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Department of **E**lectrical **S**ystems **E**ngineering

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Field : Automatic

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The automation and supervision interface with S7-1215 of water purification station in the pharmaceutical industry

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Defended on 29/06/2024 before the jury composed of:

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With my deepest respect goes to the members of the jury.

Dedication

I want to dedicate this work to my family, I wouldn't be the person I am today without them

Especially my mom, who sacrificed her youth and worked for me, my grandparents, my aunts and uncles who made sure all of my needs were met growing up.

Their support and belief in me have kept my spirits and motivation high during this process. I would also like to thank my friends Mehdi, Rochdi, Ryad, Maya and Rania for all the entertainment and emotional support.

Dedication

Firstly, I offer my deepest gratitude to God for the strength and wisdom bestowed upon me throughout this academic journey.

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This achievement is as much yours as it is mine.

Abstract

Health is an indicator of the level of the country's welfare so that it becomes a priority in the national development of the country.

This is related to efforts to improve the quality of the nation's competitiveness in the current era of global competition. The main form of the application of technology is to lead the country in this advancement.

Currently, BIOPHARM is one of the Algerian leading factories in the pharmaceutical industry, taking that step with the new oncology drug production. And without the use of purification water system there is no road.

The objectives of this study are (First) to introduce and describe the Purification Water System process in the pharmaceutical sector.

(Second) knowing the technology and automation behind it. (Third) analyzing its program and way of function with an interface for monitoring its progress.
Key words: Pharmaceutical industry, purification water system, automation, program, interface.

Résumé :

La santé est un indicateur du niveau de bien-être du pays afin qu'elle devienne une priorité dans le développement national du pays.

Cela est lié aux efforts visant à améliorer la qualité de la compétitivité du pays dans l'ère actuelle de la concurrence mondiale. La principale forme d'application de la technologie est de diriger le pays dans cette avancée.

Actuellement, BIOPHARM est l'une des principales usines algériennes de l'industrie pharmaceutique, prenant cette mesure avec la nouvelle production de médicaments oncologiques. Et sans l'utilisation d'un système d'eau purifiée, il n'y a pas de route.

Les objectifs de cette étude sont (premièrement) d'introduire et de décrire le procédé Système d'Eau Purifiée dans le secteur pharmaceutique.

(Deuxièmement) connaître la technologie et l'automatisation qui la sous-tendent. (Troisièmement) analyser son programme et son mode de fonctionnement à l'aide d'une interface de suivi de ses progrès.
Mots clés : l'industrie pharmaceutique, système d'eau purifiée, l'automatisation, programme, interface.

ملخص:

الصحة هي مؤشر على مستوى رفاهية البلاد بحيث تصبح أولوية في التنمية الوطنية للبلد. يرتبط هذا بالجهود المبذولة لتحسين جودة القدرة التنافسية للأمة في العصر الحالي للمنافسة العالمية. الشكل الرئيسي لتطبيق التكنولوجيا هو قيادة البلاد في هذا التقدم.

حاليًا، BIOPHARM هي واحدة من المصانع الجزائرية الرائدة في صناعة الأدوية، وتتخذ هذه الخطوة مع إنتاج أدوية الأورام الجديدة. وبدون استخدام نظام مياه التنقية لا يوجد طريق.. أهداف هذه الدراسة هي (أولاً) إدخال ووصف عملية نظام مياه التنقية في قطاع المستحضرات الصيدلانية. (ثانيًا) معرفة التكنولوجيا والأتمتة التي تقف وراءها. (ثالثاً) تحليل برنامجه وطريقة عمله بواجهة لرصد تقدمه..

الكلمات الرئيسية: صناعة الأدوية، نظام تنقية المياه ، الأتمتة، البرنامج، الواجهة.

Summary

CHAPTER III: Programming and Supervision

Abbreviation list

AI: Analog input

Antiscalant: polyphosphates and other organic acids

AO: Analog output

°C: degree Celsius

CFU/ml: colony-forming unit per milliliter

Cl: Chloral

CIP: Clean-in-Place

CP/M: Control Program/Monitor

CPU: Central Processing Unit

DI: Digital input.

DO: Digital output.

