Implementation of Mass and Energy Balance on ODES

Internship Report

Submitted for the partial fulfillment of the degree of

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In

Chemical Engineering

Submitted By

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0901CM201018

UNDER THE SUPERVISION AND GUIDANCE OF

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Harshit Ku Singh

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Place: Gwalior

This is to certify that the above statement made by the candidates is correct to the best of my knowledge and belief.

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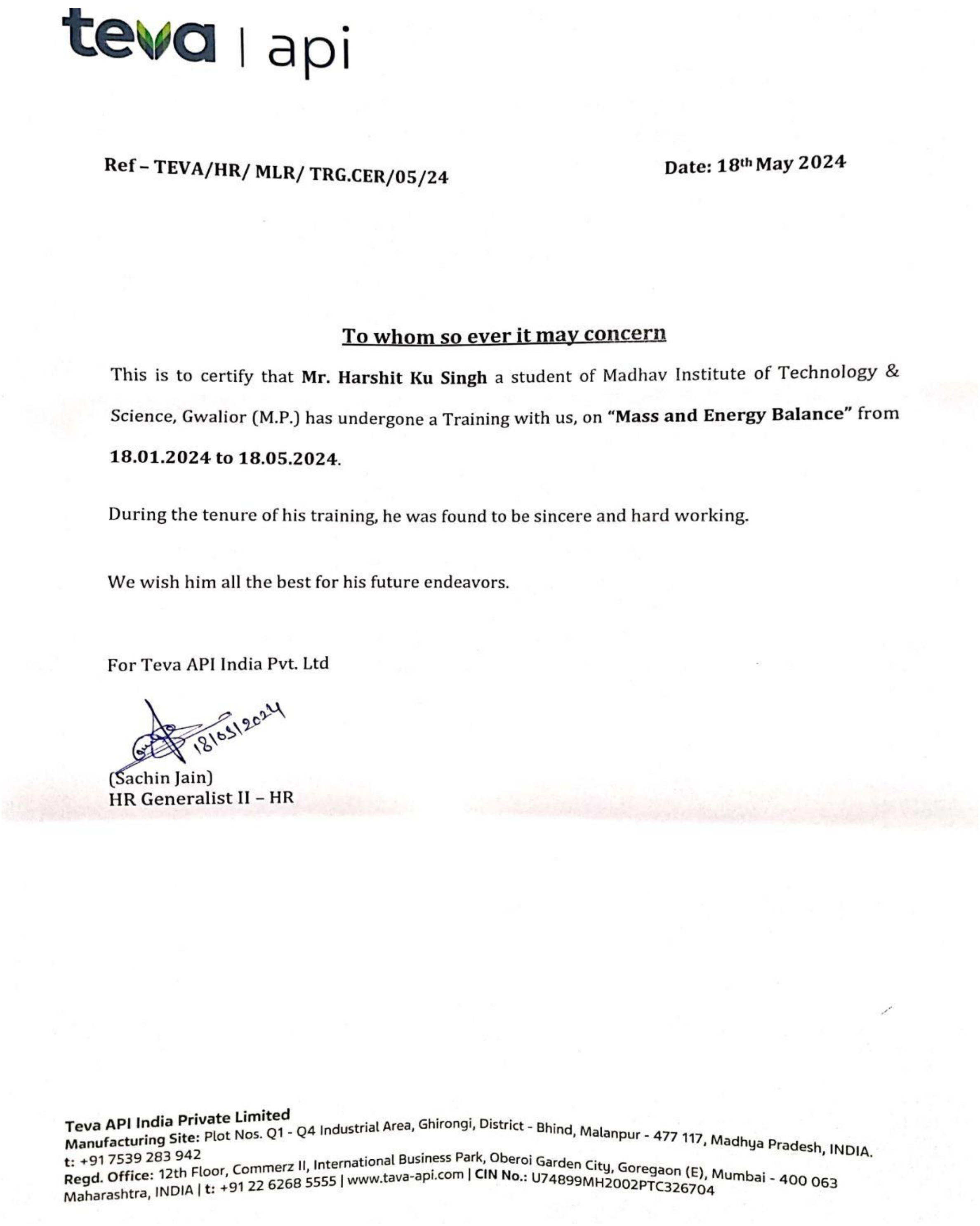

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This is to certify that **Mr. Harshit Ku Singh** a student of Madhav Institute of Technology & Science, Gwalior (M.P.) has undergone a Training with us, on **"Mass and Energy Balance"** from **18.01.2024 to 18.05.2024**.

During the tenure of his training, he was found to be sincere and hard working.

We wish him all the best for his future endeavors.

For Teva API India Pvt. Ltd

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ABSTRACT

The pharmaceutical sector plays a crucial role globally, engaging in the development, production, and distribution of medications for various medical conditions. This industry significantly advances healthcare by investing heavily in research and development to innovate and improve treatments. Among the many drugs developed by pharmaceutical companies is odes, a potent antidepressant typically prescribed for severe depressive disorder. Desvenlafaxine, a serotonin-norepinephrine reuptake inhibitor (SNRI), alleviates depression symptoms by rebalancing serotonin and norepinephrine levels in the brain. Its efficacy and safety have made it a valuable option for treating depression; however, like all medications, it must be used correctly and under medical guidance. This report examines the different equipment and processes used in the production of ODES, including the crystallization process. It also includes a mass and energy balance analysis for the solvent manufacturing of ODES. An overall mass balance was conducted, resulting in a net production of 102 kg of the medication.

Keywords: **Mass Balance, Equipments, Process Flow Diagram, Block Flow Diagram.**

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2.	SF : Sparkle Filter
3.	ODES : Ortho-Desvenlafaxine
4.	SRP : Solvent Recovery Plant
5.	API : Active Pharmaceutical Ingridient
6.	R : Reactor
7.	V : Vessel
8.	SSHL : Stainless Steel Halar Lined
9.	SS316 : Srainless Steel
10.	MSGL : Mild Steel Glass Lined
11.	KRM : Key Raw Material
12.	D1 : DI Water
13.	I1 : Isopropyl Alcohol
14.	H2 : Hyflow
15.	O1 : ODES
16.	A1 : Activated Carbon

NOMENCLATURE

1.	Δp = Pressure drop
2.	L = Length of bed
3.	μ = Fluid viscocity
4.	ϵ = Porosity
5.	Dp = Particle diameter
6.	v = Superficial velocity
7.	ρ = Density of Fluid
8.	Q = Heat added to or removed from the system
9.	m = Mass
10.	c_p = Specific heat capacity of substance
11.	Δt = temperature difference

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CHAPTER 1: INTRODUCTION

ODES is a prescribed medication that comes in the form of extended-release tablets taken orally. The extended-release formulation allows the medication to be gradually absorbed into the body over time. This tablet is available under the generic name PQ and can also be found as a generic drug, which is typically less costly than the brand-name version. ODES is used to alleviate severe symptoms of depression, such as persistent sadness and low energy. As part of the SNRI (serotonin-norepinephrine reuptake inhibitor) class of medications, it functions by helping to reestablish the normal balance of serotonin and norepinephrine in the brain.

Clinical Data

- Molecular weight : 263.381 g·mol^{-1}
- Formula : $C_{16}H_{25}NO_2$
- Chemical Safety : Irritant

Mass balance and energy balance are essential concepts in various scientific and engineering fields, serving as fundamental tools for analyzing and comprehending the behavior of systems ranging from chemical reactors to environmental ecosystems. These balances are crucial for ensuring the conservation of mass and energy within a system, offering valuable insights into processes, efficiencies, and environmental impacts. In this thorough exploration, we delve into the principles of mass balance and energy balance, highlighting their importance, applications, and interconnections.

The law of conservation of matter states that matter cannot be created or destroyed. This concept forms the basis of mass conservation, which can be expressed by stating that the mass of materials involved in any process remains constant. It is now understood that this law is limited for matter moving at speeds near the speed of light or for substances undergoing nuclear reactions. In such cases, energy and mass are mutually convertible, and the total of the two remains constant. However, in most engineering contexts, this transformation is negligible, and mass and energy are treated as independent entities. The conservation of matter dictates that materials entering any process must either accumulate or exit the process, with no loss or gain occurring. Most processes we encounter involve neither accumulation nor depletion, simplifying the law of conservation of mass to the form where input equals output. This law is often applied in the form of material balances, where a process is accounted for by everything that enters and credited with everything that leaves. The sum of the credits must equal the sum of the debits. Material balances must be valid over the entire process or equipment and over any part of it. It must apply to all materials entering and exiting the process and to each individual material passing through the process unchanged.

Mass balance, also referred to as material balance, is based on the core principle of mass conservation, which asserts that mass cannot be created or destroyed in a closed system. It involves tracking the mass of substances entering and exiting a system, ensuring that the total mass remains unchanged over time. Mass balance is widely used in chemical engineering, environmental science, and industrial processes, where it is essential for understanding material flows, reaction kinetics, and pollution control.

Energy balance, in contrast, is founded on the principle of energy conservation, which states that energy cannot be created or destroyed but can only transform from one form to another within a closed system. Energy balance involves monitoring the flow of energy into, out of, and within a system, ensuring that the total energy remains constant. This balance is crucial for analyzing heat transfer, thermodynamic processes, and energy conversion systems, and it is fundamental in fields such as thermodynamics, heat transfer, and power generation.

The interconnectedness of mass balance and energy balance is evident in many natural and engineered systems, where changes in mass often correspond to changes in energy and vice versa. For example, in chemical reactions, mass balance ensures that the total mass of reactants equals the total mass of products, while energy balance guarantees that the total energy input equals the total energy output, accounting for the heat released or absorbed during the reaction.

In environmental systems, mass balance and energy balance are crucial for evaluating the fate and transport of pollutants, energy exchanges within ecosystems, and the effects of human activities on the environment. Utilizing these balances allows scientists and engineers to model intricate environmental processes, predict pollutant levels, and develop strategies to mitigate environmental pollution.

In industrial settings, mass and energy balances are essential for optimizing operations, reducing waste, and enhancing efficiency. By carefully tracking material and energy flows, engineers can pinpoint inefficiencies, fine-tune process parameters, and reduce resource consumption, resulting in cost savings and environmental advantages.

Moreover, the principles of mass balance and energy balance extend beyond traditional engineering fields, with applications in areas such as economics, ecology, and systems biology. In economics, mass balance principles are used to analyze material flows in supply chains, while energy balance concepts assess the energy efficiency of production processes.

CHAPTER 2: LITERATURE SURVEY

Major depressive disorder (MDD) is a prevalent and severe mental health condition that necessitates personalized and comprehensive treatment. Various treatment options are available, including different classes of antidepressants, diverse psychotherapeutic methods, and psychosocial interventions. The treatment strategy for each MDD patient should be customized based on numerous clinical, personal, and contextual factors. A serotonin-noradrenaline reuptake inhibitor (SNRI) antidepressant was approved in the United States in 2008 for treating MDD in adults. Recently, this medication has gained renewed attention from physicians due to its favorable side effect profile and clinical effectiveness.[1]

In process engineering, many operations are conducted under steady-state conditions where mass and energy balances remain constant over time; thus, the input equals the output for both mass and energy. When required, mass and energy balances can incorporate a time-varying component; an accumulation or depletion term can be added or subtracted. However, this term will not be addressed in this text. All ammonia synthesis gas production is assumed to occur under steady-state conditions.[2]

The fundamental principles of the conservation of matter and energy also examine the application of the equations that describe these conservation laws. Mass and energy balances are utilized to acquire comprehensive information about the system and to develop a thorough understanding of the process.[3-4]

One of the key skills to develop in food engineering is the ability to perform mass and energy balances. These balances are essential for the design, operation, control, and analysis of processing operations, as well as for product development and waste reduction. Mass and energy balances are founded on the conservation laws of matter and energy, which assert that neither matter nor energy can be created or destroyed. With accurate measurement, you should be able to account for all the matter and energy involved in the process. Mass and energy balances offer a structured method for tracking material and energy flows into and out of the process in question. This is similar to managing your bank account, where you should be able to account for every penny.[5]

The Sugar Milling Research Institute NPC in Durban, South Africa, is performing extensive techno-economic modeling of a sugarcane biorefinery to identify products and processes with the highest implementation potential. While most of the fundamental biorefining steps are well understood, a methodology is needed to evaluate integrated processes and determine the optimal product set and production routes. SMRI's approach involves case study modeling of pre-selected plant configurations, focusing on the mass and energy balances of the individual units within the biorefinery. The initial scenario chosen is a sugar-ethanol cogeneration biorefinery. This study specifically addresses the sugar factory model in MATLAB, with particular emphasis on the boiler modeling method.[6]

Material and energy balances for fermentation processes are formulated based on the consistent heat of reaction per electron transferred to oxygen across a range of organic molecules, along with the constant number of available electrons per carbon atom in the biomass and the mass fraction of carbon in the biomass. Equations for mass-energy balance are derived, linking the biomass energy yield coefficient to experimentally determinable variables. The application of these balances in optimizing the operation of a continuous device for single-cell protein production is explored. Additionally, the changes in optimal operating conditions due to variations in yield for methanol as an organic substrate are analyzed.[7]

DES in the treatment of major depressive disorder (MDD): a critical review based on evidence of its therapeutic role. This medication comprises the active metabolite of venlafaxine and belongs to the class of serotonin-norepinephrine reuptake inhibitors (SNRIs), which has recently gained approval for managing MDD. Notably, it is among the limited options within this class of drugs accessible in the United States.[8]

Mass balance is a crucial aspect of pharmaceutical development, yet it can pose difficulties in accurate assessment. This encompasses the diverse approaches for measuring, articulating, and assessing mass balance alongside degradation chemistry. The text outlines the reasons behind mass balance challenges and suggests potential solutions, while also highlighting the pros and cons of various detection methods. Additionally, it delves into the significance of reactants beyond the primary drug, reaction stoichiometry, reaction factors, and assay variability, providing recommendations for acquiring dependable and insightful mass balance data.[9]

In the pharmaceutical industry, the involvement of analytical chemists in the development of active pharmaceutical ingredients (APIs) holds significant importance. They serve as the key observers of the process, providing essential analytical data. Without precise analytical results, the entire process would lack crucial guidance. This chapter focuses specifically on the knowledge that process engineers need regarding analytical data. It covers the essentials to ensure that the data generated, whether by an analyst or an engineer, meets the highest quality standards necessary for a specific study. [10]

CHAPTER 3: COMPANY PROFILE

Established in 1901 in Jerusalem, Teva has its global headquarters based in Israel. With a vast portfolio comprising over 3,500 medications, the company produces more than 85 billion pills and capsules across multiple production sites spanning over 30 countries. Initially, the company, originally named Salomon, Levin, and Elstein Ltd. after its chemist founders, relied on mule trains and camel caravans to distribute imported medications locally. Over time, Teva's growth was fueled by rising demand for regionally manufactured drugs. In 1976, the company rebranded as Teva Pharmaceutical Industries Ltd., reflecting its commitment to nature.

