (*Rana pipiens*)<sup>20</sup>. The

### Cocktail Effect

It refers to the cumulative impact of pharmaceutical compounds when they react with one another or they react with other chemicals already present in the environment, such as pesticides. It is a major contributor to the development of anti-microbial resistance. The presence of this mix of pharmaceuticals affect the microbial colony of the concerned environmental matrix leading to the development of resistant strains of microbes.

The persistent and diffuse exposure to low doses of pharmaceutical synthetic chemicals, for long periods of time, is not well known or studied. These compounds have a potential to bio accumulate and bio magnify in the organisms and can thus reach high trophic levels finally causing health implications to humans.

15 Pharmaceuticals in the Environment: A Growing Threat to Our Tap Water and Wildlife, Chem Trust, December, 2014

16 Pharmaceuticals in the Environment – The Global Perspective; Occurrence, Effects, and Potential Cooperative Action Under SAICM, 2014

17 Targeted Monitoring Programme for Pharmaceuticals in the Aquatic Environment, 2003

18 Pharmaceuticals in the environment: A growing threat to our tap water and wildlife, Chem Trust, December, 2014

19 Pharmaceuticals in drinking water, WHO, 2012

20 <https://www.ncbi.nlm.nih.gov/pubmed/20836066>

antidepressant Oxazepam was found to alter the behaviour and feeding rate of the wild fish species *Perca fluviatilis*<sup>21</sup>.

Apart from being present in the environment and having its own detrimental impacts, such compounds are capable of reacting with other chemical pollutants which may lead to creation of more toxic compounds. This is commonly known as a '**Cocktail Effect**'.

## Impacts of Pharmaceutical Pollution on Human Health

The impacts of pharmaceutical pollution on human health has not been studied in detail. In order to understand human health implications of pharmaceutical pollutants, a number of laboratory studies are being conducted which can be extrapolated to identify the possible human health impacts.

As per World Health Organization, in 2016, 4,90,000 people developed multidrug resistant TB globally and drug resistance is starting to complicate the fight against HIV and malaria, as well. The United Nations stated that drug-resistant diseases could cause 10 million deaths each year by 2050 and damage to the economy as catastrophic as the 2008–2009 global financial crisis<sup>22</sup>.

Another study claimed that contamination of water resources with anti-microbial pharmaceuticals is one of the major causes of spread of resistant microbes. It has been estimated that about 58,000 new-borns die from multidrug-resistant infections every year<sup>23</sup>.

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21 SAICM/ICCM/4/7

22 <https://www.who.int/news-room/detail/29-04-2019-new-report-calls-for-urgent-action-to-avert-antimicrobial-resistance-crisis>

23 <https://www.pharmaceutical-technology.com/features/pharma-and-the-environment-pollution-trend/#:~:text=The%20pollution%20of%20pharma%20products,animals%20reliant%20on%20that%20water.&text=Credit%3A%20Shutterstock.-,The%20pollution%20of%20pharma%20products%20into%20local%20water%20sources%20can,animals%20reliant%20on%20that%20water.>

# Global Regulatory Mechanisms Addressing Pharmaceutical Pollution

The issue of pharmaceutical pollution has emerged as a major challenge across the world and therefore suitable regulations have been mooted by the countries to reduce and minimise the impact of pharma pollution. Some of the major regulatory bodies have addressed the issue and have devised certain regulations which are detailed below.

## European Union

The European Union, has mandated assessment of the newly manufactured drugs prior to being put in the market. The assessment is known as an Environmental Risk Assessment (ERA)<sup>24</sup> (EC 2001a, b). Despite of some drawbacks in the ERA mechanism, as per regulation 726/2004 (as amended) a Member State may suspend the use of either a veterinary or human pharmaceutical in its territory in order to protect human health and environment.

EU has also taken actions to address the issue of anti-microbial resistance and issued an Action Plan in 2011, which was later revised in 2017.

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<sup>24</sup> Pharmaceuticals in the Environment: A Growing Threat to our Tap water and Wildlife; Chem Trust, 2014

In 2019, the EU submitted 'European Union Strategic Approach to Pharmaceuticals in the Environment'<sup>25</sup> in accordance with the EU Priority Substances Directive (2008/105/EC5 as amended by Directive 2013/39/EU6) and proposed a strategy to reduce the impact of pharma ingredients on different ecosystems.

