Life Cycle Assessment Report

Final Version

Life Cycle Assessment Study

Neuland Laboratories Limited, Unit-3, IDA Gaddapotharam, Hyderabad.

By Confederation of Indian Industry, Hyderabad, March 2024

Confederation of Indian Industry

CII-Sohrabji Godrej Green Business Centre

Cradle to Gate
Life Cycle Assessment Study Report

Neuland Laboratories Limited,
Unit-3, IDA Gaddapotharam, Hyderabad

2023 – 2024

Acknowledgement

CII – Godrej GBC acknowledges the co-operation extended to CII – Godrej GBC's team by Neuland Laboratories Limited during the Life cycle assessment study. Interactions and deliberations with Neuland Laboratories Limited team were exemplary and the whole exercise was thoroughly a rewarding experience for CII-Godrej GBC.

We deeply appreciate the interest, enthusiasm, and commitment of Neuland Laboratories Limited towards environmental protection.

We would like to sincerely thank Mr. Ashok Kumar Podisetty, Mr. N. Sundar and all the other key executives who supported us in successful completion of the study.

Finally, we would also like to appreciate the role played by Mr. Nitesh Rajput, Mr. Murali Krishna Kommanaboyina, Mr. Gummadivalli Babu Raja, Mr. Likith Dhabaker and the team that assisted in data collection for carrying out the study.

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About Neuland Laboratories Limited

Neuland Laboratories Limited, a globally recognized pharmaceutical leader with over 40 years of expertise, epitomizes innovation, quality, and excellence in Active Pharmaceutical Ingredients (APIs) and complex intermediates. Neuland’s cutting-edge API development and contract manufacturing services empower global pharmaceutical advancements, ensuring high-purity, regulatory-compliant solutions.

At the forefront of pharmaceutical innovation, Neuland’s expertise in complex chemistry and peptide synthesis sets industry benchmarks, delivering reliable and effective APIs across diverse therapeutic areas. The company’s unwavering commitment to quality and compliance makes it a trusted partner for leading global pharmaceutical firms. Committed to sustainability, Neuland integrates environmentally responsible practices, advancing health solutions that prioritize both patient well-being and global environmental stewardship.

About CII

The Confederation of Indian Industry (CII) works to create and sustain an environment conducive to the development of India, partnering industry, Government, and civil society, through advisory and consultative processes. For 126 years, CII has been working on shaping India's development journey and, this year, more than ever before, it will continue to proactively transform Indian industry's engagement in national development.

CII is a non-government, not-for-profit, industry-led and industry-managed organization, with about 9100 members from the private as well as public sectors, including SMEs and MNCs, and an indirect membership of over 300,000 enterprises from 288 national and regional sectoral industry bodies.

CII charts change by working closely with Government on policy issues, interfacing with thought leaders, and enhancing efficiency, competitiveness, and business opportunities for industry through a range of specialized services and strategic global linkages. It also provides a platform for consensus-building and networking on key issues.

Extending its agenda beyond business, CII assists industry to identify and execute corporate citizenship programs. Partnerships with civil society organizations carry forward corporate initiatives for integrated and inclusive development across diverse domains including affirmative action, livelihoods, diversity management, skill development, empowerment of women, and sustainable development, to name a few.

As India completes 75 years of Independence in 2022, it must position itself for global leadership with a long-term vision for India@100 in 2047. The role played by Indian industry will be central to the country's progress and success as a nation. CII, with the Theme for 2022-23 as Beyond India@75: Competitiveness, Growth, Sustainability, Internationalization has prioritized 7 action points under these 4 sub-themes that will catalyze the journey of the country towards the vision of India@100.

1. Background

Neuland Laboratories Limited has undertaken a Life Cycle Assessment (LCA) to evaluate the environmental impact of its pharmaceutical manufacturing processes, with a specific focus on the production of the drug Ciprofloxacin HCL. This LCA study enables Neuland Laboratories to assess, understand, and communicate the environmental footprint of Ciprofloxacin.HCl, while identifying opportunities to enhance sustainability in its production. By analysing the environmental impacts across various life-cycle stages, the study highlights the overall environmental performance and the potential benefits of adopting innovative, eco-friendly practices.

This study focuses on Neuland Pharma's Hyderabad manufacturing units involved in the production of Ciprofloxacin HCL. The assessment provides critical insights into reducing environmental impact while ensuring the delivery of high-quality and affordable healthcare solutions.

1.1 Introduction to LCA

An LCA is a standardized, scientific method for systematic analysis of flows (e.g., mass and energy) associated with the life cycle of a specific product, technology, service, or manufacturing process system. In the case of a product system, the life cycle includes raw materials acquisition, manufacturing, use and end-of-life (EoL) management. According to the International Organization for Standardization (ISO) 14040/44 standards, an LCA study consists of four phases:

1. Goal and scope (framework and objective of the study)
2. Life-cycle inventory (input/output analysis of mass and energy flows from operations along the product's value chain)
3. Life-cycle impact assessment (evaluation of environmental relevance, e.g., global warming potential)
4. Interpretation (e.g., mitigation potential).

LCA addresses potential environmental impacts throughout a product's lifecycle from raw material extraction through production, use, end of life treatment recycling and final disposal. There are multiple approaches possible for LCA, namely,

- Cradle to gate
- Cradle to grave
- Cradle to cradle

Cradle to gate includes raw material extraction, transportation, and emissions during different processing stages, until the product exits the factory gate. Cradle to grave includes raw material extraction, transportation, emissions during different processing stages, product use and disposal, until the product reaches its end of useful life (i.e., grave). Cradle to cradle includes raw material extraction, transportation, emissions during different processing stages, product use and disposal, until the product reaches its end of useful life and is either reused or recycled (i.e., cradle).

The goal and scope stage outline the rationale of the study, anticipated use of study results, boundary conditions, data requirements and assumptions to analyse the product system under consideration, and other similar technical specifications for the study. The goal of the study is based upon specific questions that the study seeks to answer, the target audience and stakeholders involved and the intended use for the study's results. The scope of the study defines the systems boundary in terms of technological, geographical, and temporal coverage of the study; attributes of the product system; and the level of detail and complexity addressed.

1.2 Functional Unit

The functional unit is a key element of LCA which must be clearly defined. The functional unit is a measure of the function of the studied system, and it provides a reference to which the inputs and outputs can be related. This enables comparison of two essential different systems.

1.3 System Boundaries

The system that will be studied in the LCA should be clearly described. Flow diagrams can be used to show the different subsystems, processes and material flows that are part of the system model.

The system boundaries determine which unit processes to be included in the LCA study. Defining system boundaries is partly based on a subjective choice, made during the scope phase when the boundaries are initially set. The following boundaries can be considered: Boundaries between the technological system and nature. A life cycle usually begins at the extraction point of raw materials and energy carriers from nature. Final stages normally include waste generation and/or disposal and recovery etc.

In System boundaries the geographical areas are also to be defined. Geography plays a crucial role in most LCA studies, e.g., infrastructures, such as electricity production, waste management and transport systems, vary from one region to another. Moreover, ecosystems sensitivity to environmental impacts differs regionally too. Time horizon. Boundaries must be set not only in space, but also in time. Basically, LCAs are carried out to evaluate present impacts and predict future scenarios. Limitations to time boundaries are given by technologies involved, pollutants lifespan, etc.

1.4 Inventory analysis

The inventory analysis involves data collection and calculation procedures to quantify the inputs and outputs that are associated with the product system(s) under study. This includes use of resources, releases to air, water, and land. Procedures of data collection and calculation should be consistent with the goal and the scope of the study. The results of the inventory analysis may constitute the input for the life cycle assessment as well as an input for the interpretation phase.

1.5 Allocation

The rule pertaining to allocation applies when there are two or more by-products, produced from a single stream or there are two or more intermediate product stages. In this study an allocation rule was not considered for by products, as the operation of Product under consideration, resulted in no more than one product from each stream.

However, certain inputs like Fuel, Electricity, DG Set generation etc. were allocated to unit processes according to mass of the output getting generated in the form of intermediate product, i.e. Mass allocation approach has been adopted

1.6 Impact assessment

In the impact assessment, the results of the inventory analysis are linked to specific environmental damage categories (e.g., CO_2 emissions are related to global warming and climate change, SOx emissions are related to damages to the ecosystem caused by acidification, etc.). The impact assessment predicts potential environmental damages (impacts) related to the system under study. More details on the methodology of impact assessment please refer the annexure.

1.7 Interpretation

According to ISO 14043, in the interpretation phase of an LCA, the results of the inventory analysis and the impact assessment are critically analyzed and interpreted in line with the defined goal and scope of the study. The findings of this interpretation may take the form of conclusions and recommendations to decision makers. It may also take the form of an improvement assessment, i.e., an identification of opportunities to improve the environmental performance of products or processes.

1.8 LCA Benefits

LCA offers the following benefits:

- A systematic evaluation of the environmental impacts associated with the products.
- Analyzing the key issues and areas of improvement within the life cycle of the product.
- Comparing alternatives to determine the more sustainable choice in material selection.
- Helps in communicating environmental performance to customers and consumers through Environment Product Declaration (EPD).
- Development and optimization of production processes.

2. Objective of the study

Lifecycle assessment study for Neuland Laboratories Limited. was aimed to establish the environmental impacts produced due to the manufacturing of the drug Ciprofloxacin HCL. The following are the major objectives of the study:

- To monitor the environmental impacts caused due to the manufacturing of Ciprofloxacin HCL.
- Establish environmental profiles for Ciprofloxacin HCL.
- To determine hot spots and key environmental parameters between cradle-to-gate operation in the manufacturing process.
- Compare the reductions in environmental impacts due to adoptions of various mitigation measure scenarios in manufacturing of Ciprofloxacin HCL.

2.1 Goal & Scope

2.1.1 Goal

The goal of the study is to assess the life cycle of the Drug CIPROFLOXACIN.HCL manufactured by Neuland Laboratories Limited and use results to identify hotspots to minimize the environmental impact. The study is based on the latest inventory data collected for the year 2023-24.

2.1.2 Scope

The study will try to include all the major components which would have significant impact. However, components that are small and have negligible mass and/or volume will be excluded from the study unless they have significant toxicity or human health impacts on account of the materials used in them or the processing of the materials contained in it. Capital and infrastructure goods will be excluded for impact analysis. The impact analysis will include non-renewable energy use, freshwater use, atmospheric ozone formation, acidification, ecotoxicity, global warming, stratospheric ozone layer depletion, eutrophication, and human health impacts.

2.1.3 Functional Unit

The functional unit for the study is one ton of CIPROFLOXACIN.HCL.

2.1.4 System boundaries

The boundary considered for the LCA study is Cradle to Gate, which includes raw material extraction, transportation and emissions during different processing stages, until the product exits the factory gate.

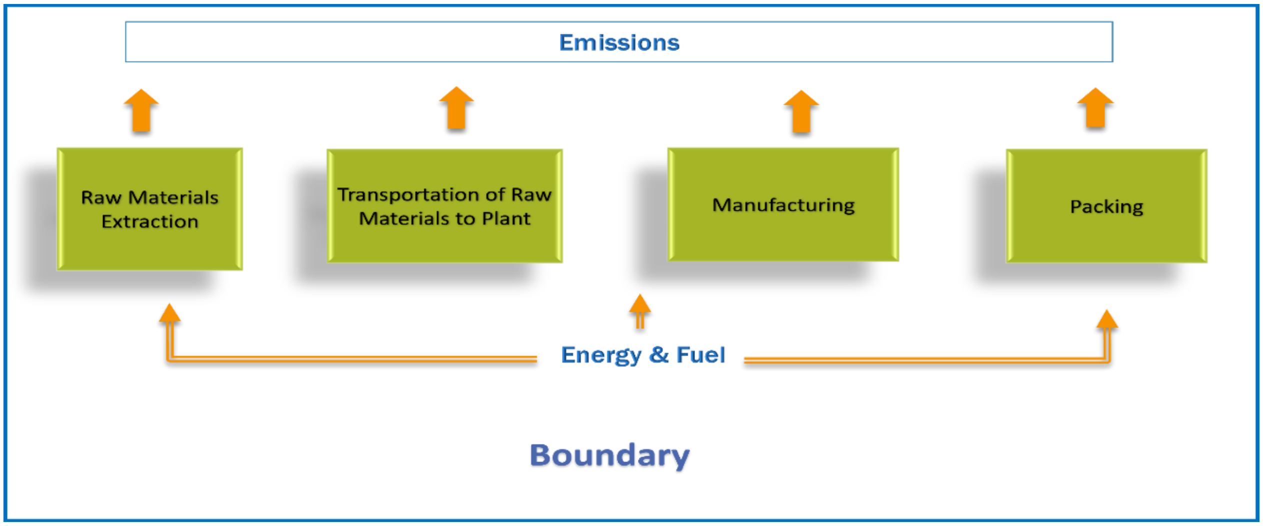

Figure 1 LCA – Boundary

2.2 Cut-off Criteria

Cut-off criteria were employed to include all the environmental impact sources while ensuring the study to be complete, relevant, accurate and consistent. Cut-off criteria considered for this study are below:

- **Mass** – For mass flow less than 1% of the total mass flow environmental impact source may be eliminated with the stipulation that impact would be marginal.
- **Energy** – For energy flow less than 1% of the total energy flow environmental impact source may be eliminated under that condition that environmental impact is not a concern.
- **Environment** – For those flows (mass or energy flow) less than 1% of the total respective flow with significant environmental concern impact source must be included for the study.