Despite its expansion, Teva maintains a steadfast dedication to its origins, with its people and culture shaping its leadership position today. Throughout its history, Teva's leadership has been marked by resilience, entrepreneurialism, and a commitment to improving people's lives. Through strategic acquisitions, Teva has significantly expanded its global presence, broadening its expertise across various therapeutic areas, markets, and both patented and generic medicines. As a leading provider of specialty and generic drugs, Teva now ranks among the top 15 pharmaceutical companies worldwide.

3.1 Products

Teva API produces approximately 400 active pharmaceutical ingredients, covering a wide range of therapeutic areas such as respiratory, cardiovascular, dermatological, hormonal, anti-inflammatory, and oncology treatments, as well as muscle relaxants and immunosuppressants. The API portfolio includes over 1,200 patents and pending applications globally. Teva API operates in fifteen locations worldwide, including Israel, Hungary, Italy, the United States, and India. It specializes in various industrial technologies, including chemical synthesis, plant extract technologies, semi-synthetic fermentation, enzymatic synthesis, and high potency production. Additionally, Teva API ensures compliance with current Good Manufacturing Practices (cGMP) regulations and other quality standards. As a distinct business unit within Teva Pharmaceutical Industries, one of the world's largest generic drug manufacturers, Teva API has a rich history dating back to 1935. It has expanded its manufacturing and development capabilities globally, ensuring adherence to the company's stringent quality standards through comprehensive integration programs for each facility.

Currently, Teva API runs 15 production plants and 6 research and development centers worldwide. Each of these establishments plays a vital role in advancing their excellence in research, development, manufacturing, and customer service. In India, Teva operates three top-tier manufacturing facilities located in Gajraula (Uttar Pradesh), Malanpur (Madhya Pradesh), and Ambernath (Maharashtra). In the district of Malanpur, Bhind, Madhya Pradesh, Teva operates a facility dedicated to manufacturing various types of active pharmaceutical ingredients (APIs), with products designed to target specific therapeutic needs:

1. Chronic Disease
2. Asthama
3. Hypertension/ Depression/Feeling Sadness
4. Diabetic/ Non Diabetic
5. Kidney

Vision

In a field that always evolving, We want to be a leader and a symbol of quality.

Mission

The goal of Teva is to improve patients lives by being a world leader in biopharmaceuticals and generics. Everything we do has a purpose becase of it, and it is what it is motivates us to go to work every morning.

CHAPTER 4: PROBLEM FORMULATION

Mass and energy balance serve as cornerstone principles in chemical engineering, significantly influencing the design, assessment, and enhancement of chemical processes. These balances are indispensable instruments in chemical engineering, facilitating the effective, secure, and environmentally conscious planning and execution of chemical processes. They are vital components in achieving financial viability, adhering to regulatory standards, and fostering innovation throughout the sector.

Perform an overall mass balance and energy balance on the ODES. Also mention every equipment and process involved for the proper understanding of the mass and energy balance also discuss the methodology.

CHAPTER 5: METHODOLOGY

ODES is a pharmaceutical prescribed to address major depressive disorder. Its manufacturing typically employs batch processing, a method where a specific amount of raw materials undergoes processing in a single batch. The objective is to develop a thorough mass and energy balance for the batch production of ODES. This involves identifying inputs, outputs, and any accumulations that occur during the process, as well as assessing energy needs to enhance process efficiency.

Objectives

Determine the Mass Balance: Establish a detailed mass balance for the batch production of ODES, considering all reactants, products, and by-products.

Analyze the Energy Balance: Calculate the energy inputs and outputs for each stage of the batch process, including heating, cooling.

Optimize Process Parameters: Use the mass and energy balance data to optimize batch process parameters, improving yield and reducing energy consumption.

System Description

The batch production of ODES involves several key steps:

Charging: Adding reactants to the batch reactor.

Reaction: Conducting the chemical reaction to produce ODES.

Separation: Isolating and purifying the product using techniques such as crystallization, filtration, and drying.

Discharge: Removing the product and by-products from the reactor.

Cleaning: Preparing the reactor for the next batch cycle.

Assumptions

- The process operates in batch mode with well-defined start and end points.
- Reactions go to completion or reach equilibrium within the batch cycle.
- Heat losses to the environment are negligible.
- Specific heat capacities of all substances are constant within the operating temperature range.
- The reactor operates under isothermal or adiabatic conditions as specified.

Mass Balance Equations

For each component in the reactor, the mass balance equation can be written as:

Input – Output + Generation – Consumption = Accumulation

For steady state, Accumulation term = 0

No generation and consumption is taking place in the reaction so these terms are = 0

Now the final Balance is,

Input = Output

Energy Balance Equations

The general energy balance equation for the batch reactor system is:

$$Q = m * C_p * \Delta t$$

Performing a detailed mass and energy balance on the batch production of ODES is essential for optimizing the process. This formulation provides a systematic approach to analyze and optimize the batch production, ensuring high yield, energy efficiency, and minimal environmental impact.

5.1 Process Equipments for Filtration

5.1.1 Filtration

Filtration is the process of separating solids from a liquid by passing the liquid through a filter medium or septum where the solids are retained. Typically, the fluid being filtered is a liquid, and the resulting stream from the filter can vary, either remaining liquid or becoming solid based on the specific needs of the process.

The movement of liquid through the filter medium is driven by a pressure gradient across the medium. Filters are categorized into two main types based on this pressure gradient: those that operate with pressure higher than atmospheric pressure on the inlet side of the filter medium, and those that operate with atmospheric pressure on the upstream side and negative pressure on the downstream side. Pressures exceeding atmospheric levels can be achieved through various means such as gravity, pumps, blowers, or centrifugal force.

The majority of industrial filters fall into three primary categories: pressure filters, vacuum filters, and centrifugal filters. These filters serve different purposes and are selected based on the specific requirements of the filtration process.

5.1.2 Principle of Filtration

Filtration represents a specialized instance of fluid flow through a porous material. Infiltration processes, the resistance to flow gradually increases as the filter medium becomes obstructed or as a filter cake develops. Key parameters of interest include the flow rate through the filter and the pressure drop across the unit. During the filtration process, either the flow rate diminishes or the pressure drop rises over time. In scenarios termed constant pressure filtration, the pressure drop is maintained at a constant level while the flow rate decreases progressively. Alternatively, in constant rate filtration, the pressure loss is incrementally augmented.

During cake filtration, liquid traverses two resistances sequentially: the resistance posed by the cake itself and that of the filter medium. In clarifying filters, only the resistance of the filter medium is significant, typically during the initial stages of cake filtration. The resistance of the cake begins at zero and amplifies as filtration advances. Should the cake undergo a washing stage post-filtration, both resistances remain constant during this period, with the resistance of the filter medium often being negligible.

The total pressure drop at any instant is the sum of the pressure drop across the medium and the cake. If pa is the inlet pressure, pb is the outlet pressure, and p' is the pressure at the boundary between the cake and the medium,

$$\Delta p = p_a - p_b = (p_a - p') + (p' - p_b) = \Delta p_c + \Delta p_m$$

where Δp = overall pressure drop

Δp_c = pressure drop over cake

Δp_m = pressure drop over medium

Pressure drop through filter cake:

A general equation named Ergun equation employed to calculate the pressure drop across the packed bed for all flow conditions, The Ergun equation combines both the laminar and turbulent components of the pressure loss across a packed bed.

Given as,

$$\frac{\Delta p}{L} = \frac{150\ \mu v(1 - \varepsilon^2\ \ )}{\varphi^2 Dp^2 \epsilon^3} + \frac{1.75\rho v^2\ (1 - \epsilon)}{\varphi \epsilon^3 Dp}$$

Δp = Pressure drop

L = Length of bed

μ = Fluid viscocity

ϵ = Porosity

Dp = Particle diameter

v = Superficial velocity

ρ = Density of Fluid

1. Sparkler Filter

The Sparkler Filter is a widely utilized filtration apparatus in various industries, including pharmaceuticals, chemicals, and beverages, for the purification of liquids. Its operational principle relies on pressure feeding. During the process, impurities are extracted and form a condensed cake. The liquid is directed through a central rod and is pushed through multiple filter inserts and plates. The filter medium, situated atop the filter plates, captures suspended particles, while the clarified filtrate exits through side apertures within the plates and is discharged from the bottom outlet. Notably, the liquid does not come into direct contact with the filter tank, ensuring the preservation of its purity. The filter plates are fully enclosed, containing both the filtrate and solids within careful manner.

Figure – 1: Pictorial figure of Sparkler Filter (i)

5.2 Equipment Used for Filtration and Drying in process

5.2.1 Drying

Generally, solid drying involves extracting minor quantities of moisture from a solid substance to decrease the residual liquid content to an acceptable level. It commonly serves as the concluding phase in a sequence of procedures, and the output from the dryer is frequently prepared for final packaging. The moisture content of the material being dried differs from one product to another, and if the material contains no moisture whatsoever, it is referred to as bone dry.

5.2.2 Agitated Nutsche Filter Dryer

This kind of equipment is used to dry wet materials and separate liquids from solids. The Agitated Nutsche Filter Dryer (ANFD) is a versatile apparatus utilised for the solid-liquid separation, cleaning, and drying of a wide range of chemicals, medications, and food items. The cylindrical jar used in the ANFD contains a stirrer inside and a perforated plate at the bottom.

Following steps involve in ANFD operation:
1. Loading: Using the top manhole, the slurry or wet cake is loaded into the vessel.
2. Filtration: Next, the stirrer stirs the slurry and produces a vacuum beneath the filter medium. After passing through the filter medium, the liquid is gathered in the vessel.

3. Washing: To get rid of any leftover product or contaminants, the solid cake is cleaned with a suitable liquid or solvent after filtering.
4. Drying: The solid cake is dried with a stirrer by using heat or a hoover after washing. A solid, dry cake is left behind as the solvent evaporates.
5. Discharging: The bottom discharge valve is used to remove the dry cake from the vessel when it has finished drying.

Compared to other filter types, the ANFD has a number of benefits, such as high filtration efficiency, less product loss, faster processing, and a closed system that removes the possibility of product contamination. The equipment is a popular option for a variety of industrial applications since it is also simple to maintain and clean.

Figure – 2: Pictorial figure of Agitated Nutsche Filter Dryer (ii)

5.3 Equipment used in process for reaction batch reactor

A batch reactor serves as a straightforward vessel employed in various chemical and industrial processes. It comprises a tank where chemical reactions occur, often equipped with an agitator and internal heating or cooling mechanisms. These reactors come in sizes ranging from small-scale vessels of one liter to larger ones of up to 15,000 liters. They find application across industries like steel, stainless steel, glass, and exotic alloy production. Substances involved in the process, whether liquids or solids, are introduced into the reactor through connections on the top cover, while any generated vapors or gases are released through similar connections. Drain holes at the bottom of the reactor allow for the removal of residual liquids post-reaction. One of the primary benefits of a batch reactor lies in its versatility, as it enables multiple operations to be conducted within a single vessel without the need for containment breaches. This feature is particularly advantageous when handling hazardous or potent compounds. Typically, a batch reactor utilizes a centrally mounted drive shaft with impeller blades attached, covering around two-thirds of the reactor's diameter. Additionally, stationary vanes known as baffles are commonly employed to disrupt flow patterns caused by the rotating agitator, either affixed to the container cover or positioned along the inner side walls.

In mixing tanks, liquids are commonly contained within vessels featuring rounded bottoms and devoid of sharp edges. The upper section of these tanks is typically mostly enclosed. Tank dimensions may vary accordingly. Normally, the depth of the liquid within the tank is equivalent to the tank's diameter to ensure uniform mixing. The tank is designed without sharp edges at the bottom to prevent the liquid from accumulating in corners. An impeller is affixed to an off-center shaft, which in turn is linked to a motor, often with a gearbox to adjust speed. Additional components such as inlet and outlet piping, coils, jackets, and wells for temperature measurement instruments like thermometers are commonly included.

Advantages of batch reactors include:

- Uniform composition throughout the reactor.

- Non-stop traffic is common

- They are the most cost effective in terms of instrumentation and construction compared to continuous reactors.

Disadvantages of batch reactors include :

- Strict temperature control is required for highly heat sensitive reactions.

- The quality of each batch may vary.

- They consume significant resources.

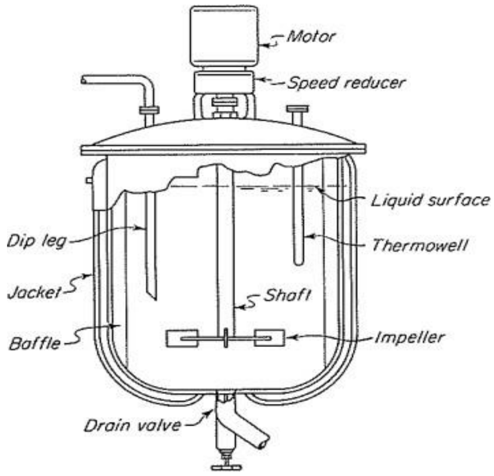

Figure - 3: Source: Pictorial figure of Batch Reactor (iii)

5.4 Types of Agitators in Batch Reactor

5.4.1 Purposes of Mixing:

Liquids are mixed for a number of purposes depending on the objectives of the processing step. These purposes includes:

1. Suspending solid particles

2. Mixing miscible liquids, e.g. methyl alcohol and water

3. Dispersion of gas by liquid in the form of small bubbles

4. Dispersing the second liquid, immiscible with the first, to form an emulsion or suspension of fine droplets

5. Support heat transfer between liquid and coil or jacket

Agitators are versatile devices capable of managing a diverse range of materials, including liquids, gases, and solids like granules and powders. They are proficient in handling various mixtures such as slurries, suspensions, and highly viscous liquids. However, the selection of an appropriate agitator type, size, and design is crucial, taking into account factors such as viscosity and susceptibility to shear stress. Agitators find widespread application across industries such as food and beverage, pharmaceuticals, agriculture, biotechnology, paint, and water treatment.

Different types of stirrers are used, here are some examples:

a) Paddle Agitator - This type of agitator features two flat blade-shaped impeller blades that extend towards the tank walls. It is employed in situations where extensive axial and radial flow is unnecessary. These impellers are adept at generating low-shear laminar flow and are suitable for mixing low-viscosity liquids, as well as tasks such as crystallization, dissolution, and heat transfer. Typically, they operate at low speeds and primarily deliver tangential flow. Additional secondary vanes can be added to the impeller blades to enhance mixing performance with more viscous materials.

b) Anchor agitator - They have impellers in the shape of an anchor. They are usually U-shaped to match the shape of the tank. They create a dominant tangential flow.

c) Propeller Stirrer - A propeller is an axial, high-speed impeller designed for mixing low-viscosity liquids. Propellers come in various sizes, each rotating at different speeds depending on the engine size: smaller propellers typically rotate at 1150 rpm, while larger ones operate within the range of 400-800 rpm. Upon exiting the impeller, fluid streams follow a specific trajectory until they are redirected by the vessel's walls or bottom. The static liquid is drawn into the highly turbulent eddy column created by the impeller's movement, which likely exceeds that of a stationary nozzle. The liquid experiences intense chopping or shearing action as it interacts with the propeller blades. Propeller stirrers are particularly beneficial for larger vessels, as they create continuous currents within the liquid.

d) Pitched - Blade Agitator: Pitched blade turbine agitators are equipped with flat blades that are inclined. Among agitators featuring inclined blades, the most prevalent type is the four-bladed turbine, which forms a 45° angle with the vertical axis. This design facilitates a blend of axial and radial flow, although axial flow predominates. The agitator generates significant shear forces and boasts efficient mixing capabilities. It finds application in tasks involving solid suspensions and gas dispersions.