## United States Environmental Protection Agency

The US Environment Protection Agency's Clean-water Act has given guidelines for the effluents from pharmaceutical industry. The guidelines have given standards only for the chemicals specific to pharmaceutical industry, thus no specific mention of APIs or their metabolites. Under the Safe Drinking Water Act (SDWA), eleven pharmaceutical chemicals like 17- $\alpha$ -estradiol, 17- $\beta$ -estradiol, Erythromycin, Ethinylestradiol, Mestranol, Norethindrone, Estrone, etc. have been listed.

In 2019, The US EPA issued a new regulation 'Management Standards for Hazardous Waste Pharmaceuticals' (US EPA, 2019)<sup>26</sup> to eliminate the intentional disposal of hazardous waste pharmaceuticals (both prescription and over-the-counter, non-credible and evaluated hazardous) to sewer systems. As per the regulation, Hazardous waste pharmaceuticals must be disposed off in permitted hazardous waste facilities for combustion or incineration.

Recognising the role of the pharma sector, 13 global pharma companies signed a declaration to address the environmental impact of manufacturing discharges at the United Nations General Assembly 2016

Source: <https://www.downtoearth.org.in/news/waste/bitter-medicine-57879>

## Strategic Approach to International Chemicals Management (SAICM)

The SAICM is a global policy framework adopted in 2006 to minimise and reduce the impact of chemicals on the environment and human health. In 2015, SAICM addressed Environmentally Persistent Pharmaceutical Pollutants (EPPPs) as an emerging issue due to the rising concentration of pharmaceutical compounds and their impacts on environment and health<sup>27</sup>.

<sup>25</sup> [https://ec.europa.eu/environment/water/water-dangersub/pdf/strategic\\_approach\\_pharmaceuticals\\_env.PDF](https://ec.europa.eu/environment/water/water-dangersub/pdf/strategic_approach_pharmaceuticals_env.PDF)

<sup>26</sup> <https://www.oecd-ilibrary.org/sites/4781cb74-en/index.html?itemId=/content/component/4781cb74-en>

<sup>27</sup> SAICM/ICCM.4/7; Implementation towards the achievement of the 2020 goal of sound chemicals management: emerging policy issues and other issues of concern: proposal on environmentally persistent pharmaceutical pollutants as a new emerging policy issue, 2015

## Regulations in India

Government of India, in January 2020 notified an amendment to the Environment (Protection) Rules. Although, it is still in the draft stage, the finalized regulations may be notified soon.

This amendment is specific to the Bulk and Formulation viz. Pharmaceutical industry. Other than general effluent parameters, the standard for APIs has been added as **0.05 mg/l**. The most important addition to the rules is the concentration values of antibiotic residues in the treated effluent of any bulk drug and formulation as well for Common Effluent Treatment Plant (CETP). It has listed out a total of 121 antibiotics against their concentration values. For e.g.:

- **Itraconazole- 0.004 µg/l**
- Amoxicillin- 0.10 µg/l
- Azithromycin- 0.01 µg/l
- Ciprofloxacin- 0.02 µg/l
- **Sulfadiazine- 288 µg/l**

The regulation also describes Zero Liquid Discharge (ZLD). ZLD system in Bulk Drug and Formulation Industry is considered when treated effluent meeting the limits prescribed for compulsory parameters shall be used in Process or Utilities (boiler/ cooling tower, etc.). The reuse of treated effluent in gardening/ horticulture shall not be considered as ZLD in Bulk Drug and Formulation Industries.

# Pharmaceutical Pollution: An Emerging Concern for India

India has emerged as a major hub for the bulk and generic drug production, as the country has observed an increasing trend in the number of drug manufacturing units in the last three decades. Further a major policy thrust also played a key factor in making it one of the top most destinations of pharmaceutical production. At the same time, due to lack of infrastructure and pollution control mechanisms, the pharmaceutical sector also evolved as one of the major contributors to the environmental crisis in the country. The Indian Pharmaceutical Industry has been ranked amongst the 17 highly polluting industries of India as per the reports of Central Pollution Control Board (CPCB) and Ministry of Environment, Forest and Climate Change (MoEF&CC)<sup>28</sup>. There are research studies which have confirmed that Indian rivers are found to be contaminated by these drugs 150 times more than the US rivers<sup>29</sup>.