2.3 Allocation

The rule pertaining to allocation applies when there are two or more by-products, produced from a single stream or there are two or more intermediate product stages. In this study an allocation rule was not considered for by products, as the operation of Product under consideration, resulted in no more than one product from each stream.

However, certain inputs like Fuel, Electricity, DG Set generation etc. were allocated to unit processes according to mass of the output getting generated in the form of intermediate product, i.e. Mass allocation approach has been adopted.

2.4 Assumptions

Cradle to Gate study approach was adopted, all the data considered for this study was obtained from primary sources. Hence, the need for assumptions was eliminated completely.

- ✓ Q-Acid, Piperazine, and Hyflo Supercell are excluded in this LCA due to unavailability of data in libraries.
- ✓ In Packing process only material impacts are considered, Electricity is not covered separately.
- ✓ In all processes, the impacts due to capital goods are not considered.

3 LCI Methodology & Analysis

Life cycle inventory analysis is a phase of life cycle assessment which involves quantification & compilation of inputs and outputs for a product throughout its life cycle.

3.1 Methodology

Lifecycle Assessment study carried out for Neuland Laboratories Limited carried out in different phases as follows:

3.1.1 Initial Discussion

An online discussion was conducted to understand the operations and major impact sources of Neuland Laboratories Limited. During the discussion, major impact sources were recorded with the consensus of the team.

3.1.2 Development of Inventory Metrics

Following the initial discussion, metrics for LCA study was established after collaborating with Neuland Laboratories Limited and established metrics would help to carry out data collection activity in the future, whilst maintaining the data accuracy. The software used for carrying out this study was SimaPro v9.6 and the datasets used were from Ecoinvent. Ecoinvent is an independent association consisting of five institutes as active members. With this step, Ecoinvent has become a not-for-profit organization whose goal is to ensure the further development of a consistent, transparent and trustworthy database for the LCA community as well as for creators of eco-design tools, decision-makers, industry and scientific research. The data was modelled using SimaPro and the results obtained were explained in detail in section 8.

3.1.3 Data Collection

System boundary was set after consulting Neuland Laboratories Limited. Having set the boundary data collection process was initiated. Since the accuracy of LCA study depends on the data availability caution was exercised during the data collection process. A questionnaire has been designed to collect the required data.

3.1.4 Data Authentication

As a part of the study data authentication was carried out to understand the assurance level provided by the collected data. This authentication process enabled Neuland Laboratories Limited to avoid any ambiguities that may encircle in the future.

3.1.5 In-House Calculation

Following the data collection and authentication process calculations were performed to evaluate and analyze the significance of different impact categories associated with the production of 1 ton of Ciprofloxacin.HCl considering cradle to gate boundary.

3.2 Life Cycle Inventory

The following are the process flow diagrams of the Drug manufacturing process at Neuland Laboratories Limited which is shared by Neuland Laboratories Limited team.

3.2.1 CIPROFLOXACIN BASE TECH

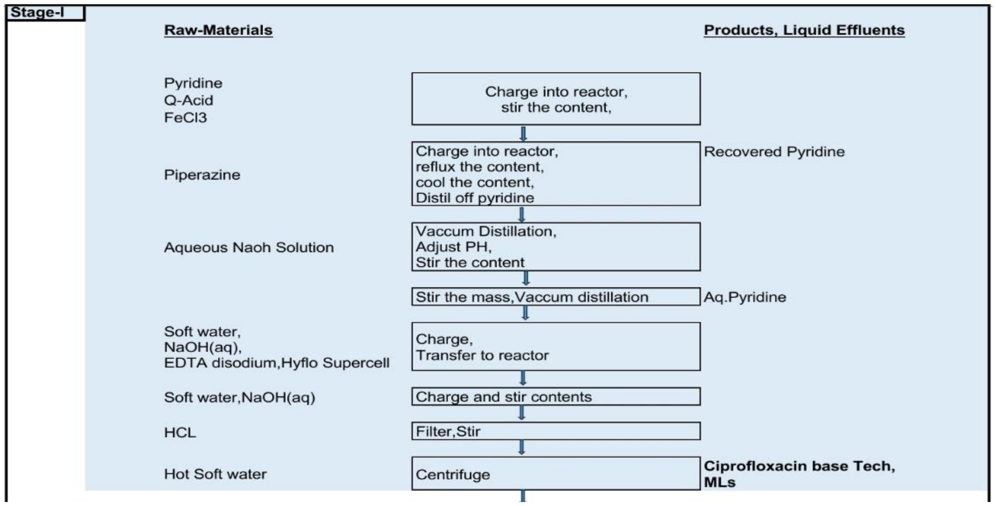

Figure 2: Process Flow Diagram- CIPROFLOXACIN BASE TECH

3.2.2 CIPROFLOXACIN BASE

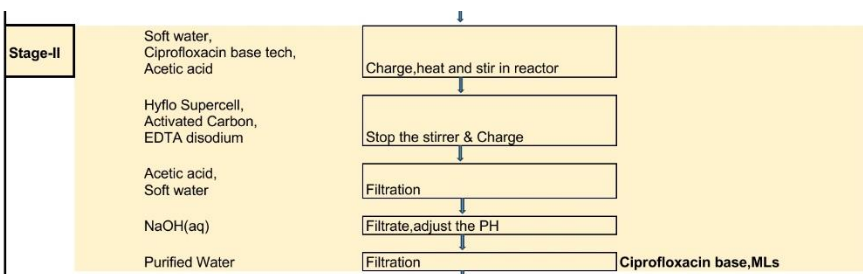

Figure 3: Process Flow Diagram – Ciprofloxacin Base

3.2.3 CIPROFLOXACIN HCL

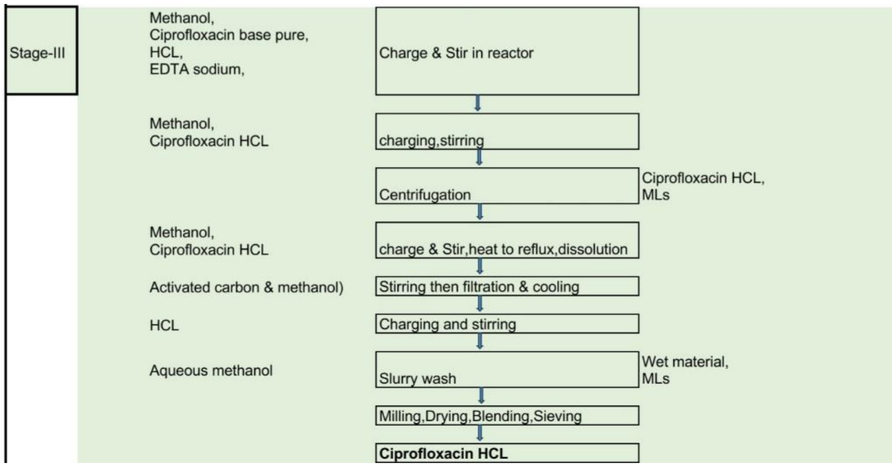

Figure 4 : Process Flow Diagram - CIPROFLOXACIN HCL

3.3 Life cycle inventory – Process wise

Functional unit for each block is defined as output, all input and output for each process was recorded. Life cycle Inventory is the data collection part of LCA. It is accounting for all the major operations in the system and detailed tracking of all the inputs and outputs in the process. For instance, including raw resources or materials, energy by type, water, and emissions to air, water, and land by specific substance.

3.3.1 CIPROFLOXACIN BASE TECH

The functional unit was considered as ton of CIPROFLOXACIN BASE TECH, inputs and outputs for this process has been listed below:

Table 1 : Inventory Data – CIPROFLOXACIN BASE TECH

S. No	Particulars	Basis	Unit	Value	Normalized Values
Inputs					
1.1	**Resources**				
a	Normal Water	Annum	KL	-	-
b	Purified Water	Annum	KL		
c	DM Water	Annum	Ton	380.52	6.04
1.2	**Avoided Products**				
a	Pyridine Recovered	Annum	Ton	63	1
1.3	**Materials**				
a	Pyridine	Annum	Ton	108.77	1.73
b	FeCl3	Annum	Ton	1.39	0.02
c	Sodium hydroxide	Annum	Ton	46.99	0.74
d	EDTA	Annum	Ton	0.17	0.0027
e	HCL	Annum	Ton	31.56	0.5
f	Coal	Annum	Ton	544.24	8.64
g	Diesel	Annum	Ton	7.62	0.12
1.4	**Fuels**				

a	Coal	Annum	Ton	544.24	8.64
b	Diesel (Forklift, DG Set, Any other)	Annum	Ton	7.62	0.12
1.5	**Electricity/Heat**				
a	Electricity	Annum	kWh	364,614	5,788
b	Electricity	Annum	kWh	31,877	502
c	Coal Combustion	Annum	MJ	108,83,288	1,72,776
Outputs					
1.1	**Material**				
a	**Ciprofloxacin Base Tech**	**Annum**	**Ton**	**63**	**1**
1.2	**Waste**				
a	Process residue	Annum	Ton	4.41	0.07
1.3	**Waste to Treatment**				
a	Mother Liquor	Annum	m3	336.1	5.43

3.3.2 CIPROFLOXACIN BASE

The functional unit for CIPROFLOXACIN BASE was considered as ton of CIPROFLOXACIN BASE, inputs and outputs for this operation has been listed below:

Table 2: Inventory Data – CIPROFLOXACIN BASE

S. No	Particulars	Basis	Unit	Value	Normalized Values
Inputs					
1.1	**Resources**				
a	Normal Water	Annum	KL	-	-
b	Purified Water	Annum	Ton	71.69	0.96
c	DM Water	Annum	Ton	426.19	5.75
1.2	**Materials**				
a	Ciprofloxacin base tech	Annum	Ton	63	0.85
b	Acetic acid	Annum	Ton	23.94	0.32
c	Activated Carbon	Annum	Ton	0.19	0.0025
d	EDTA disodium	Annum	Ton	0.02	0.00027
e	NaOH(aq)	Annum	Ton	87	1.17
1.3	**Fuels**				
a	Coal	Annum	Ton	639.27	8.63
b	Diesel (Forklift, DG Set, Any other)	Annum	Ton	8.95	0.12
1.4	**Electricity/Heat**				
a	Electricity -Grid	Annum	kWh	4,28,277	5785

b	Electricity- DG	Annum	kWh	37,440	502
c	Coal Combustion	Annum	MJ	1,32,58,370	1,78,985
Outputs					
1.1	**Material**				
a	**Ciprofloxacin Base**	**Annum**	**Ton**	**74.02**	**1**
1.2	**Waste**				
a	Process residue	Annum	Ton	-	-
1.3	**Waste to Treatment**				
a	Mother Liquor	Annum	m3	520.38	7.03

3.3.3 CIPROFLOXACIN HCL

The functional unit for CIPROFLOXACIN HCL was considered as ton of CIPROFLOXACIN HCL, inputs and outputs for this operation has been listed below:

Table 3: Inventory Data – CIPROFLOXACIN.HCL

S. No	Particulars	Basis	Unit	Value	Normalized Values
Inputs					
1.1	**Resources**				
a	Normal Water	Annum	KL	-	-
b	Purified Water	Annum	Ton	114.6	11.93
c	DM Water	Annum	KL	-	-
1.2	**Avoided Products**				
a	Methanol Recovered	Annum	Ton	385.75	11.93
1.3	**Materials**				
a	Methanol	Annum	Ton	356.43	11.02
b	Ciprofloxacin Base	Annum	Ton	74.03	2.29
c	HCL	Annum	Ton	17.01	0.52
d	EDTA	Annum	Ton	0.019	0.0006
e	Activated Carbon	Annum	Ton	1.638	0.05
f	Methanol (aq)	Annum	Ton	51.7	1.6
1.4	**Fuels**				
a	Coal	Annum	Ton	279.38	8.64
b	Diesel (Forklift, DG Set, Any other)	Annum	Ton	3.91	0.12
1.5	**Electricity/Heat**				
a	Electricity - Grid	Annum	kWh	1,87,168	5,786
b	Electricity - generator	Annum	kWh	4186.92	502.43
c	Coal Combustion	Annum	MJ	55,86,241	1,72,758

Outputs					
1.1	**Material**				
a	**Ciprofloxacin.HCl**	**Annum**	**Ton**	**32.34**	**1**
1.2	**Waste**				
a	Process residue	Annum	Ton	3.46	0.1
1.3	**Waste to Treatment**				
a	Mother Liquor	Annum	m3	223.46	6.93

4 Life Cycle Impact Assessment

4.1 LCA Tool - About SimaPro

SimaPro is a well-recognized professional tool to collect, analyse and monitor the sustainability performance data of the company's products and services. Using SimaPro, the user can model and analyse complex life cycles in a systematic and transparent way, following ISO 14040 series recommendations. The software can be used for a variety of applications, such as sustainability reporting, carbon and water foot printing, product design, generating environmental product declarations and determining key performance indicators. It helps to make conscious decisions throughout the analysis, to ensure the accuracy of the results.

SimaPro requires the user to build a life cycle of product and fill details in each stage of product life cycle such as material, process, transport, recycle, reuse and disposal; and then, the results of product life cycle network and ecological impact are presented. In data collection stage, the user can input the amount of material, processes, and relative data available in the huge databases built in the package, which are collected from a large number of sources related to variety of assessment methods.

Furthermore, the database can be modified and extended based on customer's requirement. The user can add new material or process into the database and use it in his/her application. Function equations are also supported by SimaPro when the user adds new parameters or elements.

SimaPro has clear and precise presentation of results. The breakdown network of processes and materials are represented at the right side of each element of the presentation network, ecological impact indicator is illustrated in color bar. The size of the color bar indicates the scale of the impact, the larger one represents larger ecological impact of the element. This function is helpful for designer to compare the LCIA of different products, which is useful for eco-design optimization. SimaPro v9.6 is used for this study.

4.2 Impact Assessment Methodology

In life cycle assessment (LCA), environmental impacts are classified according to the methodology used. Several life cycle impact assessment (LCIA) methods are currently used, and the method selected, and the particulars thereof may influence the results obtained.

This is the step where the LCI list that contains the corresponding materials and consumed energy quantities related to the studied product is interpreted and transformed into understandable impact indicators. These indicators express the severity of the contribution of the impact categories to the environmental load. These indicators are concluded through a series of steps recommended by the ISO standards 14042, where some of these steps are obligatory and others are optional. The obligatory steps are definition and classification of impact categories, and characterization.

The impact categories are defined and selected to describe the impacts caused by the emissions and the consumption of natural resources that are induced during the production, use and disposal of the considered product or process.

4.3 ReCiPe Method

ReCiPe is a method for the life cycle impact assessment (LCIA). The primary objective of the ReCiPe method is to transform the long list of life cycle inventory results into a limited number of indicator scores. These indicator scores express the relative severity on an environmental impact category.

In ReCiPe we determine indicators at two levels:

18 midpoint indicators

3 endpoint indicators

Each method (midpoint, endpoint) contains factors according to the three cultural perspectives. These perspectives represent a set of choices on issues like time or expectations that proper management or future technology development can avoid future damages.

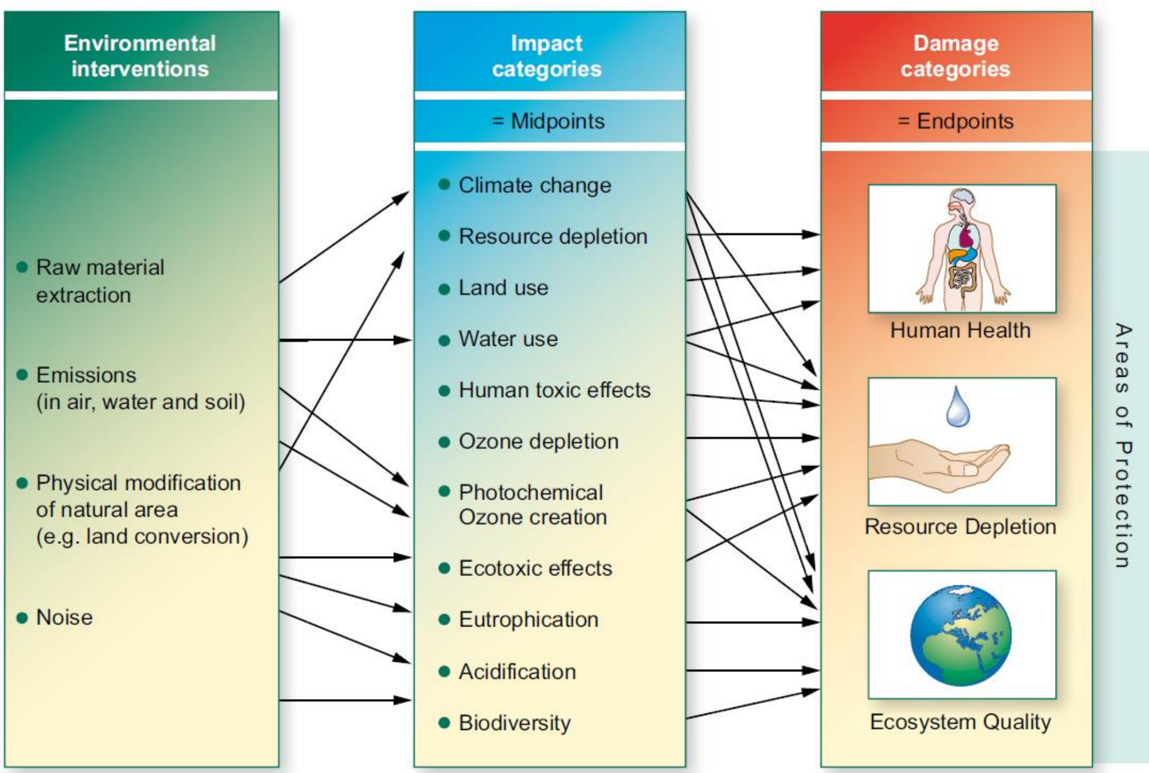

Figure 5: ReCiPe Method – Impact

Individualist: Short term, optimism that technology can avoid many problems in future.
Hierarchist: consensus model, as often encountered in scientific models, this is often considered to be the default model.
Egalitarian: long term based on precautionary principle thinking.
Some of the advantages of the ReCiPe framework relative to other approaches include:
The broadest set of midpoint impact categories. Where possible, it uses impact mechanisms that have global scope. Unlike other approaches (Eco-Indicator 99, EPS Method, LIME, and Impact 2002+) it does not include potential impacts from future extractions in the impact assessment but assumes such impacts have been included in the inventory analysis.

4.4 Analysis

After entering the inputs into the software, the analysis is run to obtain the results. The results obtained are in the form of graph which determines the kg CO_2 equivalent for one ton of the product. The characterization & normalization graphs are obtained from which the impact analysis can be drawn. It has 18 indicators each represented with different colors to analyse the impact of each indicator.

4.5 Impact Categories

Table 4: Impact categories description

Impact Categories	Units	Description	Endpoint Impact Receptor
Climate change / Global warming	kg CO2 equivalent	Alteration of global temperature caused by Greenhouse gases, this causes disturbances in global temperature and climatic phenomenon.	Ecosystem Health Human Health
Stratospheric ozone depletion	Kg CFC-11 equivalent	Diminution of the stratospheric ozone layer due to anthropogenic emissions of ozone-depleting substances. This causes an increase of ultraviolet UV-B radiation and the number of cases of skin illnesses.	Human Health
Ionizing Radiation	kBq Co-60 equivalent	It is related to the damage to human health and ecosystems that are linked to the emissions of radionuclides throughout a product or building lifecycle. The effects of radiation are health decline, cancer, illness etc.	Human Health
Fine particulate matter formation	kg PM2.5 equivalents	Suspended extremely small particles originated from anthropogenic processes such as combustion, resource extraction, etc. This causes an increase in different sized particles suspended on-air leading to a multitude of health problems especially of the respiratory tract.	Human Health
Freshwater eutrophication	kg PO43- equivalent	Eutrophication is the build-up of a concentration of chemical nutrients in an ecosystem which leads to abnormal productivity this causes excessive plant growth like algae in rivers/sea waters which causes severe reductions in water quality and animal populations. In freshwater ecosystems it is almost always caused by excess phosphorus. In coastal waters, the main contributing nutrient is more likely to be nitrogen, or nitrogen and phosphorus together.	Ecosystem Health
Marine eutrophication	kg N equivalent		
Terrestrial acidification	kg SO2 equivalent,	Reduction of pH due to the acidifying effects of anthropogenic emissions such as NH3, SOx, NOx this causes an increase in the acidity of water & soil systems	Ecosystem Health

Land Use	m2a crop equivalent,	Impact on the land due to agriculture, anthropogenic settlement and resource extractions. This causes Species loss, soil loss, amount of organic dry matter content, etc.	Ecosystem Health
Mineral Resource Scarcity	kg Cu equivalent,	Consumption of non-biological resources such as fossil fuels, minerals, metals, water etc. This causes a decrease in resources	Natural Resources
Fossil resource scarcity	kg oil equivalent,		
Water Consumption	m3,		
Photochemical Ozone formation, Human health	kg NOx equivalent,	Ground-level or tropospheric ozone is created by the formation of ozone at the ground level of the troposphere caused by photochemical oxidation of Volatile Organic Compounds (VOCs) and carbon monoxide (CO) in the presence of nitrogen oxides (NOx) and sunlight. High concentrations of ground-level tropospheric ozone can have a negative impact on human health, e.g. respiratory problems, and terrestrial ecosystems, e.g. plant biomass decrease.	Human Health
Photochemical Ozone formation, Terrestrial ecosystems	kg NOx equivalent,		Ecosystem Health
Terrestrial ecotoxicity	kg 1,4-DCB equivalent	Environmental toxicity / ecotoxicity refers to toxic effects of chemicals on three separate impact categories which examine freshwater, marine and land. This causes biodiversity loss and/or extinction of species. Assessments of toxicity are based on tolerable concentrations in air, water, air quality guidelines, tolerable daily intake and acceptable daily intake for human toxicity.	Ecosystem Health
Freshwater ecotoxicity	kg 1,4-DCB equivalent		
Marine ecotoxicity	kg 1,4-DCB equivalent		
Human carcinogenic toxicity	kg 1,4-DCB equivalent	Toxic effects of chemicals on humans, including cancer and various non-cancer effects, leading to damage on human health.	Human Health
Human non-carcinogenic toxicity	kg 1,4-DCB equivalent		

5 Life Cycle Impact Analysis (LCIA)

This chapter analyses the impacts arising from the production of ton of CIPROFLOXACIN HCL at Neuland Laboratories Limited. The method used for this LCA study was ReCiPe and the impacts categories considered were global warming potential, acidification, eutrophication, ozone depletion potential, ecotoxicity etc. The lifecycle assessment was done for all the products at Neuland Laboratories Limited.