Figure – 4: Pictorial figure of Types of Agitators (iv)

5.5 Types of Jackets used in process reactors:

a) Plane Jacket-

It could be defined as an extra layer that envelops the entire container or a specific portion of it. The area between the container wall and the covering wall, referred to as the annular space, is utilized for circulating the heating or cooling medium. Smooth coverings are suitable for smaller containers and for operations where the internal pressure exceeds the pressure of the covering by more than two-fold. To enhance heat transfer, spiral baffles can be incorporated into the covering. These baffles induce turbulence and augment the heat transfer coefficient. Consequently, a container outfitted with a smooth covering and spiral baffles can be utilized effectively.

b) Limpet Coil Jacket -

The pipe undergoes a division into two segments, with a half coil being welded onto the container's wall. This arrangement promotes high speed and turbulence within the system, while concurrently reinforcing the vessel wall, thereby leading to cost reduction. The incorporation of a half coil shell enhances structural stability, particularly beneficial for operations involving elevated temperatures. Limpet coil shells are commonly fabricated from carbon steel, although alternative materials such as stainless steel, inconel, and various alloys can also be utilized. In scenarios where jacket pressure dictates vessel wall thickness, a coil jacket with an attribute is preferred. These jackets find application in large capacity vessels and situations necessitating high circulation rates of substances like hot oils and glycols.

5.6 Utilities used in process

- Steam
- CT Water
- Chilled Water
- Chilled Brine
- Hot Water
- Hot oils
- Nitrogen
- Air
- Power

These are some utilities that are used based on the process requirements.

Now, here are some reactors mentioned which are involved in the process of manufacturing of ODES with their capacity, MOC and type of agitator used in particular reactor. Also, some filters with their capacity and MOC are mentioned in this report.

Table No. 1: Reactors used in process

Name	Capacity	MOC	Agitator
R1	4 KL	SS 316	Anchor
R2	4 KL	SS316	Propeller

Table No. 2: Filters used in process

Name	Capacity	MOC
SF	Not available	SS316
ANFD	Not available	SS316

5.7 Process Flow Diagram of ODES Formulation

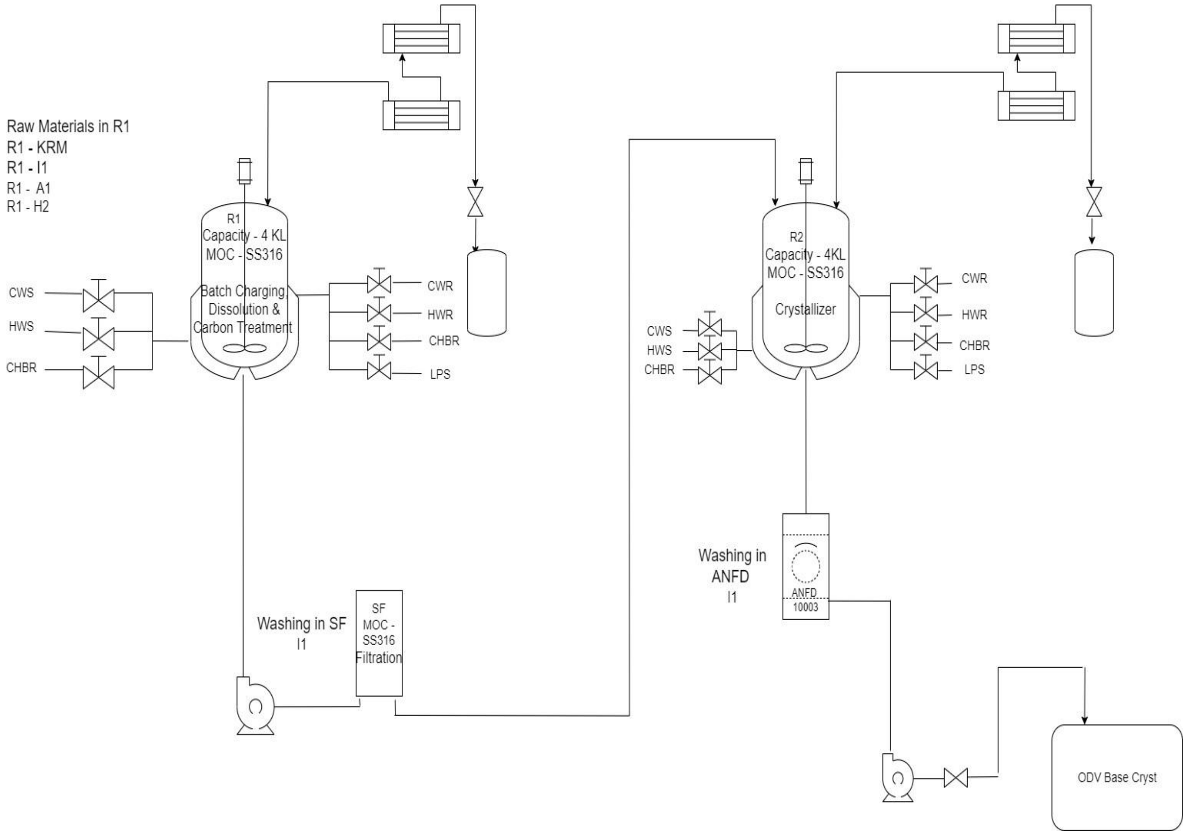

Figure – 5: Schematic figure of Process Flow Diagram of ODES

5.8 Block Flow Diagram of ODES Formulation

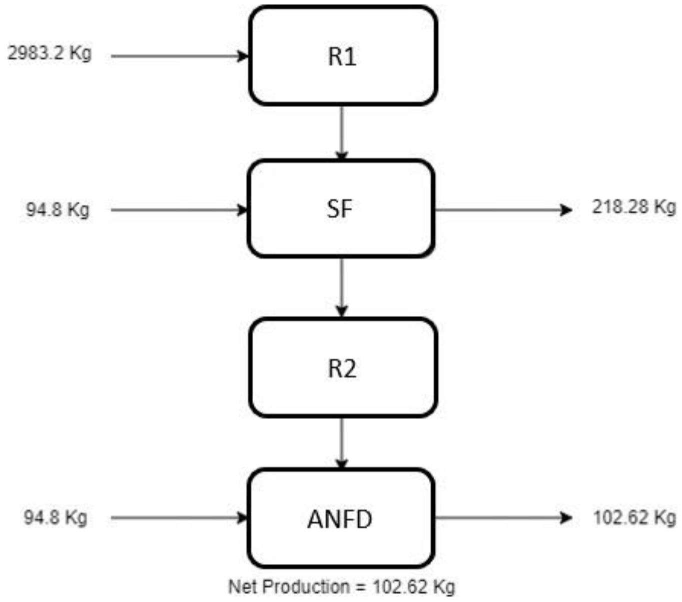

Figure – 6: Schematic figure of Block Flow Diagram

5.9 Manufacturing Process of ODES

- Reactor R1 fed with the KRM with other raw materials like I1, A1, H2 for carbon treatment and dissolution.
- Then passed through SF for removal of carbon. (Color turned Ivory-ish)
- Then Quench the material into R2 for impurity removal by crystallization.
- Material washed with I1 in ANFD and Mother Liquor is out (Material in cake).
- After filtration drying operation is performed and product obtained is dry.
- Final API ODES cryst is obtained.

CHAPTER 6: RESULTS AND DISCUSSION

The investigation on mass balance for the system yielded a value of 102 kilograms. This value represents the total mass output after accounting for all inputs, reactions, and losses within the system. The mass balance result of 102 kg falls within the established acceptable range of net production, which is 95-107 kg. This range was determined based on the expected variability and accuracy of the processes and measurements involved.

Now, coming on to Energy balance, the energy balance calculation for the process indicates that the net energy required is 94,783.196 J. This value represents the total energy input needed to drive the entire process, accounting for all energy sources, sinks, and losses.

CHAPTER 7: CONCLUSION

In conclusion, the principles of mass balance and energy balance are indispensable across various disciplines such as engineering, environmental science, and chemistry. Mass balance entails tracking the mass entering and leaving a system, ensuring a balance between inputs and outputs. It is critical for comprehending processes like chemical reactions, pollution dispersion, and material flows in industrial settings. Similarly, energy balance involves monitoring the energy flow into and out of a system, essential for assessing efficiency, heat transfer, and overall system performance. Both balances serve as foundational tools for analyzing and enhancing processes, promoting sustainability, and minimizing environmental impacts. Additionally, this report covers equipment such as filters and dryers utilized in the manufacturing of ODES. Furthermore, it includes block flow diagrams and process flow diagrams depicting the entire manufacturing process.

CHAPTER 8: OUTCOMES & SOCIETAL RELEVANCE

8.1 Achieved Outcomes

1. Identified the strategies to reduce the emissions and effluents from the process.
2. Assessed the significance of process safety using critical analysis and real-world application.
3. Comprehended the preclinical research, investigations, regulatory authorization, and commercialization procedures that make up the regulatory framework for drug development.
4. Analyzed ODES mass balance, showcasing adept project management skills by organizing, arranging, and finishing assignments on schedule.
5. Interpreted the ODES material balance in light of chemical engineering concepts to gain a deeper understanding of API production.

8.2 Social Relevance

1. It directly benefits society by ensuring the availability of high-quality medications that are essential for managing health conditions and improving overall well-being. By optimizing production processes, pharmaceutical companies can increase the affordability and accessibility of medications, making them more widely available to those in need.
2. The application of mass balance analysis in pharmaceutical production plays a crucial role in advancing healthcare outcomes, promoting patient safety, and fostering a sustainable society.
3. The mass and energy balance optimization in the production of ODES has numerous benefits for society, significantly contributing to sustainability, economic efficiency, and environmental protection.
4. By effectively treating the symptoms of major depressive disorder, ODES can help reduce the risk of suicidal thoughts and behaviors.
5. Treating depression can have positive effects on physical health. Depression is associated with an increased risk of various physical health issues, including cardiovascular disease.

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Image References

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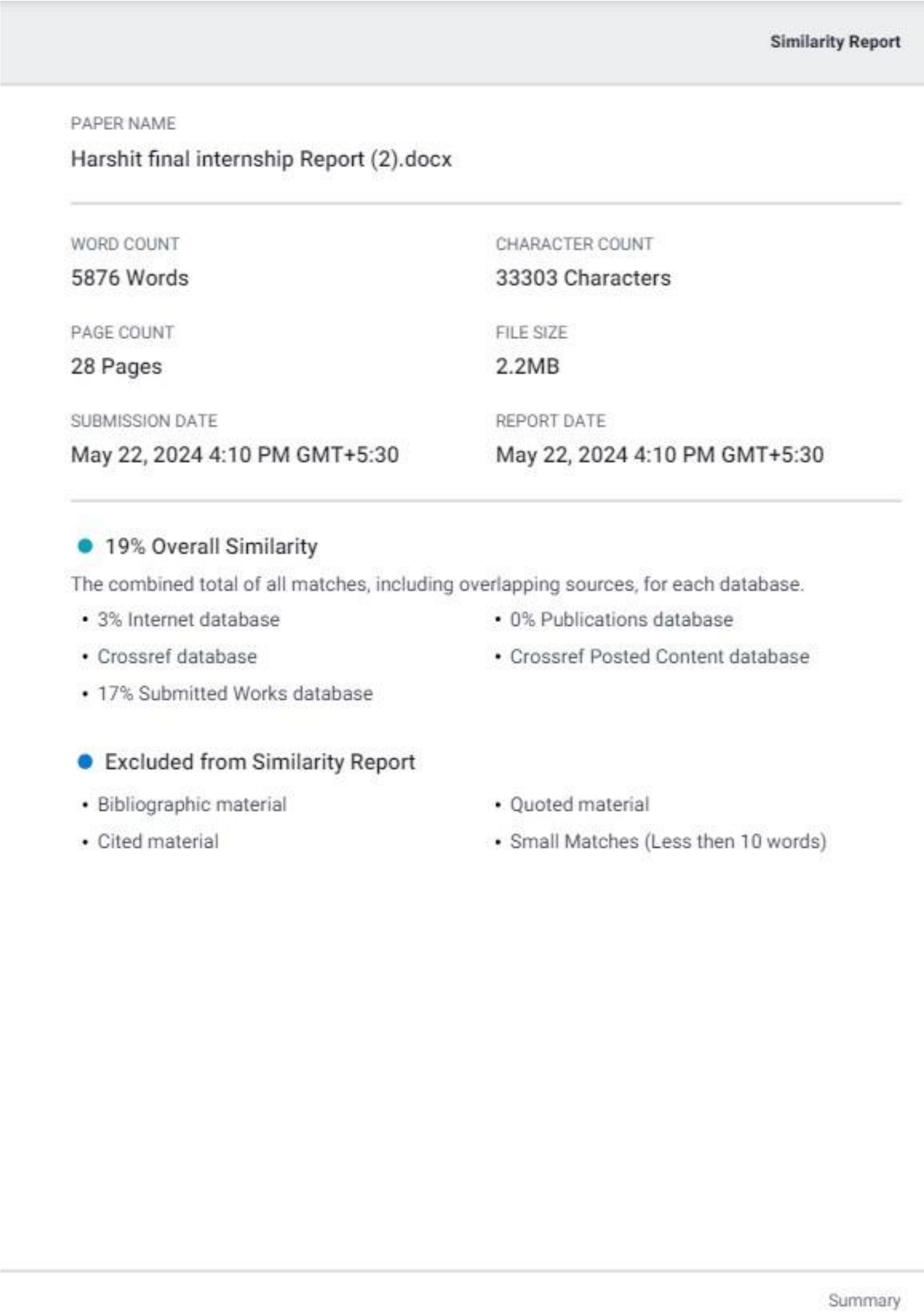
ii. Agitated pressure filter and vacuum dryer for solid-liquid separation, https://bachiller.com/en/nutsche-filter-dryer.

iii. Unit Operations of Chemical Engineering Mc Cabe and Smith.

iv. Agitators and its types - https://whatispiping.com/agitators.