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28 The Emerging Environmental Burden from Pharmaceuticals; Geetha Mathew, M K Unnikrishnan, 2012

29 <https://purewaterfreedom.com/pharmaceutical-contamination>



## Patancheru: A Wake-up Call!!

The gravity of pharmaceutical pollution in India was highlighted in 2007 by a scientist named Dr. Joakim Larsson. Dr. Larsson conducted a study<sup>30</sup> in Hyderabad, on the effluents of Patancheru Enviro Tech Limited (PETL), an effluent treatment plant near Hyderabad, India. PETL receives approximately 1500 m<sup>3</sup> of wastewater per day, primarily from about 90 bulk drug manufacturers and discharges the treated effluent into Godawari river<sup>31</sup>. All 11 drugs monitored were detected at levels >100 µg/L. The concentrations of Ciprofloxacin (up to 31,000 µg/L) were higher than the maximal therapeutic human plasma levels and the antihistamine Cetrizine at up to 1,400 µg/L. Further, the studies estimated that the amount of Ciprofloxacin entering the river could amount to up to 45 kilograms a day. This was found to be equivalent to Sweden's entire consumption over 5 days, or it was enough dose to treat about **44,000 people**. As the study tested the water for the presence of antibiotics and also found them in such high concentration, the researchers particularly linked this industrial area with the increasing issue of AMR- Anti-microbial resistance.

Another study was conducted in 2009 by Fick *et al.*, on the surface, ground and drinking water of Patancheru, Hyderabad, India<sup>32</sup>. Twelve pharmaceutical compounds were analyzed and were found in high concentrations. Cetrizine and Ciprofloxacin were particularly found in high concentrations in approximately all lakes, river and well samples. The study reported that in one of the lakes, Ciprofloxacin and Cetrizine levels even exceeded human therapeutic blood plasma concentrations. The surface and well water concentrations were also the highest reported till date. The major risk as pointed out in the 2007 study was the development of Anti-Microbial Resistance (AMR).

Further in 2016, researchers at the Indian Institute of Technology Hyderabad reported high levels of Fluoroquinolone residues in water and sediment samples of the Musi river, which receives effluents from Wastewater Treatment Plant (WWTPs) around Hyderabad. Nordea, in the year 2016, conducted a study to understand the impacts of Pharmaceutical pollution on Indian Communities<sup>33</sup> and highlighted the issues associated with the pharmaceutical pollution on the community. Later Nordea and Changing Markets conducted a follow-up study in 2018 which confirmed that pharmaceutical companies in Hyderabad are continuing to discharge untreated or inappropriately treated wastewater into the environment and that local and national authorities are failing to get the situation under control<sup>34</sup>. The report concludes that the situation in Hyderabad has not improved in the past two years – if anything, it has deteriorated.

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30 Effluent from drug manufactures contains extremely high levels of pharmaceuticals, Larsson et al., 2007

31 Effluent from drug manufactures contains extremely high levels of pharmaceuticals, Larsson et al., 2007

32 Contamination of surface, ground, and drinking water from pharmaceutical production; Fick et al, 2009

33 Impacts of Pharmaceutical Pollution on Communities and Environment in India - Nordea Asset Management, 2016

34 Hyderabad's Pharmaceutical Pollution Crisis: Heavy Metal and Solvent Contamination at factories in a major Indian drug Manufacturing Hub

In 2017, the mass scale death of fish, reported in the lake Gandigudem, north of Bollaram and west of the Kazipally Industrial Development Area near Hyderabad, is linked to Chloromethane – an extremely flammable chemical, which is used as an intermediary in the pharmaceutical industries.

### Legal Initiatives

A public interest litigation filed in the Andhra Pradesh High Court, in the year 1989, resulted in the closure of 10 pharma units, which were subsequently opened. The matters then shifted to the Supreme Court of India, in the year 1991, which directed National Environmental Engineering Research Institute (NEERI), Nagpur, to assess the damage to the local habitat. They assessed the damage at Rs 32 crore for 7 years, i.e. 1984 to 1991. However, this amount was never paid, even on the basis of the well-established legal principle of 'Polluter Pays'. Instead, a paltry sum of Rs 1,000 per acre per year for crop loss and Rs 1,200 per acre per year for leaving the land fallow was fixed by the District Collector, Medak. Subsequently a CETP was established, which is a source of pollution in itself, as tested by Dr. Larsson in 2007.