5.1 CIPROFLOXACIN BASE TECH - LCIA

For the 2023-24, the environmental impacts for one ton of Ciprofloxacin Base Tech production are highlighted in the table below:

Table 5: Environment Impact – CIPROFLOXACIN BASE TECH

Impact category	Unit	CIPROFLOXACIN BASE TECH
Global warming	kg CO2 eq	28,239.1
Stratospheric ozone depletion	kg CFC-11 eq	0.005
Ionizing radiation	kBq Co-60 eq	77.613
Ozone formation, Human health	kg NOx eq	68.559
Fine particulate matter formation	kg PM2.5 eq	51.933
Ozone formation, Terrestrial ecosystems	kg NOx eq	74.338
Terrestrial acidification	kg SO2 eq	107.42
Freshwater eutrophication	kg P eq	9.778
Marine eutrophication	kg N eq	19.244
Terrestrial ecotoxicity	kg 1,4-DCB	1,29,875
Freshwater ecotoxicity	kg 1,4-DCB	20.523
Marine ecotoxicity	kg 1,4-DCB	138.778
Human carcinogenic toxicity	kg 1,4-DCB	149.115
Human non-carcinogenic toxicity	kg 1,4-DCB	3405.855
Land use	m2a crop eq	778.723
Mineral resource scarcity	kg Cu eq	35.45
Fossil resource scarcity	kg oil eq	12,165.69
Water consumption	m3	572.178

Table 6 : % Contributions of CIPROFLOXACIN BASE TECH

Impact category	Unit	Raw Materials	Fuels	Energy	Waste Water	TOTAL %
Global warming	kg CO2 eq	38.23%	2.64%	59.12%	0.01%	100.00%
Stratospheric ozone depletion	kg CFC11 eq	41.43%	3.50%	54.87%	0.20%	100.00%
Ionizing radiation	kBq Co-60 eq	43.61%	0.58%	55.80%	0.01%	100.00%
Ozone formation, Human health	kg NOx eq	37.33%	3.15%	59.51%	0.01%	100.00%
Fine particulate matter formation	kg PM2.5 eq	23.40%	7.00%	69.59%	0.01%	100.00%

Ozone formation, Terrestrial ecosystems	kg NOx eq	41.65%	3.06%	55.28%	0.01%	100.00%
Terrestrial acidification	kg SO2 eq	24.18%	2.03%	73.79%	0.01%	100.00%
Freshwater eutrophication	kg P eq	76.57%	11.85%	11.47%	0.12%	100.00%
Marine eutrophication	kg N eq	99.56%	0.09%	0.20%	0.15%	100.00%
Terrestrial ecotoxicity	kg 1,4-DCB	76.00%	3.80%	20.18%	0.02%	100.00%
Freshwater ecotoxicity	kg 1,4-DCB	77.59%	5.34%	16.91%	0.16%	100.00%
Marine ecotoxicity	kg 1,4-DCB	74.80%	4.82%	20.33%	0.05%	100.00%
Human carcinogenic toxicity	kg 1,4-DCB	74.99%	1.68%	23.30%	0.02%	100.00%
Human non-carcinogenic toxicity	kg 1,4-DCB	49.03%	2.26%	48.24%	0.47%	100.00%
Land use	m2a crop eq	27.13%	38.90%	33.96%	0.01%	100.00%
Mineral resource scarcity	kg Cu eq	84.79%	2.57%	12.62%	0.02%	100.00%
Fossil resource scarcity	kg oil eq	33.50%	35.70%	30.80%	0.00%	100.00%
Water consumption	m3	23.92%	1.03%	76.00%	-0.95%	100.00%

The following graph summaries the impact of Production of one ton CIPROFLOXACIN BASE TECH, the impact from the **Pyridine** and **Combustion of Coal** are major contributors to the environment impacts among all the other materials used. The detailed breakup results of all the contributors are given in Annexure.

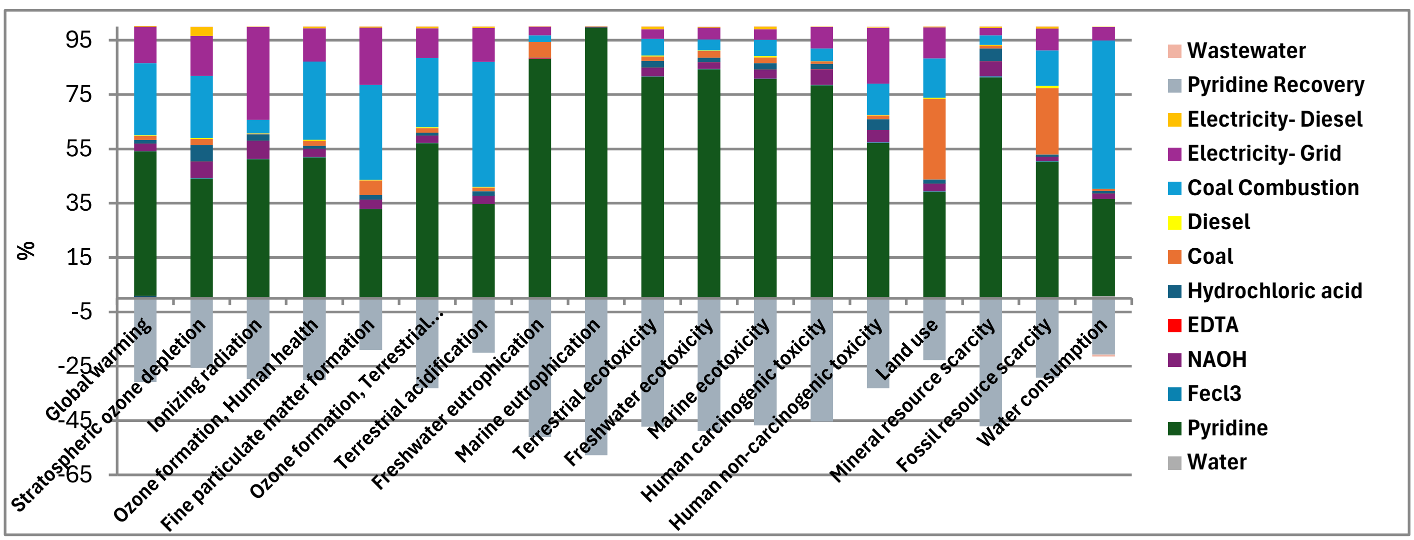

Figure 6: Impact Assessment – CIPROFLOXACIN BASE TECH

5.2 CIPROFLOXACIN BASE - LCIA

For the 2023-24, the environmental impacts for one ton of CIPROFLOXACIN BASE is highlighted in the table below:

Table 7 : Environment Impact – CIPROFLOXACIN BASE

Impact category	Unit	CIPROFLOXACIN BASE
Global warming	kg CO2 eq	44,174.97
Stratospheric ozone depletion	kg CFC-11 eq	0.009
Ionizing radiation	kBq Co-60 eq	121
Ozone formation, Human health	kg NOx eq	107.26
Fine particulate matter formation	kg PM2.5 eq	88.66
Ozone formation, Terrestrial ecosystems	kg NOx eq	112.88
Terrestrial acidification	kg SO2 eq	183.17
Freshwater eutrophication	kg P eq	10.79
Marine eutrophication	kg N eq	16.52
Terrestrial ecotoxicity	kg 1,4-DCB	1,62,793.36
Freshwater ecotoxicity	kg 1,4-DCB	25.32
Marine ecotoxicity	kg 1,4-DCB	176.40
Human carcinogenic toxicity	kg 1,4-DCB	181
Human non-carcinogenic toxicity	kg 1,4-DCB	5515.38
Land use	m2a crop eq	1,291.94
Mineral resource scarcity	kg Cu eq	45.24
Fossil resource scarcity	kg oil eq	19,302.07
Water consumption	m3	971.22

Table 8 : % Contributions of CIPROFLOXACIN BASE

Impact category	Unit	Ciprofloxacin Base Tech	Raw Materials	Energy	Fuels	Wastewater	Total
Global warming	kg CO2 eq	54.40%	5.23%	38.67%	1.69%	0.01%	100.00%
Stratospheric ozone depletion	kg CFC11 eq	50.69%	13.73%	33.33%	2.09%	0.15%	100.00%
Ionizing radiation	kBq Co-60 eq	54.51%	9.21%	35.90%	0.37%	0.01%	100.00%
Ozone formation, Human health	kg NOx eq	54.40%	4.60%	38.98%	2.01%	0.01%	100.00%
Fine particulate matter formation	kg PM2.5 eq	49.85%	4.38%	41.66%	4.10%	0.01%	100.00%
Ozone formation, Terrestrial ecosystems	kg NOx eq	56.05%	4.62%	37.30%	2.02%	0.01%	100.00%
Terrestrial acidification	kg SO2 eq	49.91%	4.42%	44.48%	1.19%	0.01%	100.00%
Freshwater eutrophication	kg P eq	77.08%	1.51%	10.55%	10.73%	0.14%	100.00%

Marine eutrophication	kg N eq	99.13%	0.29%	0.24%	0.11%	0.24%	100.00%
Terrestrial ecotoxicity	kg 1,4-DCB	67.90%	12.62%	16.43%	3.03%	0.02%	100.00%
Freshwater ecotoxicity	kg 1,4-DCB	68.98%	12.60%	13.93%	4.33%	0.17%	100.00%
Marine ecotoxicity	kg 1,4-DCB	66.95%	12.89%	16.31%	3.79%	0.05%	100.00%
Human carcinogenic toxicity	kg 1,4-DCB	70.20%	8.92%	19.47%	1.39%	0.02%	100.00%
Human non-carcinogenic toxicity	kg 1,4-DCB	52.55%	15.50%	30.17%	1.39%	0.38%	100.00%
Land use	m2a crop eq	51.30%	4.38%	20.87%	23.44%	0.01%	100.00%
Mineral resource scarcity	kg Cu eq	66.69%	21.20%	10.07%	2.02%	0.02%	100.00%
Fossil resource scarcity	kg oil eq	53.64%	4.04%	19.83%	22.49%	0.00%	100.00%
Water consumption	m3	50.14%	3.75%	46.25%	0.60%	-0.74%	100.00%

The following graph summaries the impact of Production of one ton CIPROFLOXACIN BASE, the impact from the **CIPROFLOXACIN BASE TECH, Electricity-Grid & Combustion of Coal** are major contributors to the environment impacts among all the other processes. The detailed breakup results of all the contributors are given in Annexure.

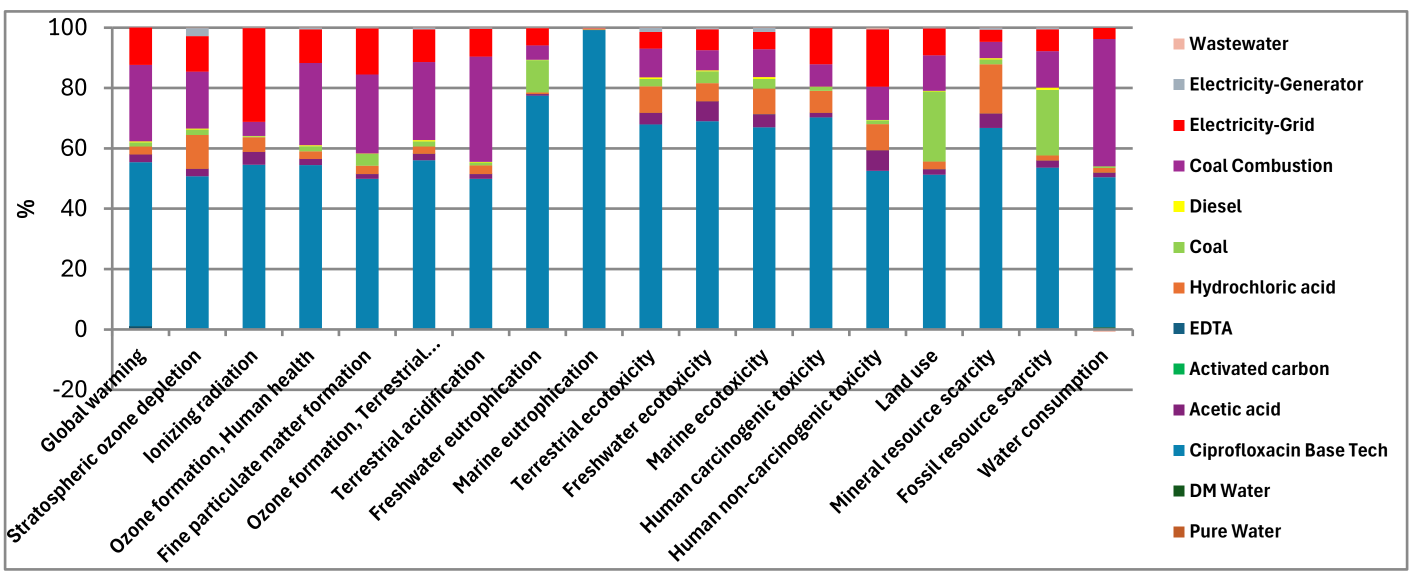

Figure 7: Impact Assessment – CIPROFLOXACIN BASE

5.3 CIPROFLOXACIN HCL (Final Product) – LCIA

For the 2023-24, the environmental impacts for one ton of CIPROFLOXACIN HCL production is highlighted in the table below:

Table 9: Environment Impact – CIPROFLOXACIN HCL

Impact category	Unit	CIPROFLOXACIN HCL
Global warming	kg CO2 eq	1,39,690
Stratospheric ozone depletion	kg CFC-11 eq	0.032
Ionizing radiation	kBq Co-60 eq	345
Ozone formation, Human health	kg NOx eq	320.81
Fine particulate matter formation	kg PM2.5 eq	259.30
Ozone formation, Terrestrial ecosystems	kg NOx eq	337.83
Terrestrial acidification	kg SO2 eq	535.48
Freshwater eutrophication	kg P eq	27.47
Marine eutrophication	kg N eq	38.11
Terrestrial ecotoxicity	kg 1,4-DCB	8,24,605
Freshwater ecotoxicity	kg 1,4-DCB	99.66
Marine ecotoxicity	kg 1,4-DCB	840.16
Human carcinogenic toxicity	kg 1,4-DCB	508
Human non-carcinogenic toxicity	kg 1,4-DCB	18,362
Land use	m2a crop eq	4,180.25
Mineral resource scarcity	kg Cu eq	171.11
Fossil resource scarcity	kg oil eq	59,337
Water consumption	m3	2,710.67

Table 10 : % Contributions of CIPROFLOXACIN HCL

Impact category	Unit	Ciprofloxacin Base	Raw Materials	Energy	Fuels	Packing	Transportation	Wastewater	Total
Global warming	kg CO2 eq	72.38%	1.02%	11.95%	0.53%	0.52%	13.59%	0.00%	100.00%
Stratospheric ozone depletion	kg CFC11 eq	64.61%	1.88%	9.23%	0.59%	0.45%	23.20%	0.04%	100.00%
Ionizing radiation	kBq Co-60 eq	80.38%	1.14%	12.55%	0.13%	0.57%	5.22%	0.00%	100.00%
Ozone formation, Human health	kg NOx eq	76.52%	0.90%	12.72%	0.67%	0.48%	8.71%	0.00%	100.00%
Fine particulate matter formation	kg PM2.5 eq	78.26%	0.73%	13.94%	1.40%	0.29%	5.38%	0.00%	100.00%
Ozone formation, Terrestrial ecosystems	kg NOx eq	76.47%	0.94%	12.16%	0.67%	0.52%	9.23%	0.00%	100.00%
Terrestrial acidification	kg SO2 eq	78.29%	0.79%	14.80%	0.41%	0.31%	5.41%	0.00%	100.00%
Freshwater eutrophication	kg P eq	89.96%	0.76%	4.08%	4.22%	0.07%	0.85%	0.05%	100.00%
Marine eutrophication	kg N eq	99.21%	0.15%	0.10%	0.05%	0.03%	0.36%	0.10%	100.00%
Terrestrial ecotoxicity	kg 1,4-DCB	45.18%	1.43%	3.18%	0.60%	0.73%	48.88%	0.00%	100.00%
Freshwater ecotoxicity	kg 1,4-DCB	58.16%	1.18%	3.48%	1.10%	0.58%	35.47%	0.04%	100.00%

Marine ecotoxicity	kg 1,4-DCB	48.05%	1.58%	3.36%	0.80%	0.81%	45.39%	0.01%	100.00%
Human carcinogenic toxicity	kg 1,4-DCB	81.39%	1.45%	6.83%	0.49%	0.48%	9.34%	0.01%	100.00%
Human non-carcinogenic toxicity	kg 1,4-DCB	68.75%	1.51%	8.95%	0.42%	0.59%	19.68%	0.11%	100.00%
Land use	m2a crop eq	70.73%	0.62%	6.33%	7.25%	0.40%	14.67%	0.00%	100.00%
Mineral resource scarcity	kg Cu eq	60.51%	2.70%	2.61%	0.53%	1.34%	32.29%	0.01%	100.00%
Fossil resource scarcity	kg oil eq	74.45%	1.39%	6.31%	7.32%	0.71%	9.81%	0.00%	100.00%
Water consumption	m3	82.00%	0.48%	16.04%	0.22%	0.17%	1.35%	-0.26%	100.00%

The following graph summaries the impact of Production of one ton of CIPROFLOXACIN HCL, the impact from the **CIPROFLOXACIN BASE & Transportation** are major contributors to the environment impacts among all the other processes. The detailed breakup results of all the contributors are given in Annexure.

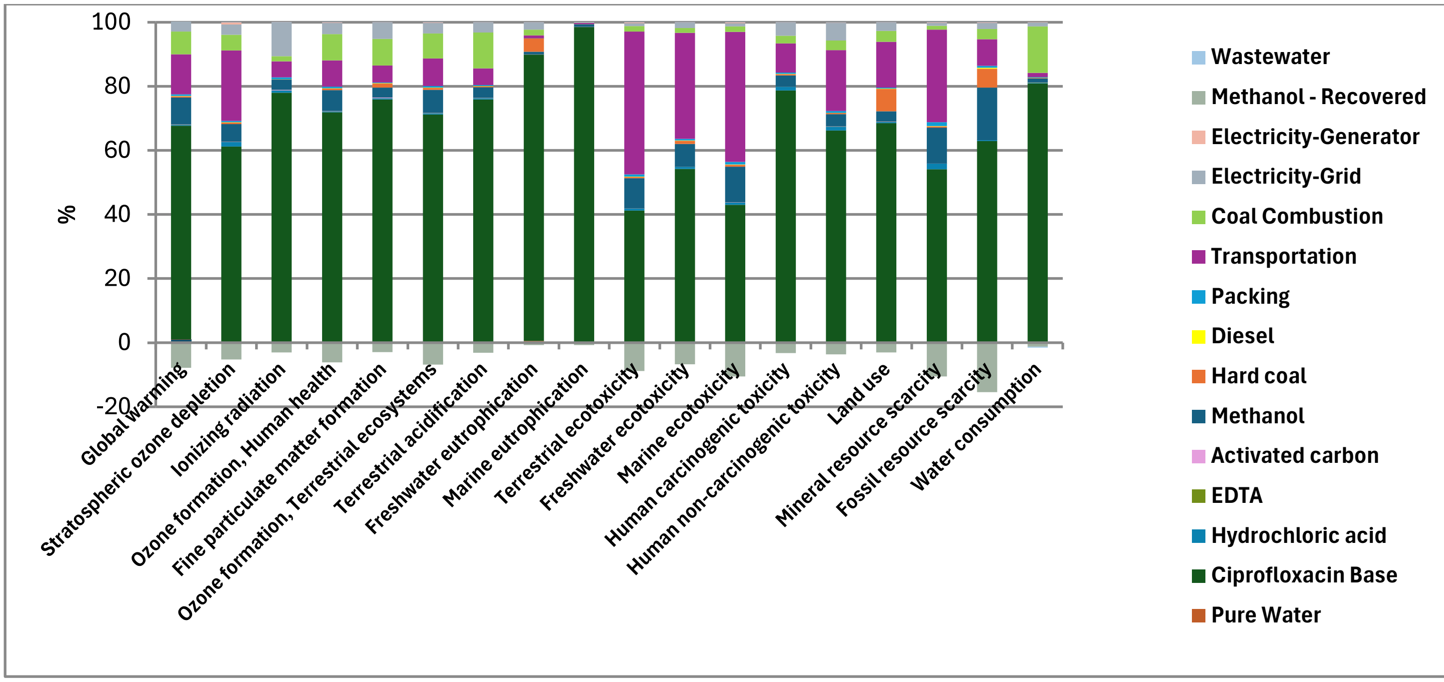

Figure 8: Impact Assessment – CIPROFLOXACIN HCL (Final Product)

5.4 LCA summary – CIPROFLOXACIN BASE TECH/CIPROFLOXACIN BASE/CIPROFLOXACIN HCL

Neuland Laboratories Limited manufactures– CIPROFLOXACIN.HCL, for which CIPROFLOXACIN BASE TECH, CIPROFLOXACIN BASE are intermediate products. Each unit process has a different mix of materials/fuels because of which they have different environmental impacts and hotspots in their life cycle.

Table 11: Summary of Environmental Impacts – CIPROFLOXACIN BASE TECH/CIPROFLOXACIN BASE/CIPROFLOXACIN HCL

Impact category	Unit	CIPROFLOXACIN BASE TECH	CIPROFLOXACIN BASE	CIPROFLOXACIN HCL
Global warming	kg CO2 eq	28,239.06	44,174.98	1,39,690.26
Stratospheric ozone depletion	kg CFC-11 eq	0.0054	0.0092	0.0324

Ionizing radiation	kBq CO-60 eq	77.61	121.17	345.01
Ozone formation, Human health	kg NOx eq	68.56	107.26	320.81
Fine particulate matter formation	kg PM2.5 eq	51.93	88.66	259.30
Ozone formation, Terrestrial ecosystems	kg NOx eq	74.34	112.88	337.83
Terrestrial acidification	kg SO2 eq	107.42	183.17	535.48
Freshwater eutrophication	kg P eq	9.78	10.79	27.47
Marine eutrophication	kg N eq	19.24	16.520	38.11
Terrestrial ecotoxicity	kg 1,4-DCB	1,29,875	1,62,793	8,24,605
Freshwater ecotoxicity	kg 1,4-DCB	20.523	25.322	99.66
Marine ecotoxicity	kg 1,4-DCB	138.78	176.40	840.16
Human carcinogenic toxicity	kg 1,4-DCB	149.12	180.78	508.38
Human non-carcinogenic toxicity	kg 1,4-DCB	3,406	5,515	18,362
Land use	m2a crop eq	778.72	1,291.94	4,180.25
Mineral resource scarcity	kg Cu eq	35.45	45.24	171.11
Fossil resource scarcity	kg oil eq	12,165.69	19,302.07	59,336.63
Water consumption	m3	572.18	971.22	2,710.67

5.4.1 Global Warming Potential

All steps are summarized on global warming environment impact (kg CO_2 eq/ton of product) and summarized below in the figure.

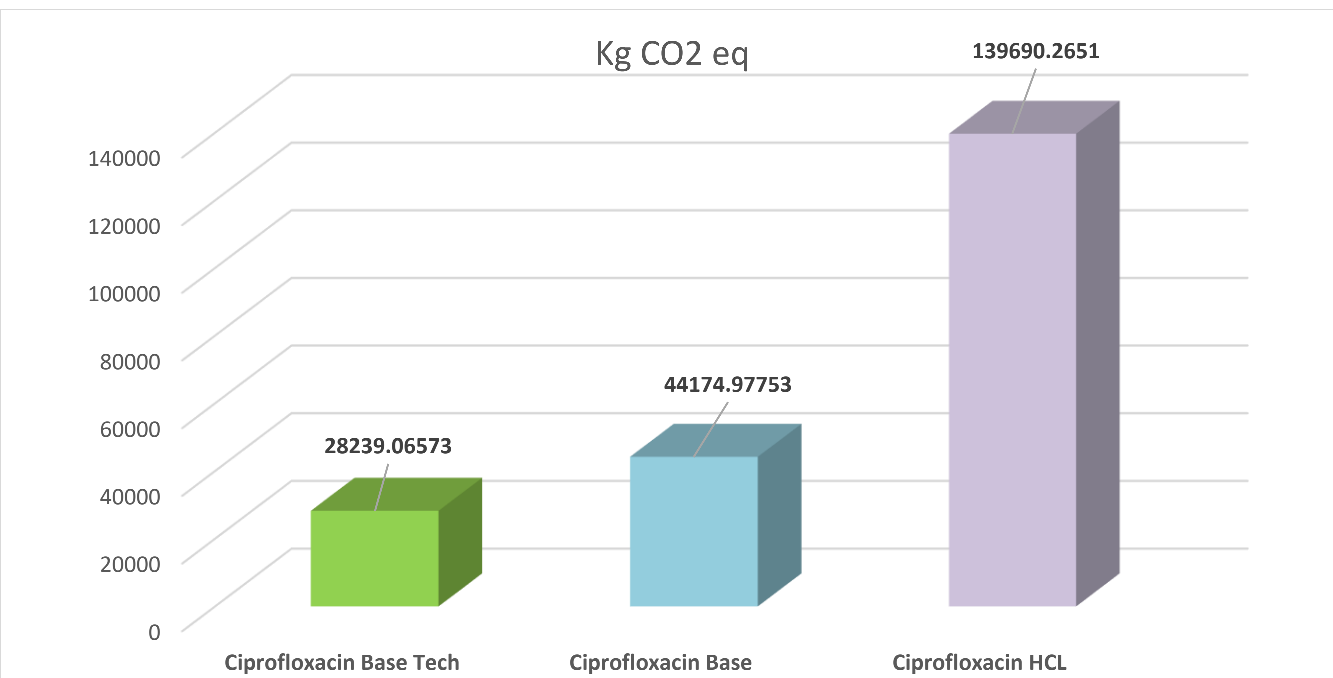

Figure 9: Global warming Intensity Comparison

Emission intensity of CIPROFLOXACIN HCL manufactured at plant is 1,39,690.2651 kg CO_2 eq/ton.