TURNITIN PLAGIARISM REPORT



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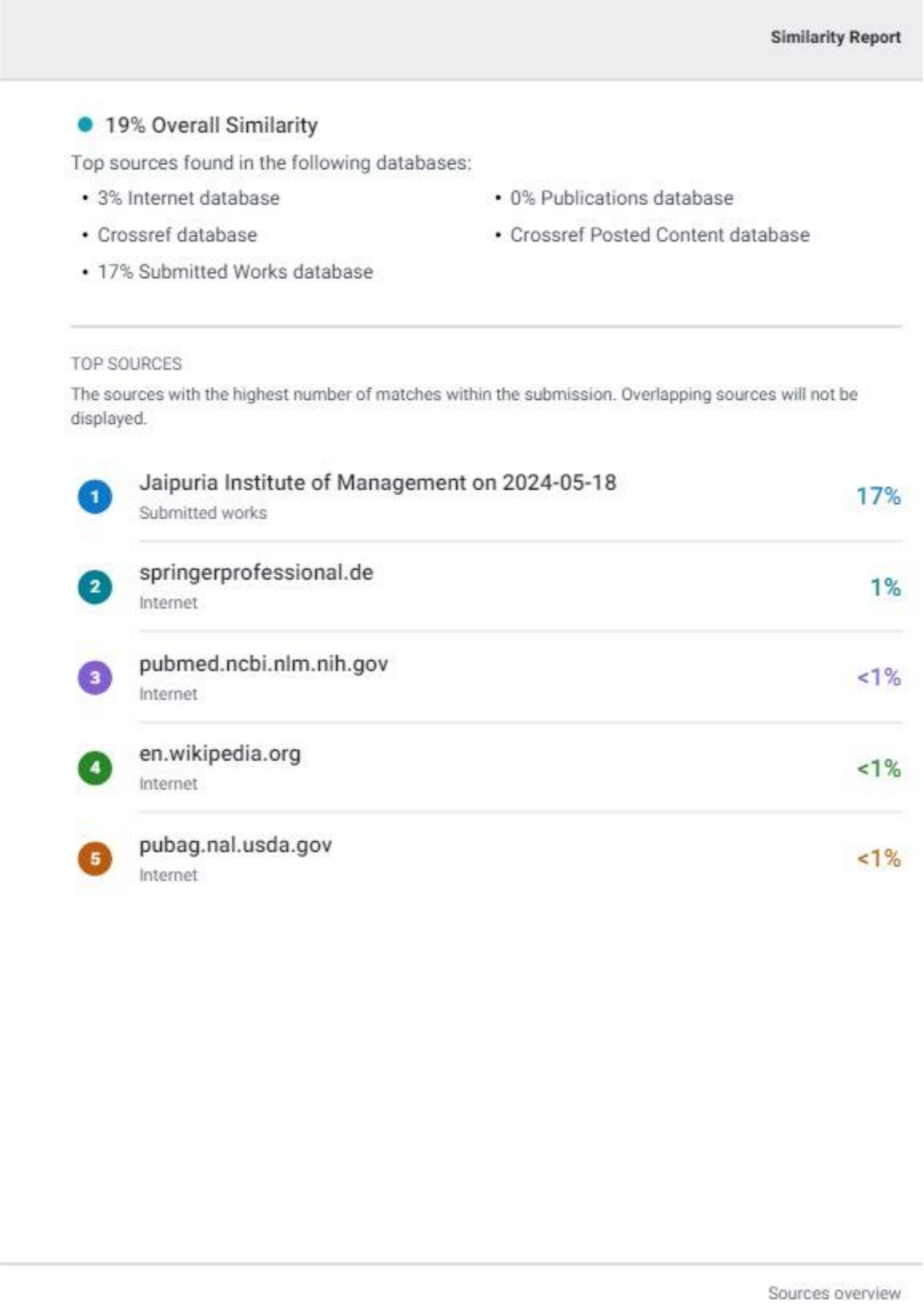

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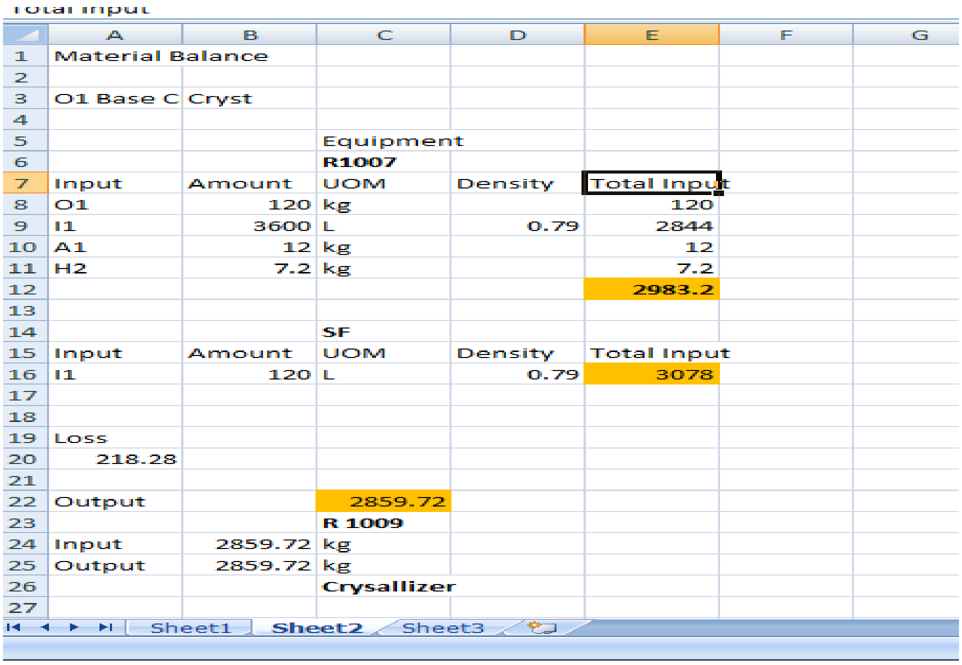
Sources overview

APPENDICES

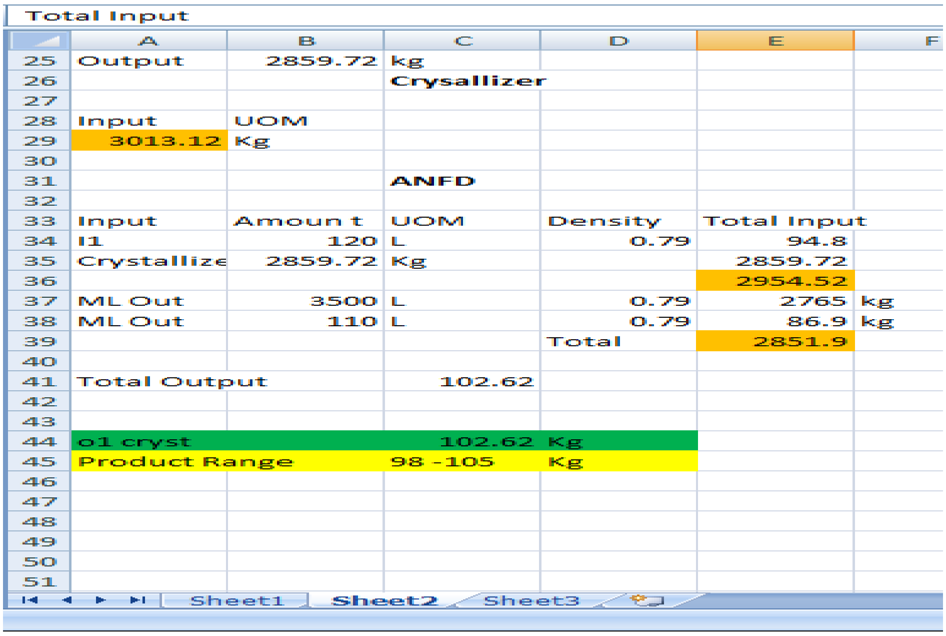
1. **Appendix A:** (Mass and Energy Balance)



Total Input

	A	B	C	D	E	F	G
1	Material Balance						
2							
3	O1 Base C	Cryst					
4							
5			Equipment				
6			**R1007**				
7	Input	Amount	UOM	Density	Total Input		
8	O1	120	kg		120		
9	I1	3600	L	0.79	2844		
10	A1	12	kg		12		
11	H2	7.2	kg		7.2		
12					2983.2		
13							
14			**SF**				
15	Input	Amount	UOM	Density	Total Input		
16	I1	120	L	0.79	3078		
17							
18							
19	Loss						
20	218.28						
21							
22	Output		2859.72				
23			**R 1009**				
24	Input	2859.72	kg				
25	Output	2859.72	kg				
26			**Crysallizer**				
27							

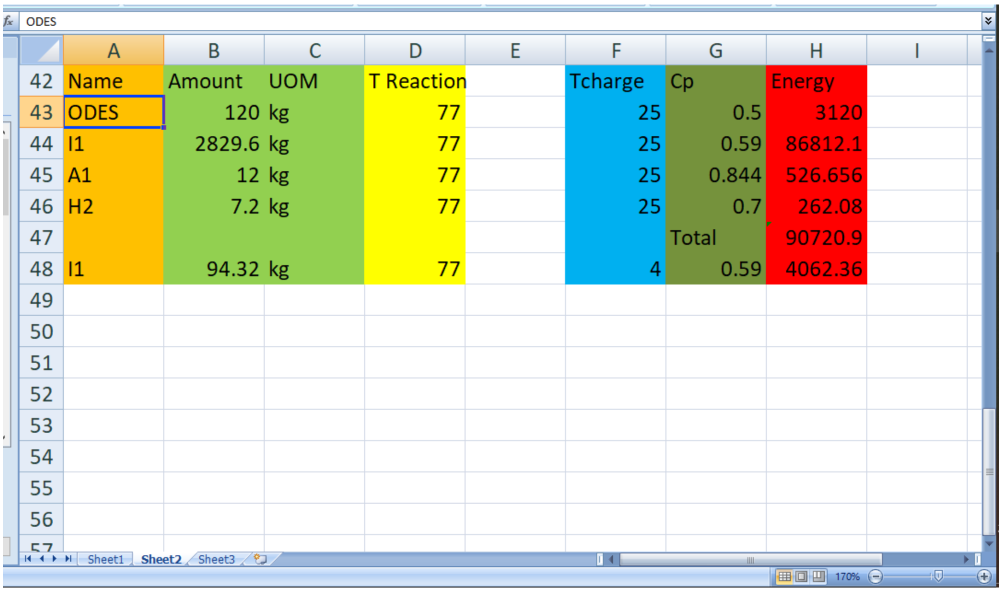
Sheet1 **Sheet2** Sheet3



Total Input

	A	B	C	D	E	F
25	Output	2859.72	kg			
26			**Crysallizer**			
27						
28	Input	UOM				
29	3013.12	Kg				
30						
31			**ANFD**			
32						
33	Input	Amoun t	UOM	Density	Total Input	
34	I1	120	L	0.79	94.8	
35	Crystallize	2859.72	Kg		2859.72	
36					2954.52	
37	ML Out	3500	L	0.79	2765	kg
38	ML Out	110	L	0.79	86.9	kg
39				Total	2851.9	
40						
41	Total Output		102.62			
42						
43						
44	o1 cryst		102.62	Kg		
45	Product Range		98 -105	Kg		
46						
47						
48						
49						
50						
51						

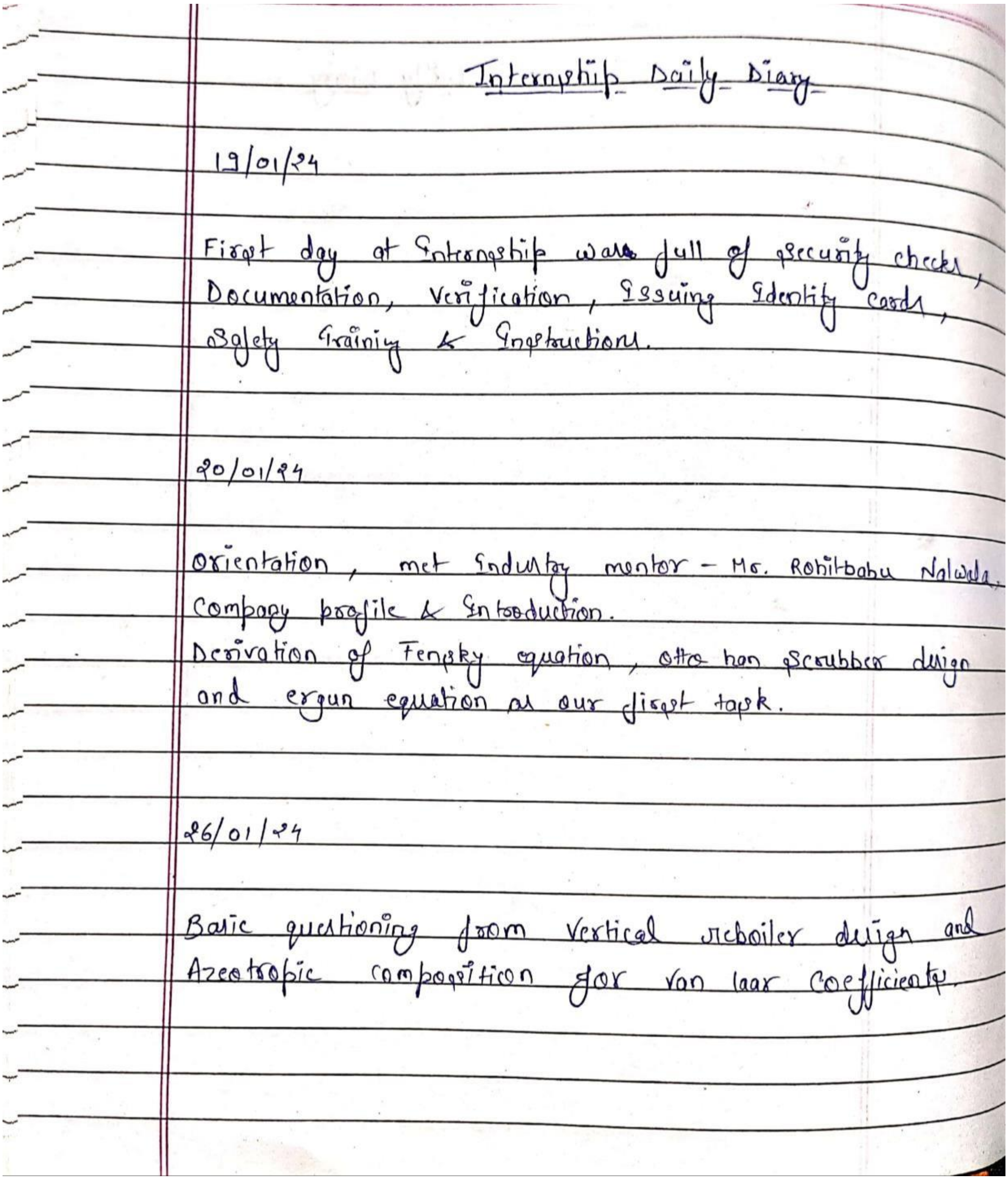
Sheet1 **Sheet2** Sheet3



ODES

	A	B	C	D	E	F	G	H
42	Name	Amount	UOM	T Reaction		Tcharge	Cp	Energy
43	ODES	120	kg	77		25	0.5	3120
44	I1	2829.6	kg	77		25	0.59	86812.1
45	A1	12	kg	77		25	0.844	526.656
46	H2	7.2	kg	77		25	0.7	262.08
47							Total	90720.9
48	I1	94.32	kg	77		4	0.59	4062.36