After the Swedish study by Dr. Larsson, Amberpet Sewage treatment plant was established in 2008, which eventually shifted the problem to another location rather than solving it. Although in 2010, MOEF imposed moratorium on setting up new industries or expanding existing ones in 8 'critically polluted areas' in India, including the Patancheru-Bollaram cluster, it was soon lifted in 2011 as the SPCB proposed pollution control measures. The state in 2012 ordered closure of 12 pharmaceutical companies in 2012 in response to a submission by NGO Citizens Forum for Better Patancheru Constituency. Yet another Moratorium was imposed on industrial expansion in Patancheru-Bollaram cluster which was further lifted in 2015.

## Pharmaceutical Pollution in Other Parts of India

### Pharma Pollution in Hyderabad

In 2014, Deccan Chronicle<sup>35</sup> quoted Hyderabad as the 'city with most polluted lakes' because of pharmaceutical pollution. They reported that about 300 bulk drug manufacturing units are discharging their effluents without meeting the discharge standards. It was mentioned by one of the members of Andhra Pradesh Pollution Control Board (APPCB) that despite of issuing orders to these firms, nothing has been done in the last two years. He pointed out that though these firms claim 'zero' discharge on paper, practically only 10% of them achieve it.

35 <https://www.deccanchronicle.com/140120/news-current-affairs/article/hyderabad-lakes-most-polluted>

Further Fluoroquinolones such as Ciprofloxacin, Lomefloxacin, Ofloxacin, Norfloxacin and others were detected in concentrations as high as 5015 µg/l in water and sediment samples from Musi river in 2017<sup>36</sup>.

## Aquatic Life at Risk in Ahmedabad

In 2015, a case<sup>37</sup> of pharmaceutical pollution was reported in Matoda village of Ahmedabad. The local villagers filed a complaint against Intas Pharmaceutical Pvt. Ltd. for discharging untreated effluent into the water body which is used for fish farming activities. The report stated the death of about 1.5 lakh fishes due to impact of this pollution.

## Yamuna: A River Filled with Drugs

Yamuna river, particularly, has been reported to be contaminated with large number of pharmaceutical pollutants, including antibiotics. A study was conducted by AIIMS, wherein the water samples were collected from Yamuna river from six different places on Wazirabad to Kalindi Kunj stretch<sup>38</sup>. Majorly three classes of antibiotics – Fluoroquinolone (used to treat respiratory and urinary tract infection), Macrolides and Penicillin (both used to treat bacterial infections like pneumonia, scarlet fever, rheumatic fever, etc.) – were analyzed. Results indicated the presence of all the antibiotics, for example Norfloxacin, Ofloxacin, Gentamicin, Amoxicillin and Azithromycin in the tested water samples. Yet again, the major issue was of the development of resistant microbial strains.

## Ganga: Loaded with Pharmaceutical Pollutants

A study conducted in 2019<sup>39</sup> highlighted the high volumes of pharmaceutical pollutants in Ganges river. The study found the pharma compounds, such as Carbamazepine, Sulfamethaxazole, Diclofenac, Ciprofloxacin, Ibuprofen and Ketoprofen, were found in varied concentrations in surface and ground water in the Ganga River Basin.

## The New Pharma Hub: Sikkim

Sikkim known for its landscapes, glaciers and ecology, has emerged as a new pharmaceutical manufacturing hub for India. The state in 2007, was included in the Centre's North East Industrial and Investment Promotion Policy (NEIIPP), under which all new units as well as existing units which go in for substantial expansion in Sikkim will be eligible for incentives for a period of ten years from the date of commencement of commercial production<sup>40</sup>. By 2009, the state has

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36 <https://ascelibrary.org/doi/10.1061/%28ASCE%29HZ.2153-5515.0000346>

37 <https://timesofindia.indiatimes.com/city/ahmedabad/locals-blame-pharma-company-toxic-discharge-for-dead-fish/articleshow/49053324.cms>

38 <http://www.asianage.com/delhi/aiims-study-finds-traces-antibiotics-yamuna-640>

39 <https://www.sciencedirect.com/science/article/abs/pii/S0048969718327323?via%3Dihub>

40 [https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/sikkim-turns-into-a-pharma-hub/articleshow/5192355.cms?utm\\_source=contentofinterest&utm\\_medium=text&utm\\_campaign=cpps](https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/sikkim-turns-into-a-pharma-hub/articleshow/5192355.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cpps)

already become home to 14 major pharma companies and has attracted pharma investment up to 2500 crores.