5.4.2 Acidification

Emission intensity of Ciprofloxacin HCL manufactured is 535.48 kg SO_2 eq/ton. Ciprofloxacin Base is the major contributor to Acidification in the production of Ciprofloxacin HCL

5.4.3 Terrestrial Ecotoxicity

The terrestrial ecotoxicity potential of Ciprofloxacin HCL is 8,24,604.73 kg 1,4-DCB/ton.

5.4.4 Fossil Fuel Scarcity

The scarcity of fossil fuel due to Ciprofloxacin HCL is 59,336.64 kg oil eq/ton.

6 Critical Review and Conclusion

The primary goal of the critical review chapter is to discuss various parameters like completeness of the data, sensitivity analysis and consistency check. In addition, this chapter provides quick insights on maximization of this study in future.

6.1 Completeness

LCA study for Neuland Laboratories Limited was carried out in accordance with the ISO 14044 standard. The data collection process was designed to cover all major impact sources considering the cut off criteria assigned for this study. Assumptions taken for the study are rationalized.

6.2 Consistency check

To check the consistency of data used for calculation, CII – Godrej GBC team has carried out the authentication and cross checked the numbers submitted with the publicly declared data available in open domain.

6.3 Way forward

Environmentally friendly manufacturing practices have become a contemporary priority for industries. With increasing awareness of environmental impacts among various industry stakeholders, assessing the performance of a product is essential. This LCA study will support Neuland Laboratories Limited in developing a comprehensive model to eliminate environmental risks associated with its production practices. Additionally, this study will serve as a platform to highlight the environmental performance of the product.

Beyond that, it will act as a strong communication tool for showcasing energy efficiency and environmental management initiatives. This exposition will provide Neuland Laboratories Limited with a competitive edge and facilitate expansion into new markets. Various scenarios have been modeled to assess the potential reduction in environmental impacts. The proposed mitigation strategies align with those outlined in the **Decarbonization Roadmap for Neuland Laboratories Limited** (detailed in the annex), ensuring a structured approach to sustainability and emissions reduction.

6.4 KEY OBSERVATIONS:

GHG Emission Intensities are as follows:

- CIPROFLOXACIN BASE TECH –28,239.06 kg CO2 e/ Ton
- CIPROFLOXACIN BASE 44,174.98 kg CO2 e/ Ton
- CIPROFLOXACIN HCL– 1,39,690.26 kg CO2 e/ Ton

- ✓ CIPROFLOXACIN HCL – Pyridine is the major contributor for environmental impacts.
- ✓ Other than Pyridine Major Impacts are contributed by, Coal Combustion, HCL, Electricity-Grid & Transportation.

- ✓ Other Opportunities to reduce environmental impacts include:
  - ➢ Waste heat recovery wherever feasible
  - ➢ Electrification of boilers
  - ➢ Renewable energy and Battery storage systems
  - ➢ Biomass based fuels replacing fossil fuels
  - ➢ Energy and Building management systems
  - ➢ Usage of Green fuels & EVs in Transportation of Materials.

Annexures

Annexure – A – About LCA

Introduction to Lifecycle Assessment

The search for innovation and cost-effective ways of resource optimization has led to the development of a wide array of concepts and tools for effective decision making. Today, a range of performance tools focusing on environment in tandem with efficiency improvements are largely espoused by industries. Studies like Life Cycle Impact Assessment (ISO 14044), Greenhouse Gas Accounting (ISO 14064) and Environmental Product Declaration, EPD (ISO 14025) are taken up by the industries for objective analysis in the areas of product design development, process improvement, economies of scale and policy strategy formulation etc. Life Cycle Impact Assessment (LCA) tool has emerged as a powerful tool for product improvement and raw material substitution to attain the twin objectives of sustainability and profit maximization.

"LCA is a technique for assessing the environmental aspects and potential impacts (damages) associated with a product, by

- Compiling an inventory of relevant inputs and outputs of a system.
- Evaluating the potential environmental impacts (damages) associated with those inputs and outputs.
- Interpreting the results of the inventory and impact (damage) phases in relation to the objectives of the study.

LCA studies the environmental aspects and potential impacts (damages) along the continuum of a product's life (i.e., Cradle-to-Cradle) from raw material acquisition through production, use and disposal & recovery/recycling. The general categories of environmental impacts needing consideration include resource use, human health, and ecological consequences" (ISO, 1998).

- Goal and scope definition (ISO 14041, 1998);
- Inventory analysis (ISO 14041, 1998);
- Impact assessment (ISO 14042, 2000);
- Interpretation (ISO 14043, 2000).

The relation between the different phases is illustrated in the following figure. The figure shows that the 4 phases are not independent of each other. It also shows that the scope, the boundaries and the level of detail of an LCA depend on the intended use of the study.

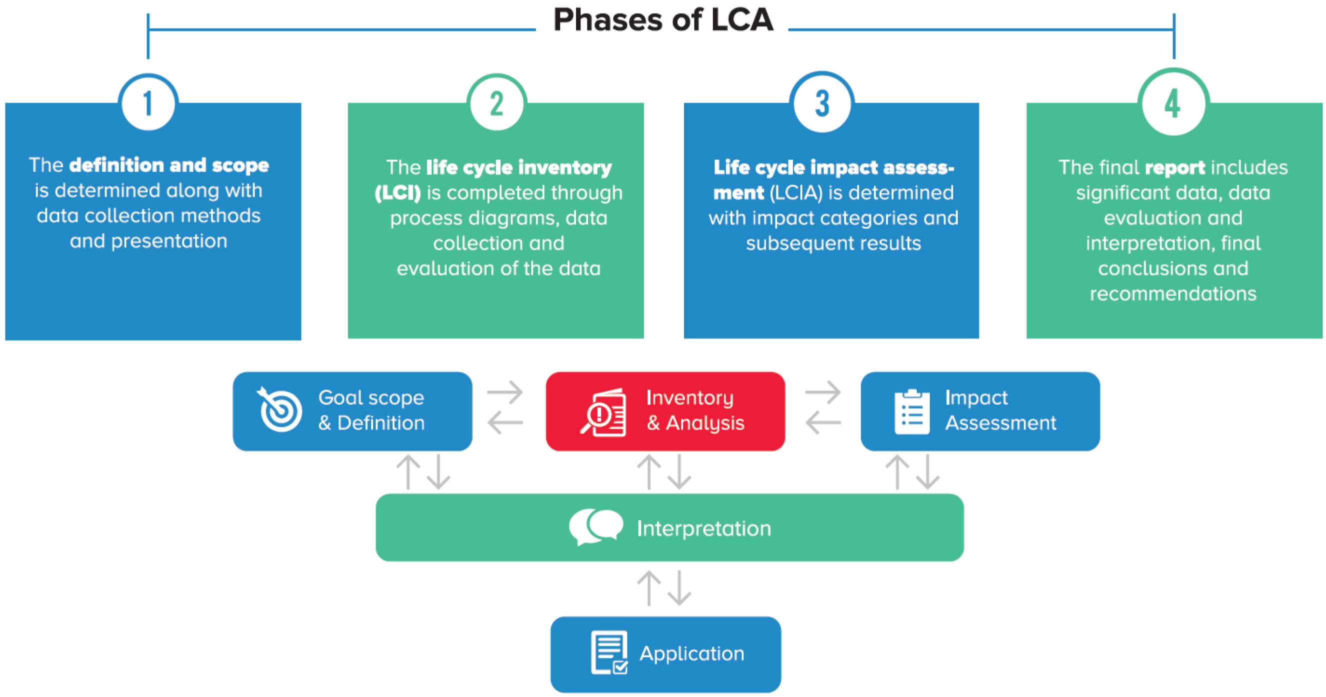

Figure 10: Lifecycle Assessment Framework

Goal and scope definition

In the first phase of an LCA, the intended use of the LCA (the goal) and the breadth and depth of the study (the scope) have to be clearly defined. The scope definition has to be consistent with the goal of the study. In the following paragraphs, aspects that should be clearly agreed upon at the start of the study are discussed briefly (ISO 14040, 1997 and ISO 14041, 1998).

The goal definition of an LCA includes a clear description of:

- The reasons for carrying out the LCA;
- The intended use of its results;
- The audience(s) to which the results are intended to be communicated.

In general, the reasons for carrying out an LCA depend on following 2 different choices:

Specific LCA:

- Determining the environmental profile of a product / process, and
- Finding out the environmental improvement opportunities of the product / process to be studied

Comparative LCA:

- Determining the environmental profile of different existing product systems, and
- Comparing the different environmental profiles.

In general, an LCA-study can be aimed at:

- Internal use: the results will be used internally (remark: the impact profile can be normalized and weighted in order to obtain one final environmental index for the system studied)
- External use: commercial use of positive results for application and marketing (remark: ISO 14040 says "in the case of comparative assertions disclosed to the public, the evaluation shall be conducted in accordance with the critical review process and presented category indicator by category indicator").

Scope of the LCA

The scoping process links the goal of the assessment with the extent of the study: what will or will not be included in the assessment? While defining the scope the following parameters are decided:

- Functional unit is defined
- The system boundaries are fixed
- Types of data required are chosen.

According to ISO 14040 and 14041 standards in defining the scope of the LCA study the following items shall be considered and clearly described:

- The functions of the product system(s);
- The functional unit;
- The product system(s) to be studied;
- The product system(s) boundaries;
- Allocation procedures;
- Types of impact and methodology of impact assessment, and subsequent interpretation to be used;
- Data requirements;
- Data quality requirements;
- Assumptions;
- Limitations;
- Type of critical review, if any;
- Type and format of the report required for the study.

The scope should be sufficiently well defined to ensure that the breadth, the depth and the detail of the study are compatible and sufficient to address the stated goal.

<u>Function and functional unit</u>

The function(s) that are fulfilled by the system(s) under study should be clearly defined. Derived from that, the functional unit has to be defined. The functional unit measures the performance of the system, and provides a reference to which the input and output data will be normalized. In comparative LCAs, comparisons can only be made on the basis of equivalent functions, i.e. LCA data can only be compared if they are normalized to the same functional unit.

<u>Description of the system(s) studied</u>

The system that will be studied in the LCA should be clearly described. Flow diagrams can be used to show the different subsystems, processes and material flows that are part of the system model.

<u>System boundaries</u>

The system boundaries of the LCA should be clearly defined. This includes a statement of:

- Which processes will be included in the study;
- To which level of detail these processes will be studied;
- Which releases to the environment will be evaluated;
- To which level of detail this evaluation will be made.

Ideally, all life cycle stages, from the extraction of raw materials to the final waste treatment, should be taken into consideration. In practice however, there is often not sufficient time, data or resources to conduct such a comprehensive study. Decisions have to be made regarding which life cycle stages, processes or releases to the environment can be omitted without compromising the results of the study. Any omissions should be clearly stated and justified in the light of the defined goal of the study.