2. **Appendix B:** (Daily Diary)



Internship Daily Diary

19/01/24

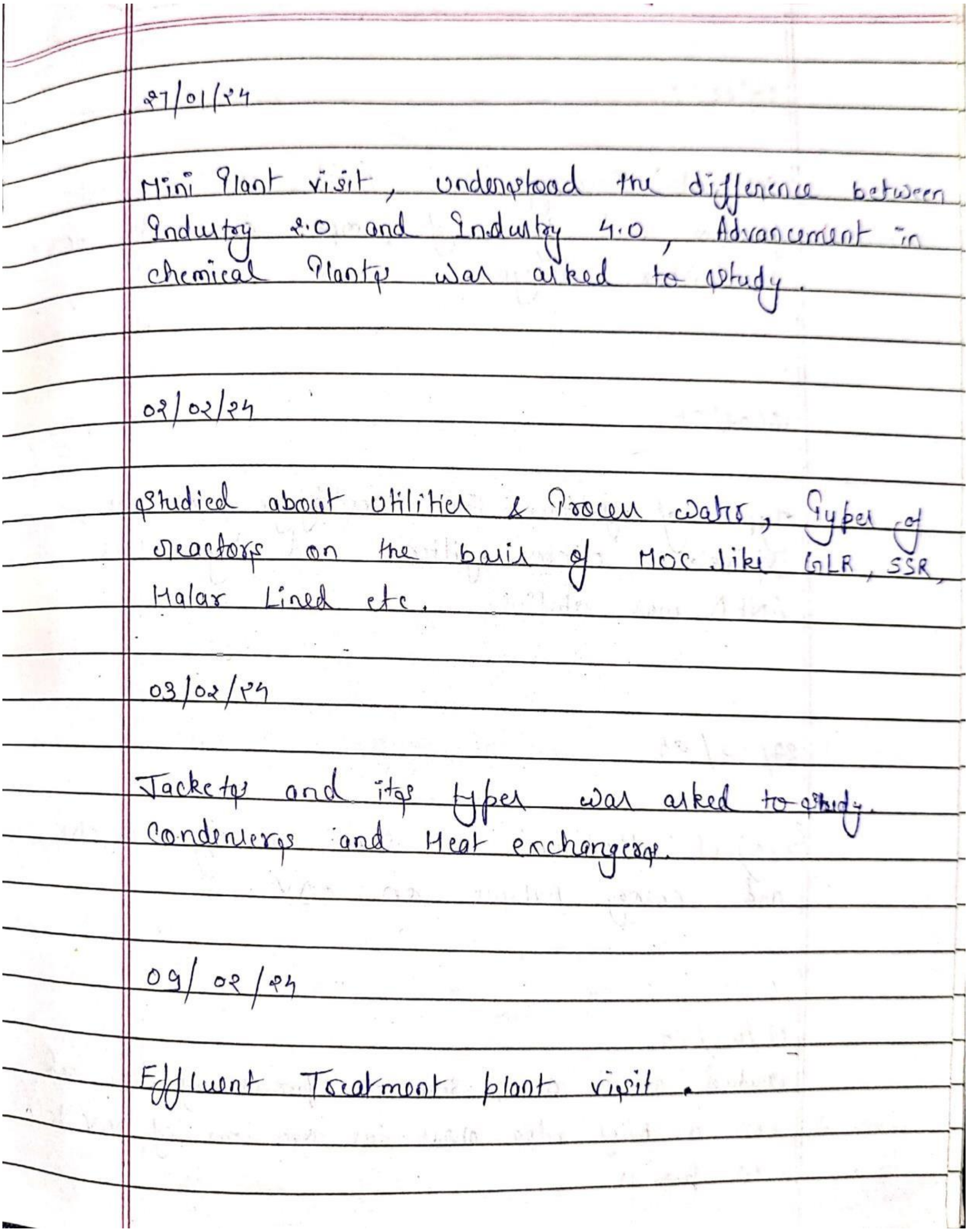
First day at Internship was full of security checks, Documentation, verification, Issuing Identity cards, safety Training & Instructions.

20/01/24

Orientation, met Industry mentor - Mr. Rohitbabu Nalwala. Company profile & Introduction.
Derivation of Fensky equation, otto hon scrubber design and ergun equation as our first task.

26/01/24

Basic questioning from vertical reboiler design and Azeotropic composition for van laar coefficients.



27/01/24

Mini Plant visit, understood the difference between Industry 2.0 and Industry 4.0, Advancement in chemical Plants was asked to study.

02/02/24

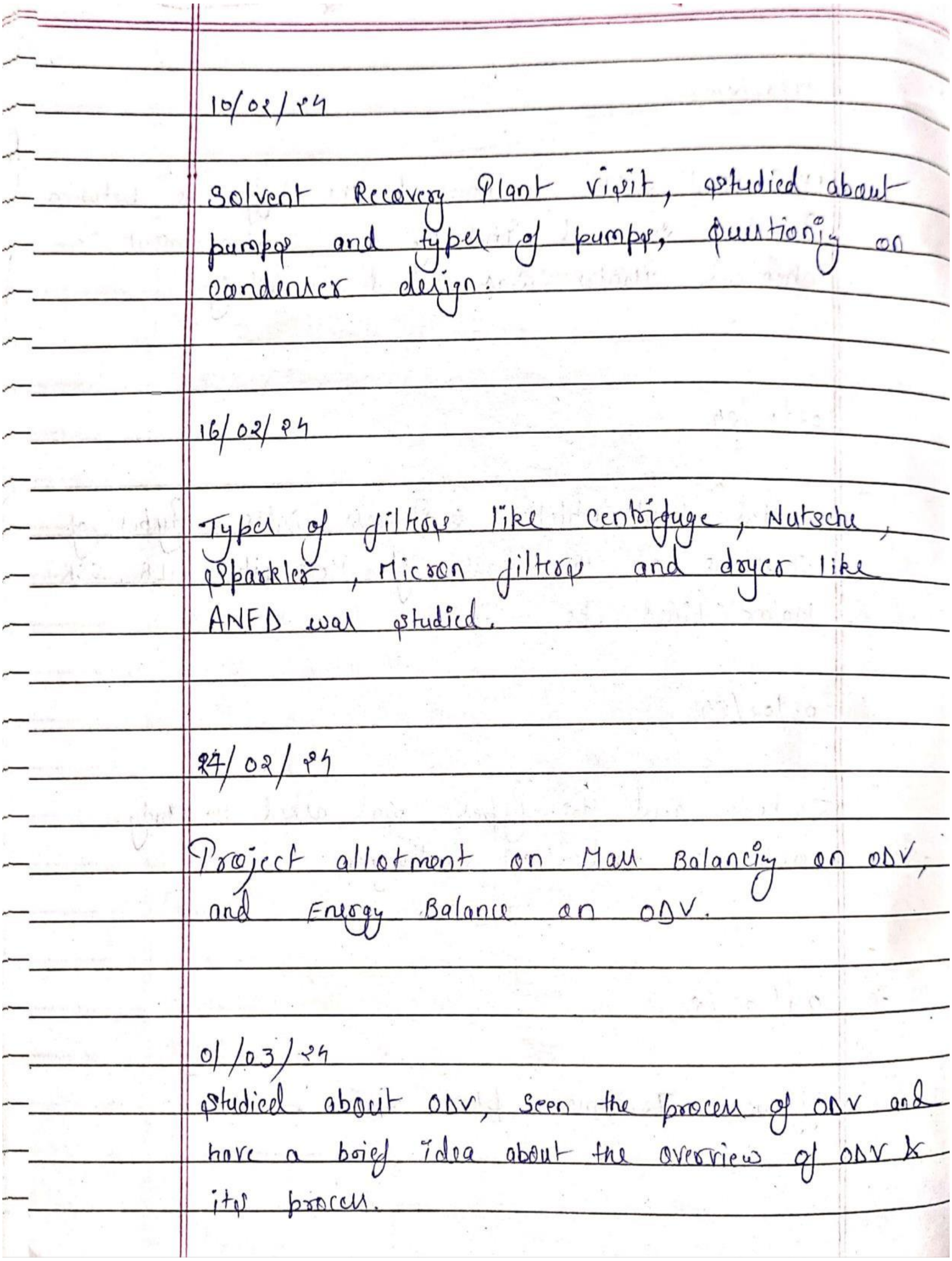
Studied about utilities & Process water, Types of reactors on the basis of MOC like GLR, SSR, Halar Lined etc.

03/02/24

Jackets and its types was asked to study. Condensers and Heat exchangers.

09/02/24

Effluent Treatment plant visit.



10/02/24

Solvent Recovery Plant visit, studied about pumps and types of pumps, questioning on condenser design.

16/02/24

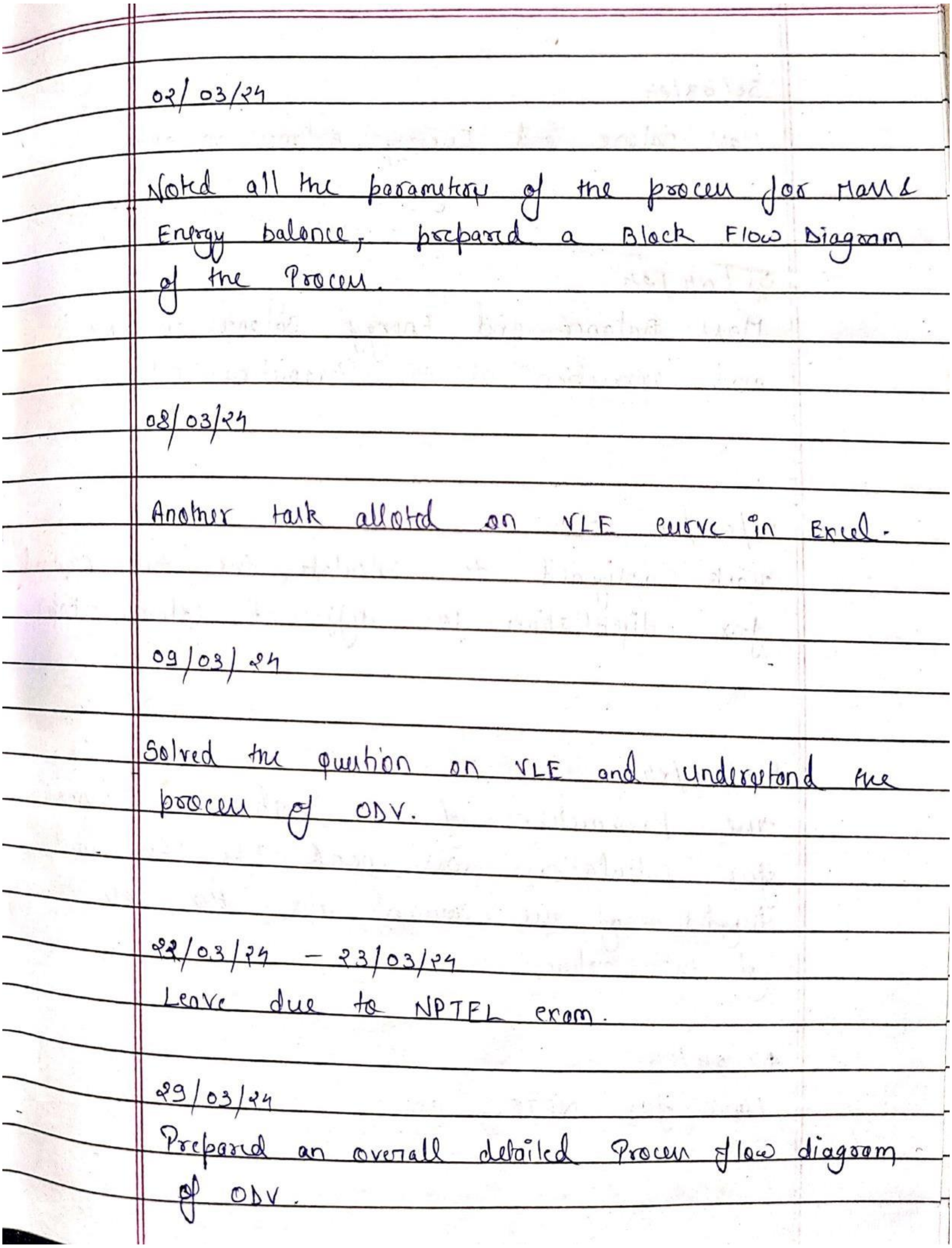
Types of filters like centrifuge, Nutsche, Sparkler, Micron filters and dryer like ANFD was studied.

24/02/24

Project allotment on Mass Balancing on ODV, and Energy Balance on ODV.

01/03/24

Studied about ODV, seen the process of ODV and have a brief idea about the overview of ODV & its process.



02/03/24

Noted all the parameters of the process for Mass & Energy balance, prepared a Block Flow Diagram of the Process.

08/03/24

Another task alloted on VLE curve in Excel.