FDA: Food and Drug Administration

GMP: Good manufacturing practices

Grafcet (SFC): GRAphe Fonctionnel de Commande Etape Transition (Sequential Function Charts)

HMI: Human Machine Interface

IU/ml: International Units per Milliliter

I/O: Input/output

KW: Kilo Watt

MPI: Multi Point Interface

NaOH: Sodium hydroxide

NLT: Not less than

NMT: Not more than

NO_3: Nitrate Ion

NTU: Nephelometric Turbidity Units

QC : Conception Qualification

QI : Installation Qualification

QO : Operational Qualification

QP : Performance Qualification

ORP: Oxidation Reduction Potential.

Ppm: part per million

Ppb = part per billion.

pH: hydrogen potential

PLC: Programmable Logic Controller

Ph. Eur: Pharmacopeia European.

Pu: pure steam

Pw: purified water

PROFINET: (Process Field Network)

PROFIBUS: (Process Field Bus)

RO: Revers osmoses

Rpm: Revolutions per minute

SMBS: Sodium Meta bisulfite

SIMATIC: Siemens Automatic

Toc: Total Organic Carbon

T/Temp: Temperature

TIA Portal: Totally Integrated Automation Portal

UV: Ultraviolet

WHO: Word Health Organization

WFI: water for injection

µs/cm: Micro Siemens per centimeter

List of tables

Aucune entrée de table d'illustration n'a été trouvée.

CHAPTER I: A General report on the water treatment process and its description

Aucune entrée de table d'illustration n'a été trouvée.

CHAPTER III: Programming and Supervision

Table of figures

GENERAL INTRODUCTION

GENERAL INTRODUCTION

Intensive competition on the global market, and the human needs, put great pressure on manufacturing companies to develop and produce products that meet requirements from customers and investors.

Designing an automated system is a powerful tool to increase efficiency and be on top of the pyramid, making it the top priority in modern industries.

A debate on this phenomenon has always been controversial as the machine tends to replace man in several tasks.

The pharmaceutical industry on the other hand is built on the purpose of serving the human race and maintaining its longevity, and there is no production without the aid of the machine. So, is the machinery here still a foe or a need?

Before getting deeper, we first identify the entire system and limit of the intervention. In this work, we have an already automated system in process, it is a water purification station of raw water from the drilling at the company's disposal (BIOPHARM), making it a very delicate process, since the water is going to be used in the making of the very first Algerian oncology injectable drugs.

Because of the water coming from several stations (underground SEAAL pipes for example) it can be prone to different types of impurities and especially bacteria, contaminating the drugs and harming the equipment, this station is composed of a pretreatment by sand and other types of fillers, water purification system, water for injection and pure steam process. Making it possible to have a quality water, pure and demineralized, set for the drug making.

To this end, this thesis is divided into three chapters describing the main process of the water purification whole system and its main components. Where our training took place.

The first chapter deals with general information and good manufacturing process (GMP), and quality control standards on water treatment station that has to maintain, to describing the filtration process and the water's reasons to be purified.

The second chapter is devoted to the development of the functional analysis, and the various equipment (instruments and actuators) that pushes the plant to operate.

The last and third chapter will proceed to go deeper with the automation side with the making and presentation of the GRAFCET of the station, discussing the S7-1215 programmable logic controller and the SIEMENS engineering software which is the TIA portal

V17 used, that deals with the programming which is our objective, thus It will be detailed and explained.

To last but not least, making an HMI supervision interface, putting an eye on the process.

Finally, we conclude with a general conclusion.

CHAPTER I

A General report on the water treatment process and its description

I.1. Introduction:

The pharmaceutical industry is one of the most complex industries in terms of regulation and validation of manufacturing circuits. Each step must be perfectly mastered to guarantee the quality of the products and public health.

Water purification treatment in the pharmaceutical industry is even more complex. There is no product that is not at least rinsed with water during its production, it is an essential component of production of every type of drugs.

GMP, quality indicators and process digitization, all means are good to guarantee the quality of care and follow-up of patients.

I.2. General presentation of the company:

The BIOPHARM Group is an Algerian pharmaceutical company that invested in the pharmaceutical sector in the early 1990s. It has currently several production units compliant with international standards, as well as a distribution network that covers the entire territory of Algeria and which serves wholesalers and pharmacies.

I.2.1. Newest Manufacturing History and location:

Built on a site of 8 000 m2, our unit of Oued Smar (Algiers, Algeria) manufactures today some 35 million units per year, through 9 lines of production, that is two (2) lines for the liquid forms (small and large volumes), a line of creams and gels, two lines of suppositories and four lines of dry forms (bags, powder, pills and tablets). Our production range includes nearly hundreds of generics covering the main therapeutic classes.