LCA study is categorized into different types based on the system boundary as follows:

- **Cradle to Grave** system analyses and identifies environmental impacts associated from raw material extraction for the product development to end of life phase of the same product

- **Gate to Gate** system studies the environmental impacts associated with the product occurring within the plant boundary excluding the impacts associated with upstream and downstream process

- **Cradle to Gate** system explores the environmental impacts associated with the product from upstream phase to manufacturing phase, but does not include impacts arising from downstream system

Allocation procedures

Allocation procedures are needed when dealing with systems involving multiple products. The materials and energy flows as well as associated environmental releases shall be allocated to the different products according to clearly stated procedures, which shall be documented and justified.

Methodology

The impact assessment phase of the LCA is aimed at evaluating the significance of potential environmental impacts using the results of the life cycle inventory analysis. In general, this process involves associating inventory data with specific environmental impacts and attempting to understand those impacts. The level of detail, choice of impacts evaluated and methodologies depends on the goal and scope of the study. The LCA ends with the environmental profile of the alternatives, in which the contribution of each alternative is shown for each individual environmental impact or damage category.

Data and data quality requirements

It should be identified which data are needed in order to meet the goal of the study, and which level of detail is required for different data categories. The different data sources that will be used should be stated. This may include measured data, data obtained from published sources, calculated or estimated data. The data requirements are dependent on the questions that are raised in the study. Efforts do not need to be put in the quantification of minor or negligible inputs and outputs that will not significantly change the overall results of the study.

A complete description of the required data quality includes the following parameters:

- Geographical coverage;
- Time period covered;
- Technology coverage;
- Precision, completeness and representativeness;
- Consistency and reproducibility;
- Sources of the data and their representativeness;
- Variability and uncertainty of the information and methods.

Assumptions and limitations

All assumptions made during the course of the project and the limitations of the study will be commented on in the report. The results of the LCA will be interpreted in agreement with the goal and scope and therefore with the ISO 14041 and 14043 guidelines.

Critical review

A critical review is a process to verify whether an LCA has met the requirements of international (ISO) standards for methodology, data collection and reporting. Whether and how a critical review will be conducted should be specified in the scope of the study.

Three types of critical review are defined by ISO 14040:

- Internal review, performed by an internal expert independent of the LCA study;
- Expert review, performed by an external expert independent of the LCA study;
- Review by interested parties, performed by a review panel chaired by an external independent expert - the panel includes interested parties that will be affected by conclusions drawn from the LCA study, such as government agencies, non-governmental groups.

When an LCA study will be used to make a comparative assertion that is disclosed to the public, ISO standards require a critical review by interested parties to be conducted. In all other cases, critical reviews in LCA are optional and may utilize any of the three review options mentioned above.

Type and format of the report

The results of the LCA will be fairly, completely and accurately reported to the intended audience, in keeping with ISO 14040.

Inventory analysis

The inventory analysis involves data collection and calculation procedures to quantify the inputs and outputs that are associated with the product system(s) under study. This includes use of resources, releases to air, water and land. Procedures of data collection and calculation should be consistent with the goal and the scope of the study. The results of the inventory analysis may constitute the input for the life cycle assessment as well as an input for the interpretation phase.

Input and output data have to be collected for each process that is included in the system boundaries. After collection, the data for the different processes have to be normalized to the functional unit and aggregated. This corresponds to a calculation of all inputs and outputs referenced to the functional unit, which is the final result of the inventory analysis.

Inventory analysis is an iterative process. As data are collected and the system is better known, new data requirements or limitations may become apparent. This may require better or additional data to be collected or system boundaries to be refined.

Allocation

A special issue related to the inventory analysis is the so-called allocation problem. This refers to the allocation of environmental inputs and outputs of a process to different products. Examples of processes were allocation is needed are:

- **Co-production:** processes in which two or more products are produced simultaneously; the environmental inputs and outputs of these processes need to be allocated to the different products;

- **Processing of mixed waste streams:** processes in which two or more waste streams are processed simultaneously; the environmental inputs and outputs of these processes need to be allocated to the different waste streams;

- **Open-loop recycling:** processes in which a discarded product from one product system is used as a raw material for another product system; the environmental inputs and outputs of these processes need to be allocated to the different product systems.

Different approaches can be used for carrying out allocation. The following stepwise allocation procedure is recommended by ISO and by Society of Environmental Toxicology and Chemistry (SETAC) - Wherever possible, allocation should be avoided or minimized. This can be done by detailing multiple processes into two or more sub processes, some of which can be located outside the system boundaries. It can also be done by expanding the system boundaries so that inputs/outputs remain inside the system.

- Where allocation cannot be avoided, it should preferentially be based on causal relationships between the system inputs and outputs. These causal relationships between the flows into and out of the system may be based on physical or economic parameters.

- Where causal relationships cannot be established, allocation to different products may be based on their economic value.

Impact assessment

In the impact assessment, the results of the inventory analysis are linked to specific environmental damage categories (e.g. CO_2 emissions are related to global warming and climate change, SO_2 emissions are related to damages to the ecosystem caused by acidification, etc.). It is important to note that the inventory results generally do not include spatial, temporal, dose-response or threshold information. Therefore, impact assessment can not and is not intended to identify or predict actual environmental impacts. Instead, the impact assessment predicts potential environmental damages (impacts) related to the system under study.

Methodology

Various methods are in use to assess the environmental effects of products and systems. Almost all methods operate on the assumption that a product's entire life cycle should be analyzed. One of the methods is the Eco-indicator 99 method (Goedkoop et al., 2000). This method is used for impact assessment in the study.

For a more detailed description of the Eco-indicator 99 method, we refer to annex 1 of this report.

The framework proposed by ISO 14042 and followed by the Eco-indicator method consists of the following elements:

- Selection of impact categories, category indicators and characterization models;

- Classification: assignment of inventory data to impact categories;

- Characterization: calculation of category indicator results;

- Normalization: calculating the magnitude of category indicator results relative to reference information
- Grouping: sorting and possibly ranking of the impact categories;
- Weighting (valuation): converting and possibly aggregating indicator results across impact categories using numerical values based on value-choices.

The first three elements are mandatory, the last three are optional. ISO 14040 says "in case of comparative assertions disclosed to the public, the evaluation shall be conducted in accordance with the critical review process and presented category indicator by category indicator".

Interpretation

According to ISO 14043, in the interpretation phase of an LCA, the results of the inventory analysis and the impact assessment are critically analyzed and interpreted in line with the defined goal and scope of the study. The findings of this interpretation may take the form of conclusions and recommendations to decision makers.

It may also take the form of an improvement assessment, i.e. an identification of opportunities to improve the environmental performance of products or processes.

Annexure -B- LCA Detailed Results

1. Ciprofloxacin Base Tech:

Impact category	Unit	Water	Pyridine	Fecl3	NAOH	EDTA	HCL	COAL
Global warming	kg CO2 eq	4.082	21,647.155	19.080	1,136.934	18.423	506.987	623.861
Stratospheric ozone depletion	kg CFC11 ec	0.000	0.003	0.000	0.000	0.000	0.000	0.000
Ionizing radiation	kBq Co-60 e	0.018	56.452	0.120	7.334	0.073	2.546	0.379
Ozone formation, Human health	kg NOx eq	0.010	50.904	0.050	2.936	0.034	1.142	1.825
Fine particulate matter formation	kg PM2.5 ec	0.008	21.031	0.041	2.216	0.023	1.016	3.512
Ozone formation, Terrestrial ecosystems	kg NOx eq	0.010	63.392	0.051	3.005	0.036	1.183	1.862
Terrestrial acidification	kg SO2 eq	0.014	46.543	0.083	4.029	0.049	2.211	1.845
Freshwater eutrophication	kg P eq	0.000	17.558	0.001	0.067	0.001	0.028	1.158
Marine eutrophication	kg N eq	0.000	45.388	0.001	0.034	0.011	0.013	0.014
Terrestrial ecotoxicity	kg 1,4-DCB	20.112	200,755.642	270.825	7,717.662	155.727	6,059.548	4,021.036
Freshwater ecotoxicity	kg 1,4-DCB	0.002	33.807	0.027	1.005	0.017	0.647	1.000
Marine ecotoxicity	kg 1,4-DCB	0.022	210.749	0.294	8.279	0.162	6.363	5.543
Human carcinogenic toxicity	kg 1,4-DCB	0.020	214.142	0.368	15.482	0.193	5.644	2.315
Human non-carcinogenic toxicity	kg 1,4-DCB	0.453	2,913.467	9.880	227.045	2.340	204.225	70.066
Land use	m2a crop ec	0.080	395.746	0.848	29.110	0.339	14.381	299.680
Mineral resource scarcity	kg Cu eq	0.009	54.599	0.200	3.685	0.044	3.145	0.732
Fossil resource scarcity	kg oil eq	0.973	8,655.598	4.713	283.590	5.962	138.167	4,194.069
Water consumption	m3	6.060	260.446	0.204	14.348	0.147	6.508	4.962

Impact category	**Unit**	**Diesel**	**Heat**	**Electricity grid**	**Electricity, generato**	**Pyridine recovery**	**Wastewater**	**Total**
Global warming	kg CO2 eq	122.441	10,801.438	5,489.568	404.039	-12,537.737	2.796	**28,239.066**
Stratospheric ozone depletion	kg CFC11 eq	0.000	0.002	0.001	0.000	-0.002	0.000	**0.005**
Ionizing radiation	kBq Co-60 eq	0.067	5.456	37.740	0.113	-32.696	0.010	**77.613**
Ozone formation, Human health	kg NOx eq	0.335	28.201	12.016	0.583	-29.483	0.006	**68.559**
Fine particulate matter formation	kg PM2.5 eq	0.121	22.381	13.547	0.213	-12.181	0.004	**51.933**
Ozone formation, Terrestrial ecosystems	kg NOx eq	0.414	28.302	12.127	0.665	-36.716	0.007	**74.338**
Terrestrial acidification	kg SO2 eq	0.331	61.759	16.878	0.627	-26.957	0.008	**107.420**
Freshwater eutrophication	kg P eq	0.001	0.498	0.621	0.001	-10.169	0.011	**9.778**
Marine eutrophication	kg N eq	0.004	0.016	0.019	0.003	-26.288	0.030	**19.244**
Terrestrial ecotoxicity	kg 1,4-DCB	916.040	15,042.946	8,829.192	2,331.811	-116,274.929	29.623	**129,875.233**
Freshwater ecotoxicity	kg 1,4-DCB	0.097	1.611	1.751	0.108	-19.581	0.032	**20.523**
Marine ecotoxicity	kg 1,4-DCB	1.148	15.725	10.045	2.440	-122.063	0.071	**138.778**
Human carcinogenic toxicity	kg 1,4-DCB	0.197	12.895	21.583	0.273	-124.028	0.032	**149.115**
Human non-carcinogenic toxicity	kg 1,4-DCB	6.822	586.819	1,047.255	9.020	-1,687.440	15.903	**3,405.855**
Land use	m2a crop eq	3.255	146.186	115.162	3.087	-229.211	0.059	**778.723**
Mineral resource scarcity	kg Cu eq	0.180	2.341	1.843	0.288	-31.623	0.007	**35.450**
Fossil resource scarcity	kg oil eq	148.809	2,249.896	1,378.671	117.937	-5,013.204	0.511	**12,165.691**
Water consumption	m3	0.911	398.128	35.946	0.792	-150.847	-5.427	**572.178**