09/03/24

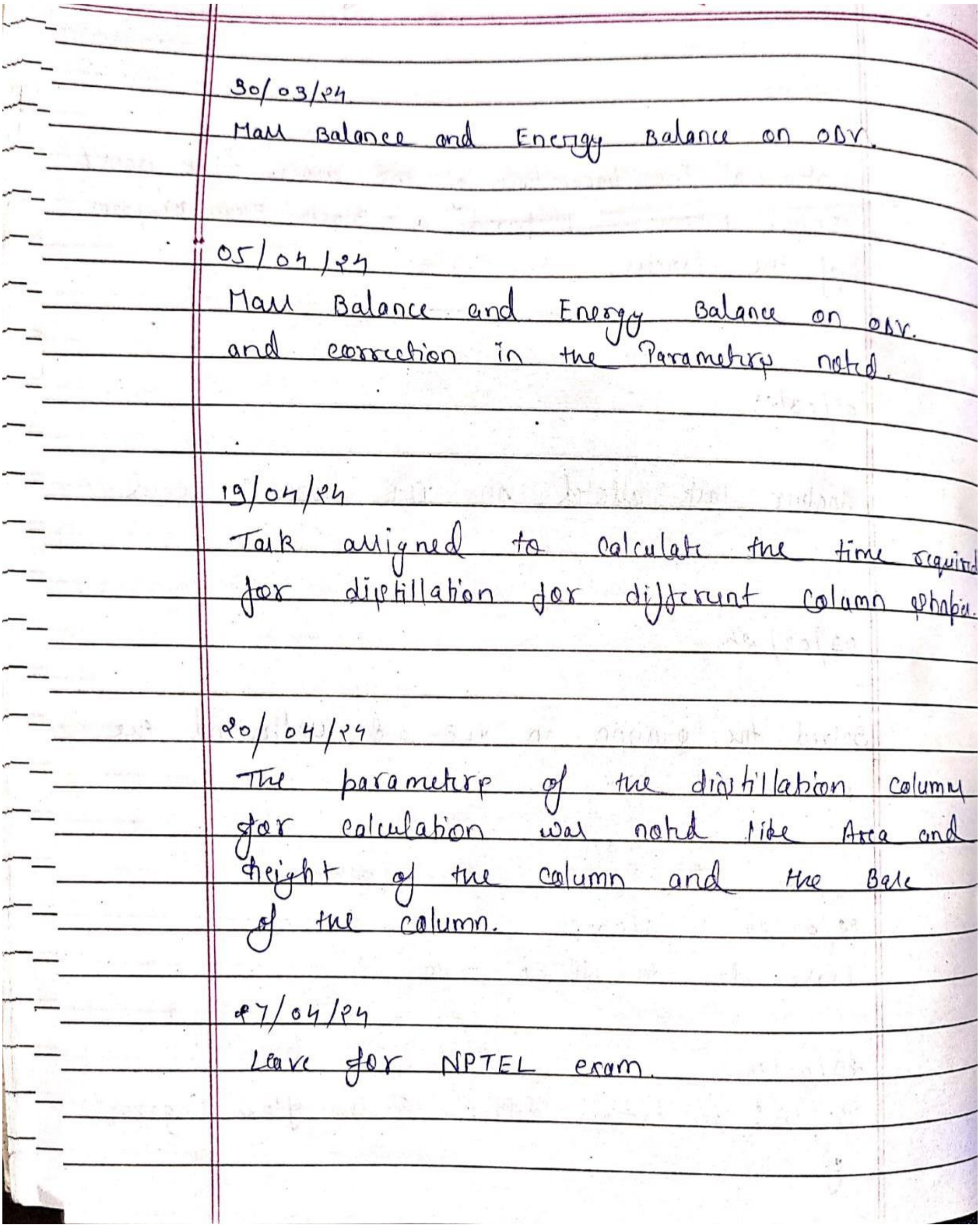
Solved the question on VLE and understand the process of ODV.

22/03/24 – 23/03/24

Leave due to NPTEL exam.

29/03/24

Prepared an overall detailed Process flow diagram of ODV.



30/03/24

Mass Balance and Energy Balance on ODV.

05/04/24

Mass Balance and Energy Balance on ODV.
and correction in the Parameters noted.

19/04/24

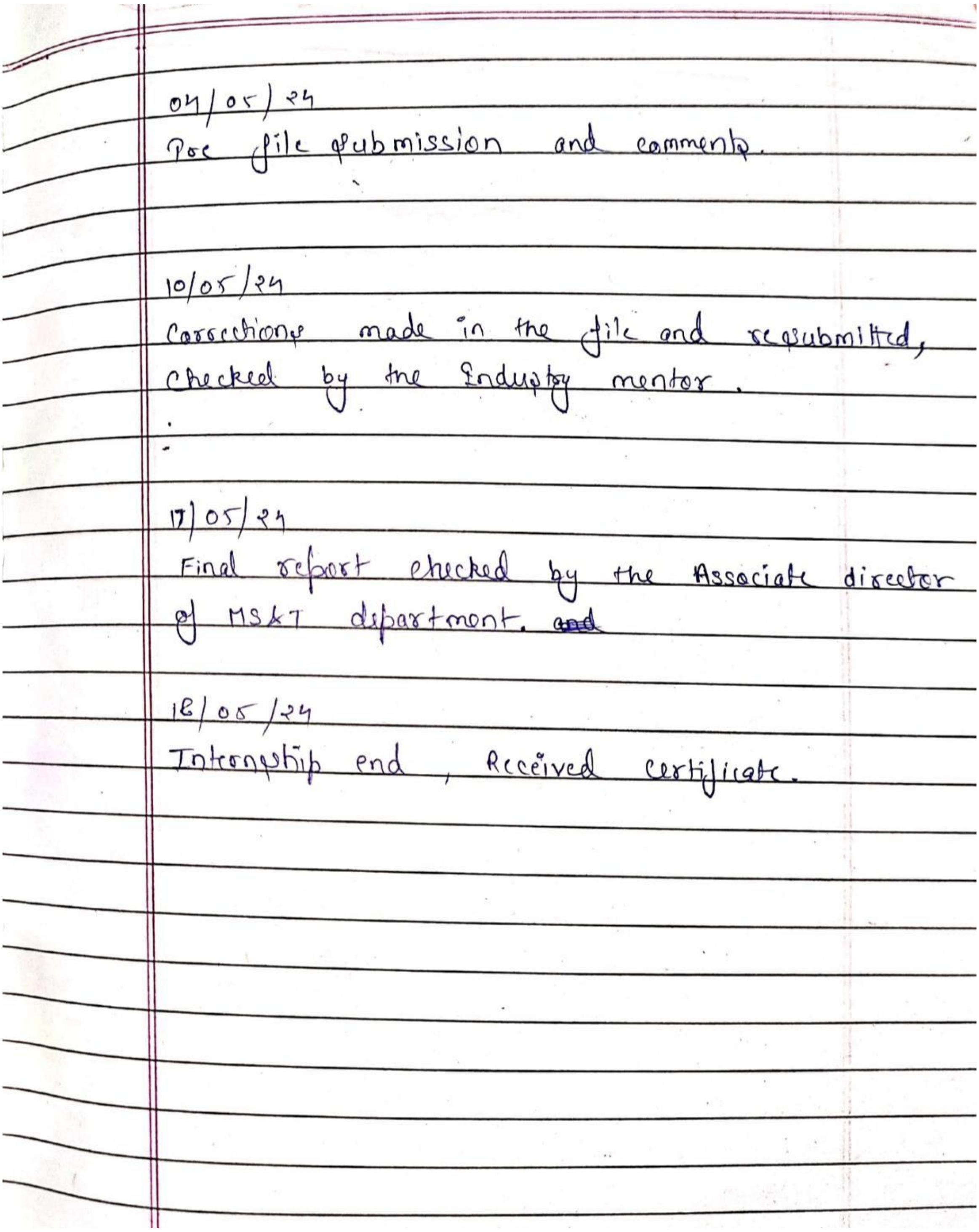
Task assigned to calculate the time required
for distillation for different column shapes.

20/04/24

The parameters of the distillation column
for calculation was noted like Area and
height of the column and the Base
of the column.

27/04/24

Leave for NPTEL exam.



04/05/24

Poc file submission and comments.

10/05/24

Corrections made in the file and resubmitted, Checked by the Industry mentor.

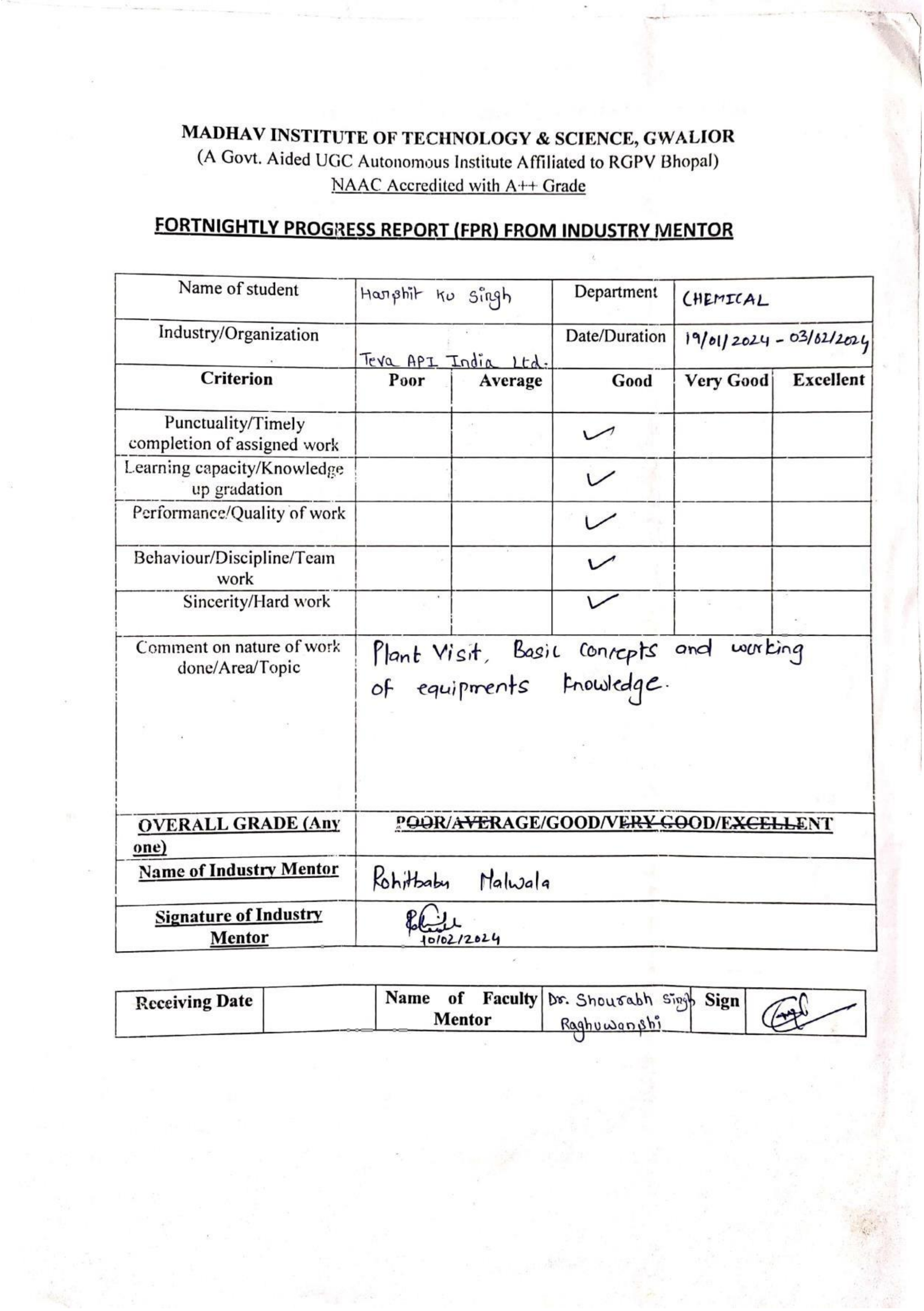
17/05/24

Final report checked by the Associate director of MS&T department. ~~and~~

18/05/24

Internship end, Received certificate.

3. **Appendix C:** FPRs



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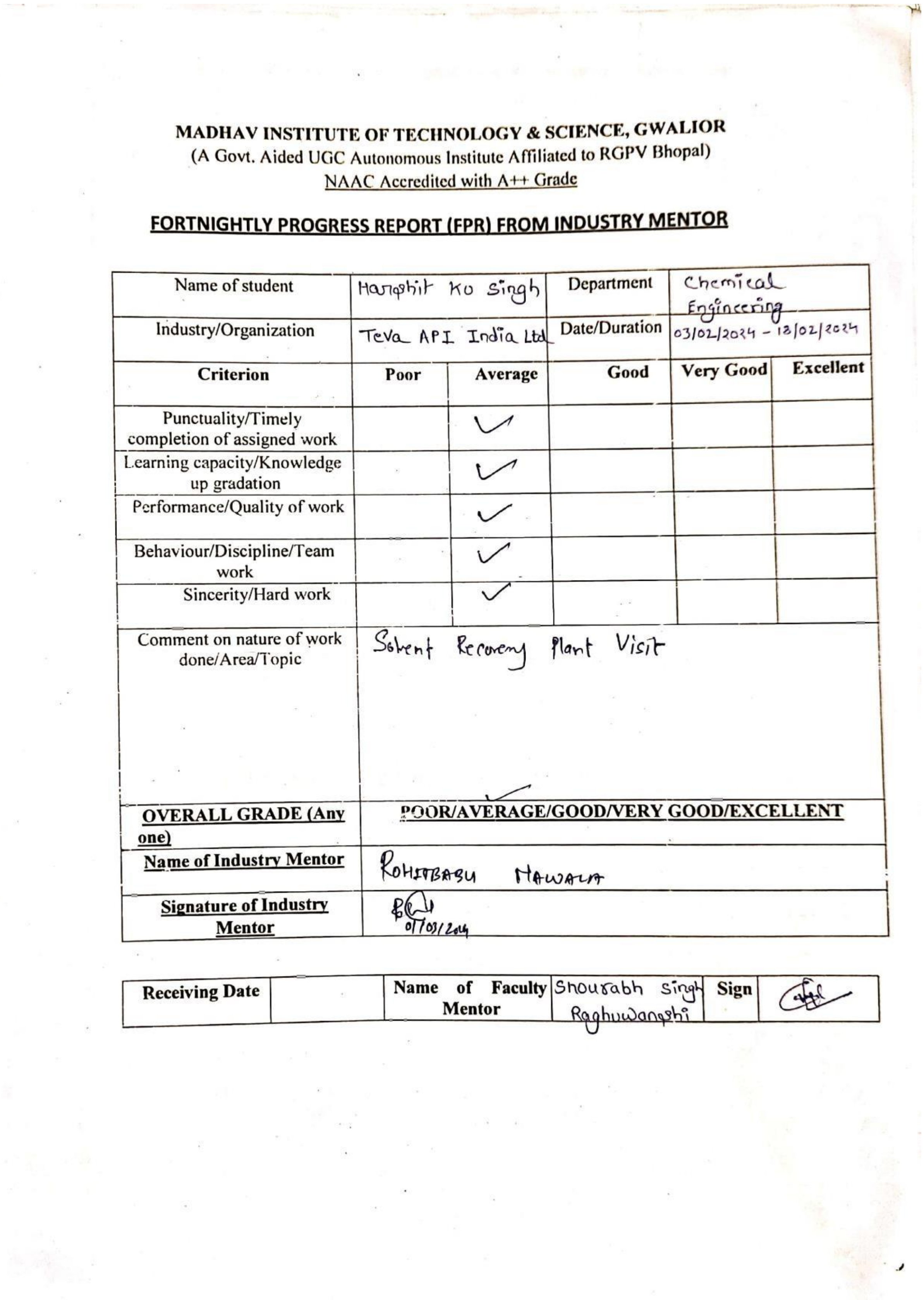
FORTNIGHTLY PROGRESS REPORT (FPR) FROM INDUSTRY MENTOR

Name of student	Harshit Ku Singh		Department	CHEMICAL	
Industry/Organization	Teva API India Ltd.		Date/Duration	19/01/2024 - 03/02/2024	
Criterion	**Poor**	**Average**	**Good**	**Very Good**	**Excellent**
Punctuality/Timely completion of assigned work			✓		
Learning capacity/Knowledge up gradation			✓		
Performance/Quality of work			✓		
Behaviour/Discipline/Team work			✓		
Sincerity/Hard work			✓		
Comment on nature of work done/Area/Topic	Plant Visit, Basic concepts and working of equipments knowledge.				
OVERALL GRADE (Any one)	**P~~OO~~R/~~AVE~~RAGE/GOOD/V~~ERY GOOD~~/E~~XCELLE~~NT**				
Name of Industry Mentor	Rohitbabu Malwala				
Signature of Industry Mentor	10/02/2024				