However, with the rising number of manufacturing plants, pollution from pharmaceutical industries also emerged as a major challenge in Sikkim. In 2019, the SPCB issued a closure notice to pharmaceutical companies in Sikkim – Alembic Pharmaceuticals and Ideal Cures Ltd<sup>41</sup>. The SPCB reportedly found the two industries discharging industrial waste beyond the permissible limits into Teesta river. Alembic Pharmaceutical was allegedly discharging 100 KLD effluent into Teesta river. It was also found that for the last two years highly toxic effluents from the plant's collection tank is being siphoned off and dumped in the river<sup>42</sup>.

Although, the locals have made allegations that heat ailments, pregnancy problems and diabetes<sup>43</sup> have increased in parts of the state with rising pollution, there is a need for further investment and action to understand the implications of the vast manufacturing plants and monitor their waste treatment facilities.

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41 <https://www.thesikkimchronicle.com/sikkimtwo-pharma-companies-face-temporary-shutdown-waste-discharge-beyond-prescribed-limit/>

42 <https://www.groundxero.in/2019/04/27/alembic-pharmaceuticals-sikkim-unit-discharging-highly-toxic-wastewater-effluent-in-tista-river/>

43 <https://www.news.anypursuit.org/article26819-BIG-PHARMA-MESSING-UP-SIKKIM-ENVIRONMENT>

# Pharmaceutical Pollution in Baddi-Barotiwala-Nalagarh (BBN)

Baddi is an industrial town and a Nagar panchayat in the Southwestern Solan district of Himachal Pradesh, a hill state of northern India. The town lies on the border of Himachal Pradesh and Haryana in the Shivalik Hills; around 35 kilometres west of Solan<sup>44</sup>. It has recently emerged as the capital of pharmaceutical industries.

More than half of India's pharmaceutical production, mainly formulations, would originate from Himachal Pradesh in few years as 200 odd medium and large-scale units are coming up in and around Baddi.

Source: <http://test.pharmabiz.com/chronicle%20specials/baddi-emerging-as-india-s-pharma-capital-31755>

It all began in 2002, when the State Government provided tax and central excise concessions to attract companies to establish manufacturing units. The excise concessions ranged from 30-100 per cent along with capital investment subsidy up to 15% for commercial drug production<sup>45</sup>.

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44 <https://thepharmaupdate.com/2019/12/16/list-of-pharmaceutical-companies-in-baddi/>

45 <https://thepharmaupdate.com/2019/12/16/list-of-pharmaceutical-companies-in-baddi/>

The Baddi-Barotiwala-Nalagarh industrial belt is now considered to be the second largest pharma cluster of India. The state supplies 35 per cent of pharma formulations in Asia through approximately 700 manufacturing units, around 650 of which are in Baddi. The total turnover of the pharma industry in this belt is around Rs 40,000 crore, contributing a significant share in the Rs 1.10 lakh crore domestic pharma market<sup>46</sup>.

## Environmental Challenges in Baddi-Barotiwala-Nalagarh Cluster

During the last few years, a number of environmental pollution cases have come into notice in this industrial area. BBN Industrial Area, now one of the largest manufacturing hubs in India, has been the root cause of the contamination of Sirsa river. The industrial area has been categorised as severely polluting category, viz Red category<sup>47</sup>. As per a recently published report by Himachal Pradesh State Pollution Control Board<sup>48</sup>, the main source of pollution in Sirsa river includes commercial and industrial waste from this industrial area.

Locals have also complained<sup>49</sup> that most of the industries do not comply with the regulations and they discharge the liquid waste through pipes and other outlets that open behind the plant or run underground and open into bushy areas. This released wastewater accumulates in or flows through nallahs, canals and rivulets into the Sirsa river. It has also been noticed that the effluents are also injected into the ground at night by digging bore wells or released during rains.

Recently, in March 2020, a tanker was caught dumping untreated industrial effluent from a pharmaceutical unit into Malpur khud<sup>50</sup> (which is a tributary of Sirsa river). The entire khud or rivulet turned dark blue as soon as the effluent was dumped into it. The SPCB officials caught the tanker while dumping the waste and thus started further investigation. They found that the waste belonged to Helios Pharma.