2. Ciprofloxacin Base:

Impact category	Unit	Pure Water	DM Water	Ciprofloxacin Base Tech	Acetic acid	Activated carbon	EDTA	HCL
Global warming	kg CO2 eq	6.399	3.891	24,033.252	1,100.585	8.727	1.796	1,189.363
Stratospheric ozone depletion	kg CFC11 eq	0.000	0.000	0.005	0.000	0.000	0.000	0.001
Ionizing radiation	kBq Co-60 eq	0.041	0.017	66.053	5.098	0.024	0.007	5.973
Ozone formation, Human health	kg NOx eq	0.015	0.010	58.348	2.204	0.021	0.003	2.680
Fine particulate matter formation	kg PM2.5 eq	0.012	0.008	44.198	1.466	0.016	0.002	2.384
Ozone formation, Terrestrial ecosystems	kg NOx eq	0.015	0.010	63.266	2.395	0.021	0.003	2.775
Terrestrial acidification	kg SO2 eq	0.020	0.013	91.421	2.824	0.041	0.005	5.187
Freshwater eutrophication	kg P eq	0.044	0.000	8.321	0.053	0.000	0.000	0.065
Marine eutrophication	kg N eq	0.006	0.000	16.377	0.009	0.000	0.001	0.031
Terrestrial ecotoxicity	kg 1,4-DCB	75.370	19.171	110,532.135	6,197.431	23.401	15.182	14,215.372
Freshwater ecotoxicity	kg 1,4-DCB	0.005	0.002	17.466	1.662	0.003	0.002	1.517
Marine ecotoxicity	kg 1,4-DCB	0.085	0.021	118.109	7.665	0.025	0.016	14.928
Human carcinogenic toxicity	kg 1,4-DCB	0.030	0.019	126.906	2.793	0.014	0.019	13.241
Human non-carcinogenic toxicity	kg 1,4-DCB	0.628	0.431	2,898.600	373.706	1.049	0.228	479.101
Land use	m2a crop eq	0.114	0.077	662.743	22.542	0.136	0.033	33.737
Mineral resource scarcity	kg Cu eq	0.016	0.008	30.170	2.183	0.004	0.004	7.377
Fossil resource scarcity	kg oil eq	1.525	0.928	10,353.782	449.947	2.244	0.581	324.131
Water consumption	m3	1.057	5.776	486.960	14.240	0.020	0.014	15.267

Impact category	Unit	Hard coal	Diesel	Coal Combustion	Electricity-Grid	Electricity-Generator	Wastewater	Total
Global warming	kg CO2 eq	623.650	122.399	11,189.598	5,487.714	403.918	3.685	44,174.978
Stratospheric ozone depletion	kg CFC11 eq	0.000	0.000	0.002	0.001	0.000	0.000	0.009
Ionizing radiation	kBq Co-60 eq	0.379	0.067	5.652	37.728	0.112	0.013	121.166
Ozone formation, Human health	kg NOx eq	1.824	0.334	29.215	12.012	0.583	0.008	107.257
Fine particulate matter formation	kg PM2.5 eq	3.511	0.121	23.185	13.543	0.213	0.005	88.663
Ozone formation, Terrestrial ecosystems	kg NOx eq	1.861	0.414	29.319	12.123	0.665	0.009	112.876
Terrestrial acidification	kg SO2 eq	1.844	0.330	63.979	16.872	0.626	0.011	183.174
Freshwater eutrophication	kg P eq	1.158	0.001	0.516	0.621	0.001	0.015	10.796
Marine eutrophication	kg N eq	0.014	0.004	0.017	0.019	0.003	0.039	16.521
Terrestrial ecotoxicity	kg 1,4-DCB	4,019.678	915.729	15,583.529	8,826.210	2,331.115	39.033	162,793.356
Freshwater ecotoxicity	kg 1,4-DCB	0.999	0.097	1.669	1.750	0.108	0.043	25.322
Marine ecotoxicity	kg 1,4-DCB	5.541	1.148	16.290	10.042	2.439	0.094	176.402
Human carcinogenic toxicity	kg 1,4-DCB	2.314	0.197	13.358	21.575	0.273	0.042	180.782
Human non-carcinogenic toxicity	kg 1,4-DCB	70.043	6.820	607.906	1,046.901	9.017	20.955	5,515.386
Land use	m2a crop eq	299.578	3.254	151.439	115.123	3.086	0.078	1,291.942
Mineral resource scarcity	kg Cu eq	0.732	0.180	2.425	1.843	0.288	0.010	45.241
Fossil resource scarcity	kg oil eq	4,192.652	148.758	2,330.748	1,378.205	117.902	0.673	19,302.077
Water consumption	m3	4.960	0.911	412.435	35.934	0.792	-7.151	971.216

3. Ciprofloxacin HCL:

Impact category	Unit	Pure Water	Ciprofloxacin Base	HCL	EDTA	Activated carbon	Methanol	Coal	Diesel
Global warming	kg CO2 eq	23.409	101,104.155	532.203	4.054	173.110	12,629.508	623.796	122.428
Stratospheric ozone depletion	kg CFC11 eq	0.000	0.021	0.000	0.000	0.000	0.002	0.000	0.000
Ionizing radiation	kBq Co-60 eq	0.149	277.314	2.673	0.016	0.467	11.427	0.379	0.067
Ozone formation, Human health	kg NOx eq	0.054	245.482	1.199	0.007	0.407	22.031	1.825	0.335
Fine particulate matter formation	kg PM2.5 eq	0.045	202.925	1.067	0.005	0.308	8.411	3.512	0.121
Ozone formation, Terrestrial ecosystems	kg NOx eq	0.055	258.342	1.242	0.008	0.415	26.263	1.862	0.414
Terrestrial acidification	kg SO2 eq	0.074	419.234	2.321	0.011	0.810	18.066	1.845	0.331
Freshwater eutrophication	kg P eq	0.159	24.710	0.029	0.000	0.008	0.212	1.158	0.001
Marine eutrophication	kg N eq	0.022	37.811	0.014	0.002	0.001	0.305	0.014	0.004
Terrestrial ecotoxicity	kg 1,4-DCB	275.729	372,588.410	6,360.940	34.271	464.202	84,579.205	4,020.613	915.941
Freshwater ecotoxicity	kg 1,4-DCB	0.017	57.955	0.679	0.004	0.057	7.574	0.999	0.097
Marine ecotoxicity	kg 1,4-DCB	0.311	403.734	6.680	0.036	0.490	104.776	5.542	1.148
Human carcinogenic toxicity	kg 1,4-DCB	0.110	413.760	5.925	0.042	0.285	18.169	2.315	0.197
Human non-carcinogenic toxicity	kg 1,4-DCB	2.296	12,623.174	214.383	0.515	20.802	730.007	70.059	6.821
Land use	m2a crop eq	0.418	2,956.893	15.096	0.075	2.697	140.844	299.648	3.255
Mineral resource scarcity	kg Cu eq	0.058	103.543	3.301	0.010	0.085	21.373	0.732	0.180
Fossil resource scarcity	kg oil eq	5.580	44,177.050	145.039	1.312	44.515	11,455.458	4,193.628	148.793
Water consumption	m3	3.867	2,222.841	6.832	0.032	0.400	36.316	4.961	0.911

Impact category	Unit	Packing	Transportation	Coal Combustion	Electricity-Grid	Electricity-Generator	Methanol	Wastewater	Total
Global warming	kg CO2 eq	731.552	18,986.021	10,800.302	5,488.991	404.007	-11,936.892	3.621	139,690.265
Stratospheric ozone depletion	kg CFC11 eq	0.000	0.008	0.002	0.001	0.000	-0.002	0.000	0.032
Ionizing radiation	kBq Co-60 eq	1.982	18.014	5.456	37.737	0.112	-10.800	0.013	345.007
Ozone formation, Human health	kg NOx eq	1.543	27.945	28.198	12.015	0.583	-20.822	0.008	320.810
Fine particulate matter formation	kg PM2.5 eq	0.760	13.953	22.379	13.546	0.213	-7.950	0.005	259.298
Ozone formation, Terrestrial ecosystems	kg NOx eq	1.759	31.198	28.299	12.126	0.665	-24.823	0.008	337.834
Terrestrial acidification	kg SO2 eq	1.639	28.956	61.753	16.876	0.627	-17.075	0.011	535.477
Freshwater eutrophication	kg P eq	0.019	0.234	0.498	0.621	0.001	-0.201	0.015	27.466
Marine eutrophication	kg N eq	0.011	0.138	0.016	0.019	0.003	-0.288	0.038	38.111
Terrestrial ecotoxicity	kg 1,4-DCB	6,028.965	403,037.631	15,041.365	8,828.264	2,331.625	-79,940.789	38.363	824,604.735
Freshwater ecotoxicity	kg 1,4-DCB	0.574	35.346	1.611	1.751	0.108	-7.158	0.042	99.655
Marine ecotoxicity	kg 1,4-DCB	6.792	381.384	15.724	10.044	2.439	-99.030	0.092	840.160
Human carcinogenic toxicity	kg 1,4-DCB	2.465	47.501	12.894	21.580	0.273	-17.173	0.041	508.384
Human non-carcinogenic toxicity	kg 1,4-DCB	107.648	3,612.773	586.757	1,047.145	9.019	-689.972	20.595	18,362.023
Land use	m2a crop eq	16.732	613.232	146.171	115.150	3.087	-133.120	0.077	4,180.254
Mineral resource scarcity	kg Cu eq	2.294	55.253	2.341	1.843	0.288	-20.201	0.010	171.110
Fossil resource scarcity	kg oil eq	422.174	5,823.542	2,249.659	1,378.526	117.928	-10,827.228	0.662	59,336.636
Water consumption	m3	4.523	36.515	398.087	35.942	0.792	-34.325	-7.028	2,710.665

Annexure – C – Mitigations as per Decarbonization Roadmap for Neuland Laboratories Limited:

Description Of Scenarios

Net Zero Scenario: **Scope 1**

Scope-1 Mitigations			
Mitigation-1	Thermal Energy Reduction & process changes (Annual change)	2025-30	0.75%
		2031-40	0.25%
		2041-45	0.50%
Mitigation-2	Biomass Share	By 2030	50%
		By 2035	100%
Mitigation-3	Diesel vehicles, forklifts to be converted to electric vehicles	By 2030	25%
		By 2040	100%
Mitigation-4	Using Green Refrigerants with lower GWP	FY 2031-40	10%

Net Zero Scenario: **Scope 2**

Scope-2 Mitigations			
Reduction of Carbon emission intensity in Grid y-o-y in line with India's NDCs.		By 2030, 60% of 2005 level	
		2031-45	9%
Mitigation-1	Electrical Energy reduction & process Changes	2025-30	1%
		2030-40	0.75%
		2040-45	1%
Mitigation-2	Renewable Energy Share	By 2025	0%
		By 2030	20%
		By 2035	40%
		By 2040	75%
		By 2045	90%

Net Zero Scenario: Scope 3

Category		Scope-3 Mitigation Strategy	Target	% Reduction
Category-1 Purchased Goods and Services	Mitigation-1	Key Material Yield optimization, Key Material Yield optimization, Reducing raw material consumption, Handholding with upstream suppliers to reduce their GHG Emissions, Capacity building of upstream suppliers,	By 2030	30%
			By 2035	65%
			By 2040	75%
			By 2045	80%
	Mitigation-2	Green procurement policy	By 2030	35%
			By 2035	75%
			By 2040	85%
			By 2045	90%
Category-2 Capital Goods	Mitigation-3	Green procurement policy	By 2030	5%
			By 2035	10%
			By 2040	15%
			By 2045	30%
Category-3 Fuel and Energy related	Mitigation-4	Thermal & Electrical Energy efficiency; Biomass based fuels Usage of Green refrigerants	By 2030	60%
			By 2035	75%
			By 2040	85%
			By 2045	90%
Category-4 Upstream Transport & Distribution	Mitigation-5	Optimization of routes, Handholding with logistics suppliers, Backward integration, Solvent / chemical storage enhancements Backhauling	By 2030	25%
			By 2035	65%
			By 2040	70%
			By 2045	80%
Category-5 Waste generated in the operations	Mitigation-6	Product stewardship, Product stewardship, Co-processing of solid and liquid wastes in cement kilns, recycle, reduce and reuse, Green chemistry	By 2030	20%
			By 2035	45%
			By 2040	60%
			By 2045	75%
Category-6 Business Travel	Mitigation-7	Logistic and travel policy, Optimise routes	By 2030	15%
			By 2035	30%
			By 2040	55%
			By 2045	70%
Category-7 Employee Commute	Mitigation-8	Optimize routes, WFH / Hybrid options, Adopting EVs, Employee awareness & Incentives	By 2030	15%
			By 2035	30%
			By 2040	50%
			By 2045	60%
Category-8 Upstream Leased assets (Employee Shuttle)	Mitigation-9	Green Supply Chain Policy Optimize routes, WFH / Hybrid options, Adopting EVs, Employee awareness & Incentives	By 2030	15%
			By 2035	30%
			By 2040	50%
			By 2045	60%