Receiving Date		**Name of Faculty Mentor**	Dr. Shourabh Singh Raghuwanshi	**Sign**	



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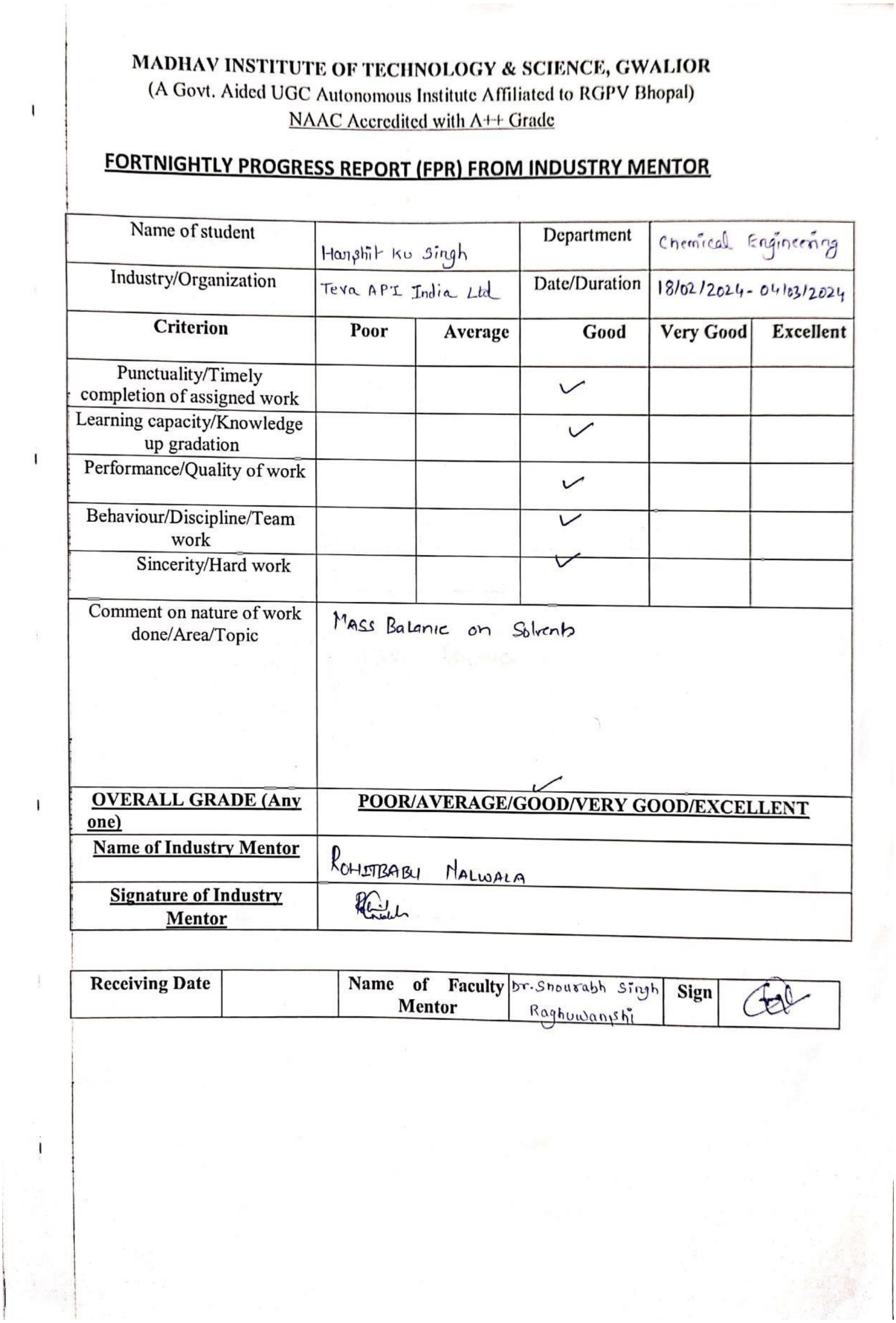
Name of student	Harshit Ku Singh		Department	Chemical Engineering	
Industry/Organization	Teva API India Ltd		Date/Duration	03/02/2024 - 18/02/2024	
Criterion	**Poor**	**Average**	**Good**	**Very Good**	**Excellent**
Punctuality/Timely completion of assigned work		✓			
Learning capacity/Knowledge up gradation		✓			
Performance/Quality of work		✓			
Behaviour/Discipline/Team work		✓			
Sincerity/Hard work		✓			
Comment on nature of work done/Area/Topic	Solvent Recovery Plant Visit				
OVERALL GRADE (Any one)	**POOR/[✓ AVERAGE]/GOOD/VERY GOOD/EXCELLENT**				
Name of Industry Mentor	ROHITBABU HAWALA				
Signature of Industry Mentor	01/03/2014				

Receiving Date		**Name of Faculty Mentor**	Shourabh Singh Raghuwanshi	**Sign**	



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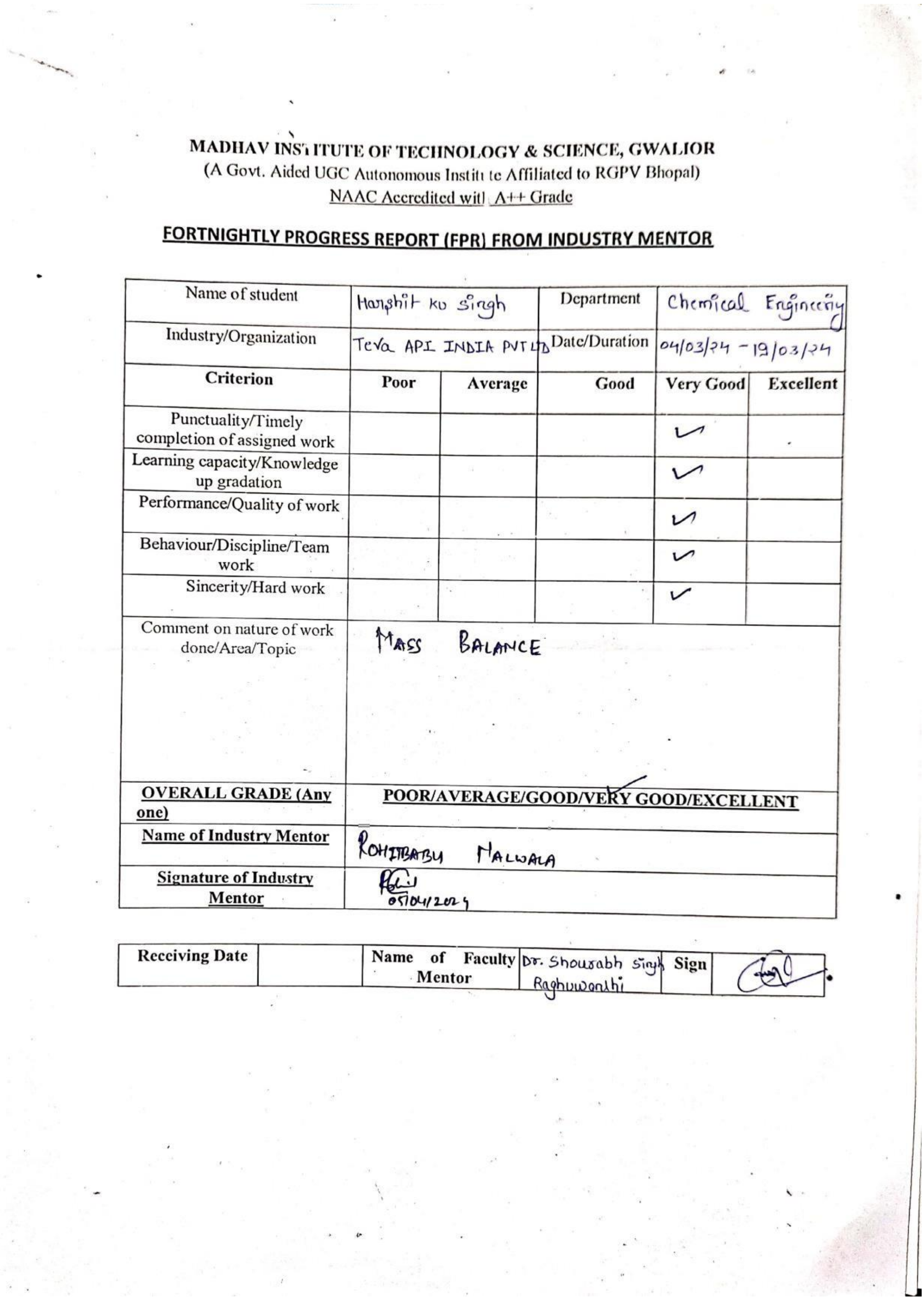
Name of student	Harshit Ku singh		Department	Chemical Engineering	
Industry/Organization	Teva API India Ltd		Date/Duration	18/02/2024 - 04/03/2024	
Criterion	**Poor**	**Average**	**Good**	**Very Good**	**Excellent**
Punctuality/Timely completion of assigned work			✓		
Learning capacity/Knowledge up gradation			✓		
Performance/Quality of work			✓		
Behaviour/Discipline/Team work			✓		
Sincerity/Hard work			✓		
Comment on nature of work done/Area/Topic	Mass Balanic on Solvents				
OVERALL GRADE (Any one)	**POOR/AVERAGE/[✓ GOOD]/VERY GOOD/EXCELLENT**				
Name of Industry Mentor	ROHITBABU NALWALA				
Signature of Industry Mentor					

Receiving Date		**Name of Faculty Mentor**	Dr. Shourabh Singh Raghuwanshi	**Sign**	



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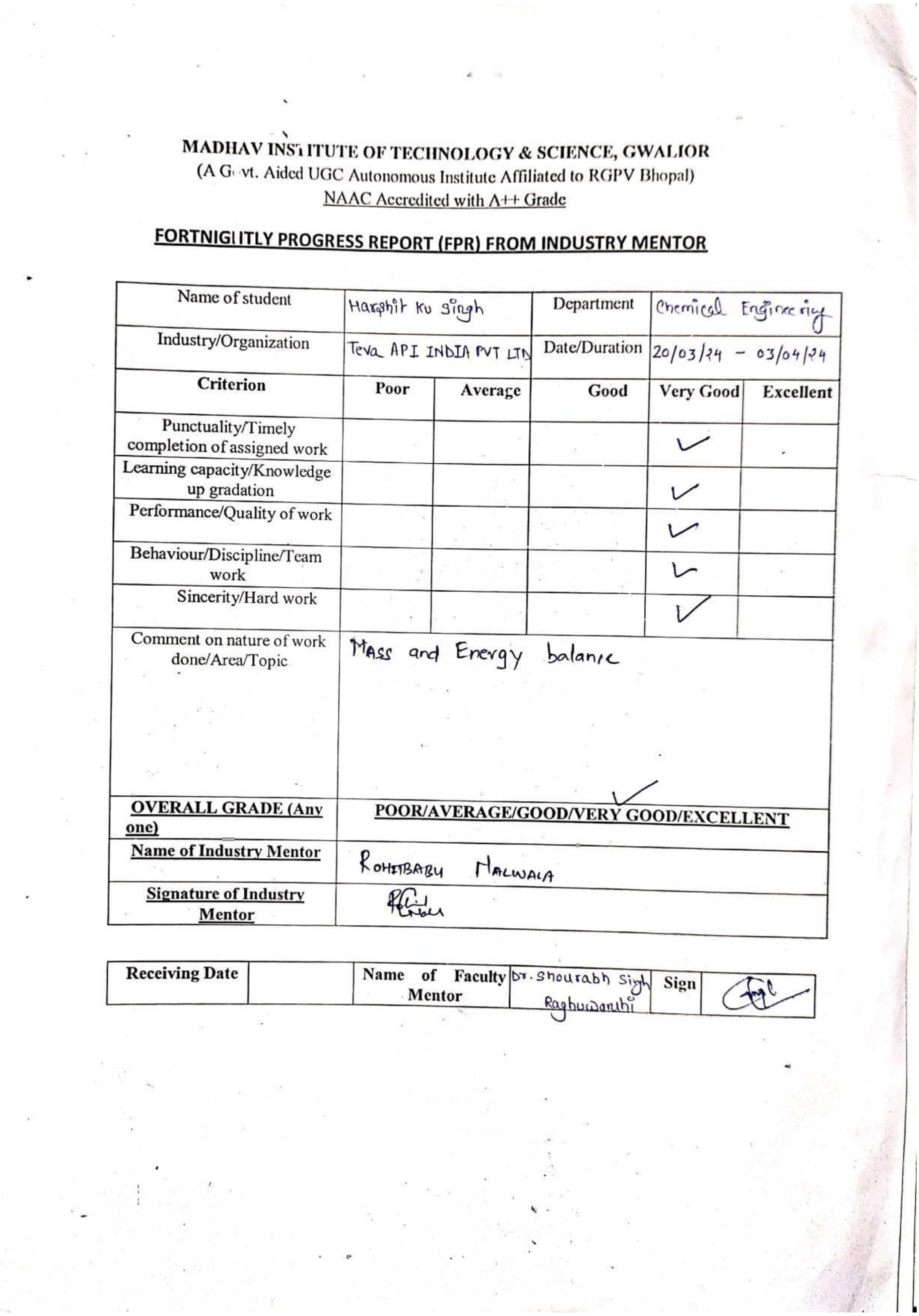
Name of student	Harshit ku singh		Department	Chemical Engineering	
Industry/Organization	Teva API INDIA PVT LTD		Date/Duration	04/03/24 – 19/03/24	
Criterion	**Poor**	**Average**	**Good**	**Very Good**	**Excellent**
Punctuality/Timely completion of assigned work				✓	
Learning capacity/Knowledge up gradation				✓	
Performance/Quality of work				✓	
Behaviour/Discipline/Team work				✓	
Sincerity/Hard work				✓	
Comment on nature of work done/Area/Topic	MASS BALANCE				
OVERALL GRADE (Any one)	**POOR/AVERAGE/GOOD/[✓ VERY GOOD]/EXCELLENT**				
Name of Industry Mentor	ROHITBABU MALWALA				
Signature of Industry Mentor	05/04/2024				

Receiving Date		**Name of Faculty Mentor**	Dr. Shourabh Singh Raghuwanshi	**Sign**	