## Issue of Common Effluent Treatment Plant in Baddi

Himachal Pradesh Pollution Control Board has identified Morepen Laboratories (Bulk Drug Pharmaceutical Unit) and Common Effluent Treatment Plant (CETP) at Baddi, named **Baddi Infrastructure**, as the two establishments under 17 categories of highly polluting industries located in catchment of river Sirsa<sup>51</sup>.

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46 <https://baddi.expresspharmaonline.com/whybaddi.html>

47 <https://www.tribuneindia.com/news/archive/himachal/drug-park-needs-to-have-mechanism-to-mitigate-pollution-in-bbn-area-864652>

48 Comprehensive Report on Prevention and Control of Pollution in River Sirsa: Action Plan, Haryana State Pollution Control Board

49 <https://www.downtoearth.org.in/news/waste/bitter-medicine-57879>

50 <https://www.tribuneindia.com/news/himachal/water-body-in-baddi-turns-blue-after-industrial-waste-dumped-52859>

51 <https://www.downtoearth.org.in/news/waste/bitter-medicine-57879>

**Figure 3 Baddi Industrial Hub on the Banks of Sirsa River**



In 2019, Himachal Pradesh State Pollution Control Board fined the CETP Rs. 1 crore for failing to comply with the norms and for polluting Sirsa river. Following the action initiated by the HPPCB, a monitoring committee from NGT, visited the CETP. The committee detected glaring irregularities, including the effluents discharged into Sirsa river, not meeting the prescribed standards of biological oxygen demand, total dissolved solids, sulphide and bioassay<sup>52</sup>. The committee also recommended the CETP to take the necessary steps and stop discharging untreated effluent in the river. The CETP was provided a time of six months to install ZLD technology and ensure that no effluents find a way to the river. Concerns about sending mixed waste to the CETP has also been raised. As the CETP is connected to a number of different types of industries, be it Pharma, textile or any other chemical unit, it is at the receiving end of an effluent containing varied chemical composition which also affects the proper functioning of the plant.

<sup>52</sup> <https://www.tribuneindia.com/news/archive/himachal/baddi-effluent-treatment-plant-fined-rs-1-crore-849412>

## High Court's Stance on CETP

The High Court of Himachal directed the state to come up with the status report as part of CWPIIL 11/2016. In the affidavits filed in the case in October 2016, it became clear that only 42 industries had connected with CETP out of the 428 that were expected to connect. Even in the interim order dated 6th October 2016, there is a mention of the confusion vis-a-vis the number of units operational in the industrial area.

It was after the High Court took up the matter that the SPCB, which had failed to ensure compliance to environmental norms by individual units, started moving on the matter and ensured that notices were issued to 386 units who were not connecting to the CETP. Following this over the year, tripartite agreements were signed with 294 units for connecting to the CETP up until 29.3.2017. The court ordered for the disconnection of electricity and suspension of the consent to operate for those units who would not connect with the CETP. The High Court disposed of the matter on 14th November 2017 stating that "that the units that complied with the directions issued by this Court, its application shall be considered favourably and water & electricity connection restored".

*Source: <https://sandrp.in/2017/11/15/failing-cetp-in-himachals-pharma-hub-poisons-river-sirsa-villagers-lives-non-stop/>*



# Toxics Link's Assessment in Baddi-Nalagarh Industrial Area

### Indicative Research Study

Toxics Link has initiated an indicative study to assess possible impacts of the effluents being released from the pharmaceutical units in Baddi-Nalagarh industrial zone. Though most of the pharmaceutical units in this industrial zone are formulation units and are categorised as 'Orange Category' industry, however some literature studies have indicated instances of APIs releasing from these industries to the nearby streams. Therefore, these industries should take utmost precaution to prevent the release of these pollutants into the environment. In this context, Toxics Link did the physical assessment of the zone and also collected water samples from some of the locations to get an indication of the presence of pharmaceutical compounds in the water.