Which made it able to manufacture some 4000 pharmaceutical products that are delivered on the whole of Algerian territory including the most remote regions of the country, through a powerful logistics and sales network comprising 14 distribution centers, a fleet of more than 300 vehicles, more than 150 wholesalers and 3000 pharmaceutical pharmacies.

Figure 1.1: BIOPHARM's station.

I.2.2. Latest financial release:

BIOPHARM has achieved 82.9 billion dinars in 2023. With manufacturing more than 150 products in its production units, including the one in Oued Smar, which was the first Algerian unit to obtain the Good Manufacturing Practices (GMP) certification of the French National Safety of Medicines (ANSM).

With a rise of consolidated capital expenditure for 2023 to 5,476 million dinars, against 3,561 million dinars from 2022, an increase of 54%. These investments, confirming the Group's commitment to supporting growth in the medium-long term through production (especially oncology products).

Split into Subsidiary companies:

- SPA BIOPHARM Distribution: specialized in the distribution mainly of the products of the Parent company and the products of importation.
- SPA BIOPURE: whose activity is distribution to pharmacies.
- SPA BIOLOGIE: logistics company on behalf of the group companies.
- SPA HHI: company dedicated to the promotion of the group's products.
- PROPHAM SPA: specialized in the manufacture of oncology products.
- SPA IMPSA: the sale to pharmacies.
- BIORMONE SPA: Hormone Manufacturing.

I.2.3. Propham:

After nearly two decades of intense activity, BIOPHARM achieves an important stage of its development which required a reorganization, a new site for oncology.

Propham is a new building attached to BIOPHARM's main station. It is 5 stories building (From -2 to +2) containing three separate level blocks for three different new products.

- In level -1 we find the water treatment system, which is our work station and project to be presented.
- In level 0 is the injectable sterile Nasal drugs making station.
- In level +1 is a dry form non-sterile drug (Anatrex & Lenazax).
- In level +2 is the main product and also an injectable named Cyclotron FDG, which is pet-scan contrast products for cell cancer diagnosis.

Propham will lead as the first oncology drugs manufacturing site in the Algerian territory, making it a tremendous achievement for the Algerian industry and market as something to be proud of. Intending to pursue a sustained rate of growth over the next few years.

Figure 1.2: PROPHAM's station.

I.2.4. Propham's current projects:

Provided with more than 15 billion dinars in investments. The plan is to revolve around the launch of the injectable oncology manufacturing unit At the Oued-Semar site, we will manufacture dry-form oncology drugs, Cyclotron FDG, which are pet-scan contrast products for cell cancer diagnosis.

At the same time, we will inaugurate the production line of liquid form nasal medications, with the option of advancing in the automation production industry. By the end of 2024, Algeria will be sheltered from the importation of oncology products.

I.3. Good manufacturing practice:

Good Manufacturing Practice or GMP is a process, procedures and documents system made to ensure the quality, safety and effectiveness of products (drugs) while they're being manufactured, following quality standards, that are enforced by regulatory authorities such as the FDA (food and drug administration).

I.3.1. The requirements of good manufacturing practices in the pharmaceutical industry:

In pharmaceuticals, the standards ensure that medicines and health products are designed in accordance with the required quality standards. To help the business achieve satisfaction. Here are some key aspects of GMP in the pharmaceutical industry:

1) **Facilities and Equipment:**

To insure product quality, accuracy and the ability to manufacture the drugs intended to make, the firm must have the necessities a safe, convenient and practical environment and equipment to work with.

2) **Personnel:**

The personnel must be trained and qualified to meet the GMP compliance and should follow established procedures, wear appropriate attire, and maintain hygiene.

3) **Documentation and Records:**

Detailed documentation is required at every stage of production and should be accessible for any type of investigation.

4) **Quality Control and Testing:**

Raw materials (packaging, labelling etc.) and finished products have to be regularly checked. To control the quality standards that they are up to.

5) Qualification and validation:

The qualification and Validation procedure confirm that the production processes, installation utilities, equipment, and systems consistently produce desired results.

6) Raw Materials and Components:

Manufacturers must use approved raw materials and components such as Proper storage, handling, and labeling.

7) Product Packaging and Labeling:

Packaging materials must be suitable for the product and protect it from contamination.

8) Hygiene and Sanitation:

In point to protect products from potential contamination, systematic habits of cleanliness and hygiene should be applied on regular basis.