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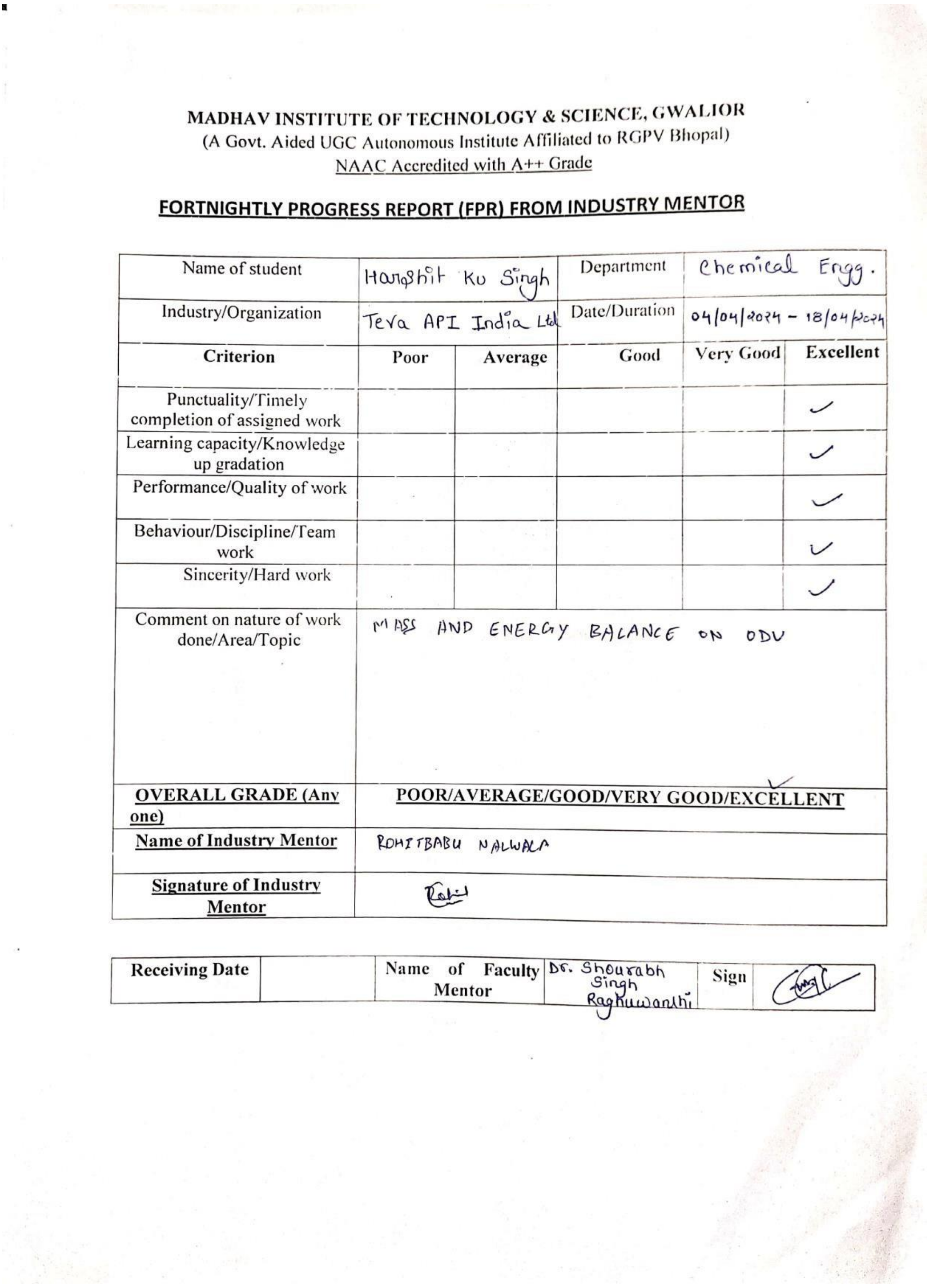
Name of student	Harshit Ku Singh		Department	Chemical Engineering	
Industry/Organization	Teva API INDIA PVT LTD		Date/Duration	20/03/24 – 03/04/24	
Criterion	**Poor**	**Average**	**Good**	**Very Good**	**Excellent**
Punctuality/Timely completion of assigned work				✓	
Learning capacity/Knowledge up gradation				✓	
Performance/Quality of work				✓	
Behaviour/Discipline/Team work				✓	
Sincerity/Hard work				✓	
Comment on nature of work done/Area/Topic	Mass and Energy balance				
OVERALL GRADE (Any one)	**POOR/AVERAGE/GOOD/[✓ VERY GOOD]/EXCELLENT**				
Name of Industry Mentor	ROHITBABU MALWALA				
Signature of Industry Mentor					

Receiving Date		**Name of Faculty Mentor**	Dr. Shourabh Singh Raghuwanshi	**Sign**	



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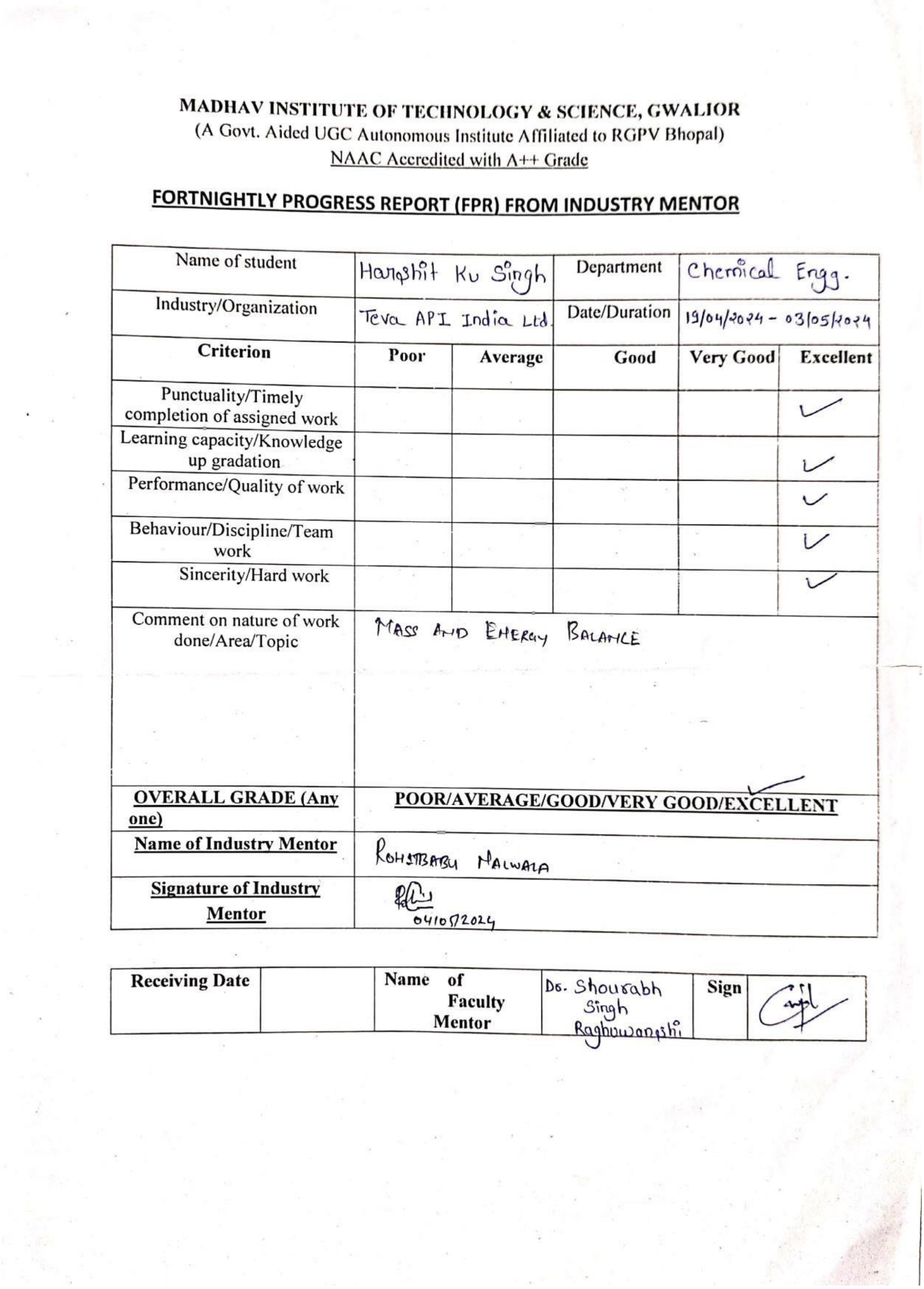
Name of student	Harshit Ku Singh		Department	Chemical Engg.	
Industry/Organization	Teva API India Ltd		Date/Duration	04/04/2024 - 18/04/2024	
Criterion	**Poor**	**Average**	**Good**	**Very Good**	**Excellent**
Punctuality/Timely completion of assigned work					✓
Learning capacity/Knowledge up gradation					✓
Performance/Quality of work					✓
Behaviour/Discipline/Team work					✓
Sincerity/Hard work					✓
Comment on nature of work done/Area/Topic	MASS AND ENERGY BALANCE ON ODU				
OVERALL GRADE (Any one)	**POOR/AVERAGE/GOOD/VERY GOOD/[✓ EXCELLENT]**				
Name of Industry Mentor	ROHITBABU NALWALA				
Signature of Industry Mentor	Rohit				

Receiving Date		**Name of Faculty Mentor**	Dr. Shourabh Singh Raghuwanshi	**Sign**	



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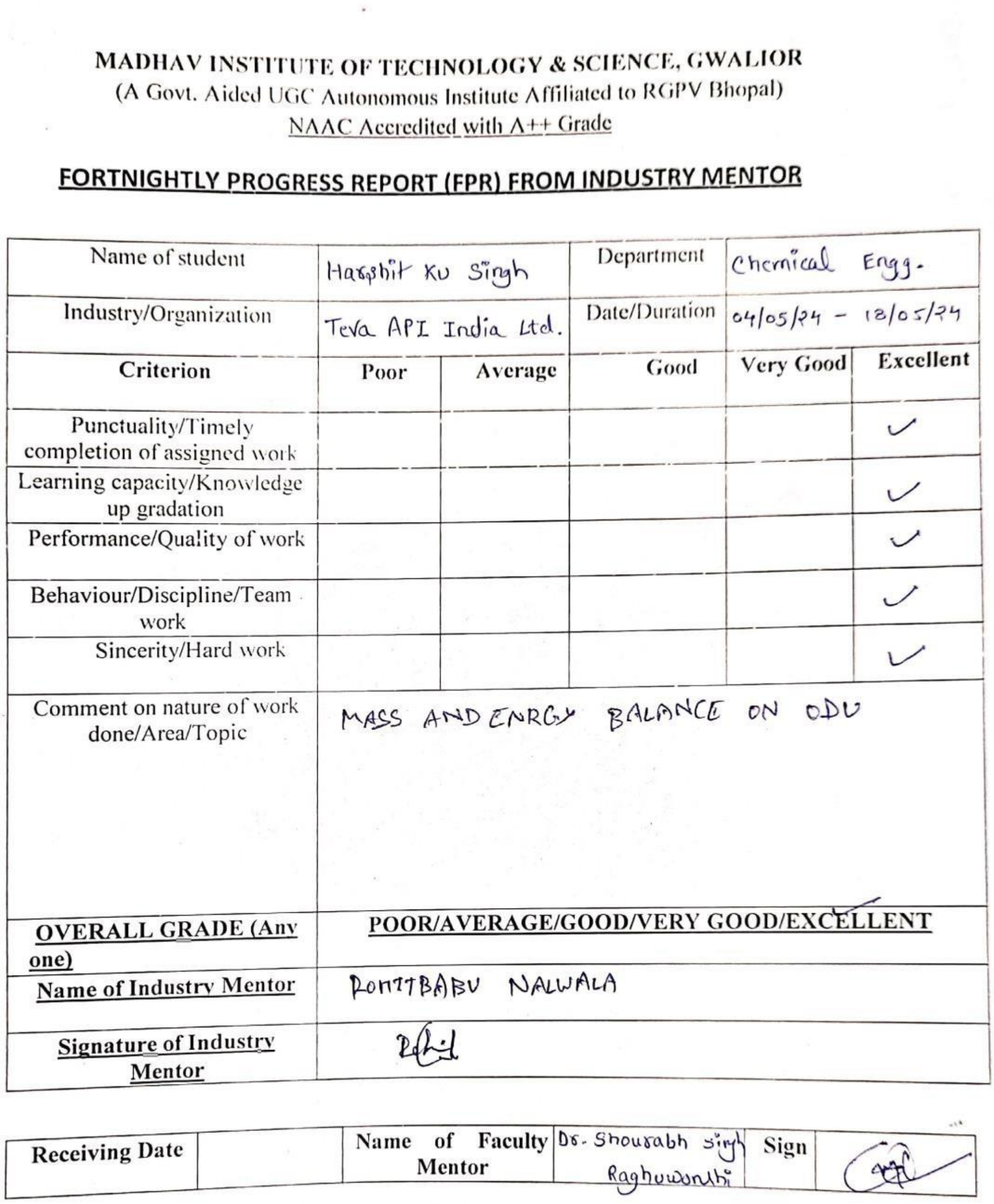
FORTNIGHTLY PROGRESS REPORT (FPR) FROM INDUSTRY MENTOR

Name of student	Harshit Ku Singh		Department	Chemical Engg.	
Industry/Organization	Teva API India Ltd.		Date/Duration	19/04/2024 - 03/05/2024	
Criterion	**Poor**	**Average**	**Good**	**Very Good**	**Excellent**
Punctuality/Timely completion of assigned work					✓
Learning capacity/Knowledge up gradation					✓
Performance/Quality of work					✓
Behaviour/Discipline/Team work					✓
Sincerity/Hard work					✓
Comment on nature of work done/Area/Topic	MASS AND ENERGY BALANCE				
OVERALL GRADE (Any one)	**POOR/AVERAGE/GOOD/VERY GOOD/[✓ EXCELLENT]**				
Name of Industry Mentor	ROHITBABU MALWALA				
Signature of Industry Mentor	04/05/2024				

Receiving Date		**Name of Faculty Mentor**	Dr. Shourabh Singh Raghuwanshi	**Sign**	



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FORTNIGHTLY PROGRESS REPORT (FPR) FROM INDUSTRY MENTOR

Name of student	Harshit Ku Singh		Department	Chemical Engg.	
Industry/Organization	Teva API India Ltd.		Date/Duration	04/05/24 – 18/05/24	
Criterion	**Poor**	**Average**	**Good**	**Very Good**	**Excellent**
Punctuality/Timely completion of assigned work					✓
Learning capacity/Knowledge up gradation					✓
Performance/Quality of work					✓
Behaviour/Discipline/Team work					✓
Sincerity/Hard work					✓
Comment on nature of work done/Area/Topic	MASS AND ENRGY BALANCE ON ODU				
OVERALL GRADE (Any one)	**POOR/AVERAGE/GOOD/VERY GOOD/[✓ EXCELLENT]**				
Name of Industry Mentor	ROHITBABU NALWALA				
Signature of Industry Mentor					

Receiving Date		**Name of Faculty Mentor**	Dr. Shourabh Singh Raghuwanshi	**Sign**	