### Overall Observation

During the study it was observed that the industrial zone is very poorly planned to manage the effluents released from the different industries. During the visit and after discussion with the villagers in the surrounding areas, it came into the light that apart from pharma industries there are also number of textile industries located in this industrial zone. Baddi is the old industrial zone and now the new pharma

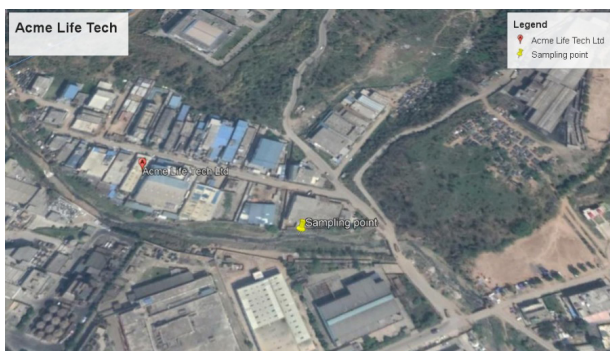
industries are coming up in Barotiwala-Nalagarh zone. Moreover, though some of the industries in Baddi are connected to CETP, lack of any treatment facilities in Nalagarh is posing a serious challenge to the environment in the surrounding location. Even the villagers have reported that pollution is evolved as a serious concern in surrounding Nalagrah area day-by-day. Shockingly, the villagers exposed the secret outlet which is used by the industries to release the effluents from their units and this clearly shows the mind-set of the industries being 'solution to pollution is dilution', without realising the larger impact of API on the ecosystem. Also, it was quite evident that the effluents were being discharged during the night to avoid scrutiny.

## Sampling Locations

The water samples were collected from these secret effluent outlets which are connected directly to the small nallah. Two water samples were collected from the above-mentioned sampling points. There are enough indications that the effluents were released in the night. As the effluents were being released in the night, the water samples were collected from the left-over water in the outlets. The samples were collected in plastic bottles.

The water samples were sent to Shriram Institute of Industrial Research and Spectro Laboratory in New Delhi for analysis. Refer to **Annex 1** for testing methodology.

**Figure 4 Sampling Point 1**



**Figure 5 Sampling Point 2**



## Results and Discussion

The test result found Ciprofloxacin in a concentration of 296.1 µg/l. Though the concentration of Di-chloro methane could not be assessed, it was detected in one of the sampling locations.

**Table 1 Concentration of Pharmaceutical Compounds in Water**

Parameter	Concentration (µg/l)	Sampling point
<b>Ciprofloxacin</b>	296.1	One
<b>Di-chloro methane</b>	Detected	Two

Thus, the results of the study indicate towards the possibility of the presence of pharmaceutical ingredients in the water bodies in BBN area. It is to be noted that Ciprofloxacin was also detected in Patancheru in very high concentration raising concerns about its implications. Incidentally there are no previous studies on the presence of pharma ingredients in the water bodies of BBN area. Perhaps this is the first kind of study where these pharmaceutical pollutants are detected in BBN area. Most importantly, the concentration is also quite high as the new draft regulation on pharma has the discharge limit of 0.02 µg/l for Ciprofloxacin. The detected concentration of 296 (µg/l) is 14800 times higher than the required concentration. Moreover, the presence of these two pharmaceutical ingredients have raised the larger issue of the magnitude of pharmaceutical pollution in this area.

High concentration of pharmaceutical pollutants, including antibiotics, are known to cause detrimental environmental and human health impacts. Once in the environmental matrix, they play the same role and can thus cause detrimental effects on the exposed species. They also attack certain bacteria who, in turn, become resistant to these compounds ultimately leading to antibacterial/microbial resistance.<sup>53</sup>

### AMR Effects on COVID

With the world today facing one of the biggest pandemics COVID-19, AMR can probably make the pandemic even more deadly. In a recent report in Wuhan, China, it was found that 50% of the patients who died from Corona Virus were also tested positive for secondary infections. Since, antibiotics act as our first line of defence and the number of cases of anti-microbial resistance are already on the rise, it is important to conduct more studies to understand the implications of AMR on such pandemics. The current COVID-19 pandemic threatens to further weaken the already crumbling antibiotic management infrastructure. There are perhaps more interlinkages between AMR and COVID which needs to be studied and, most importantly, the countries like India which has AMR on the rise need to establish a connect between the two and study the potential impacts of anti-microbial resistance on the outcomes of COVID-19 patients.

<sup>53</sup> Impacts of Pharmaceutical Pollution on Communities and Environment in India - Nordea Asset Management, 2016

In this context due to lack of any data on the pharma ingredients in BBN area and poor monitoring, the industrial area may witness multiple increase in AMR cases in the coming days.

Therefore, it is imperative for the respective agencies to understand the grave concerns of pharma pollution on the ecosystem and, most importantly, human health. The need of the hour is to develop an inventory on the presence of antibiotics and other pharmaceutical pollutants in the country with specific focus on BBN area so that appropriate action can be initiated to get rid of the problems associated with the pharmaceutical ingredients.

# Conclusion and Recommendations

### Conclusion

It has been established that there is a correlation between the increasing amount of drug production and use, and the number of pharmaceuticals (and its metabolites) that are being detected in various environmental matrices. The ill impact of the pharma pollution has been well-documented globally and in India, therefore, there is an emerging need to reduce this pollution load from the environment. Globally a number of countries have initiated regulatory and technological interventions to minimise the impact of pharmaceutical pollution. With India emerging as a major producer of generic drug manufacturer and with the ever-increasing use of drugs in the country, there is a need to develop appropriate regulatory mechanisms, with adequate monitoring system in place, so that the impact of the pharmaceutical pollution can be reduced. In this context some recommendations are proposed.

## Recommendations

- 1 The proposed draft regulation should be enforced immediately and with adequate monitoring and surveillance system in place.
- 2 The regulation must also consider inclusion of other pharmaceutical pollutants apart from 121 antibiotics that it has listed at present.
- 3 The SPCB and CPCB should be capacitated and trained to do more testing and also need to sensitize the magnitude of problems associated with AMR.
- 4 Stringent legal and punitive actions must be taken against the industries, which are illegally discharging their untreated wastewater into nearby water bodies.
- 5 The ETP and STP infrastructure as well as Treatment Storage and Disposal Facility (TSDF) facilities should be equipped with the latest technology to minimize the risks and remove the API from the wastewater.
- 6 The industries need to accept their responsibilities for their products and should place adequate management system from cradle to grave.
- 7 The industries should adopt utmost precautionary approach and install pollution control devices to prevent discharge of pharma waste along with wastewater. In case of availability of common treatment plants, the industries should make sure that they connect to the plant to effluent treatment.
- 8 The government should support small-scale manufacturers to install and implement environmentally sound waste treatment facility. Manufacturers with high-end WWTPs should also be strictly monitored.
- 9 The approval of pharma industries needs to be strictly scrutinized considering the level of threat associated with these industries.
- 10 There should be provisions of conducting an ERA before releasing any new drugs in the markets to minimize the impact of pharma pollution from the end use.

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# ANNEX 1

## Test Methodology

The collected water samples were sent to Shriram Institute of Industrial Research and Spectro laboratory in New Delhi for analysis.

Spectro Laboratory tested the water sample for **Di-choloro methane** using GC-MS. This method involves purging the sample with an inert gas and passing the gas through a trap containing 2,6-diphenylene oxide polymer, silica gel, and coconut charcoal to adsorb the purged Chloromethane and other halocarbons (called the 'purge and trap' method). After the purging is complete, the trap is heated to desorb the Chloromethane. The desorbed Chloromethane is analyzed by GC MSD directly by injecting.

**Ciprofloxacin** was analyzed by The Shriram Institute using LC-MS. The method of analysis was as follows:

- i. Prior to sample preparation, Oasis HLB cartridge was pre-conditioned by adding 4 mL MeOH and 6 mL Distilled Water (DW).
- ii. Then took 50 mL of the sample and adjusted its pH to 6. This was filtered using 0.45 µm Millipore filter to remove any impurities present.
- iii. The water sample was passed through the pre-conditioned cartridge at flow rate of 5-B mL/ min using a vacuum extraction manifold.
- iv. Next, 10 mL of ultra-pure water was used to wash the cartridge, which was subsequently air-dried for 5 min.
- v. Acidified methanol (10 mL of MeOH, 3 mL of 0.5 N HCL) was used to elute the analyte into a glass test tube.
- vi. The extracts were completely dried under a gentle flow of nitrogen, and the volume was reconstituted to 1 mL using a mix of water/methanol (9:1).
- vii. The extracts were filtered through 0.45 µm filters, transferred to auto sampler vials, and were analyzed using LCMS/MS.



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