9) Cleaning rooms:

The rooms where drug processing occurs should be up to high hygiene standards, from cleanness to temperature to the staff.

10) Complaint Handling and Product Recall:

Complaints about any type of product should be handled and investigated to prevent deviations.

11) Audits and Inspections:

Plan and conduct regular inspections to ensure GMP compliance and quality system effectiveness.

I.4. Definition of Purified Water in Pharma:

The term “purified water” is frequently used in pharmaceutical operations. Simply put, it is water that has undergone multiple purification processes to remove impurities and contaminants such as Bacteria, Parasite, and Metals like copper, chemical pollutants etc.

It is a type of pharmaceutical-grade water that is frequently employed as an excipient in the manufacturing of sterile medications. Used as an inactive substance in the production of non-parenteral preparation including tests and analyses, formulation and cleaning, and must meet specific criteria for factors such the temperature, pH, conductivity, and microbial content. Overall, purified water is crucial for ensuring the purity and integrity of the products.

I.4.1. Specification of purified water:

Specifications for purified water in the pharmaceutical industry follow a collection of guidelines set by regulatory agencies such the European Pharmacopoeia (Ph. Eur.). Marking the quality criteria that must be met. Here are some of the specification mentioned.

Table 1.1: specifications needed for purified water.

S.No	Parameters	Specifications
1.	Appearance	Clear, colorless, no visible particles
2.	Odor	Odorless
3.	PH	5.1-7.0
4.	Acidity or alkalinity	NMT 0.1 ML OF 0.01M NaOH/Hcl
5.	Heavy metal	0.1 ppm
6.	Nitrate NO_3	≤0.2 ppm
7.	Total dissolved solid	NMT 1.0 ppm
8.	Conductivity	<1.1 µS/cm² at 20°C
9.	Microbial count	100 CFU/ml & absence of pathogenic bacteria
10.	TOC	≤0.5 mg/l
11.	Bacterial count	≤100 CFU/ml
12.	Bacterial endotoxins	<0.25 IU/ml

Pharmacopoeias limit the permitted final water purification stage in the production of two other vessels known as water for injection and pure steam, to be later used for the maintenance of several following types of process.

I.5. Water for injection:

Water for Injection (WFI) is one of the primary applications for the purified water produced by the distillation process. It is among the highest levels of water purity you can achieve.

Since it's most commonly used as a diluent for dehydrated medical drugs, this means that this water is usually injected directly into patients' bloodstreams, tissues and organs. Usually checked for few parameters including, the following characteristics mentioned in the table below.

Table 1.2: specifications needed for water for injection.

S.No	Parameters	Specifications
1.	Appearance	Clear ,colorless , no visible particles
3.	PH	5.1-7.0
6.	Nitrate NO_3	≤0.2 ppm
7.	Total dissolved solid	NMT 1.0 ppm
8.	Conductivity	<1.1 µS/cm²at 20°C
9.	Aluminum	≤ 10 ppb
10.	TOC	≤0.5 mg/l
11.	Bacterial count	≤10 CFU/ml
12.	Bacterial endotoxins	<0.25 IU/ml

I.6. Pure steam:

Pure steam also known as clean steam, refers to steam that has been generated from high-quality, purified water from non-condensable gases.it is the third form of treated water to be distributed. Coming from ordinary steam produced by boilers, as it undergoes additional purification steps like degrees of superheating, and saturation tests to ensure its suitability.

I.6.1. Characteristic of PS:

Table 1.3: Specifications needed for pure steam.

S.No	Parameters	Specifications
1.	PH	5.1-7.0
2.	Non-condensable gases	<40 ml/kg
3.	Temperature, pressure	Correlation with dry saturated steam
4.	Conductivity	<1.1 µS/cm at 20°C
5.	Moisture	<5%
6.	Superheat	<5°C
7.	Bacterial endotoxins	<0.25 EU/ml

I.7. The Process of water treatment system in pharmaceutical industries:

The process of producing purified water in the pharmaceutical industry involves several stages of purification to remove impurities and contaminants, ensuring the water meets the required quality standards for its intended use. Here are the key steps of the typical process:

I.7.1. Raw Water Source:

The process begins with sourcing water from a suitable raw water source, such as municipal water (SEAAL corporate), well water, or surface water.

I.7.2. Pre-treatment:

This is the first step of the process, it depends on the quality of the feed water and the requirement of the process, this stage may include the following processes:

Raw water undergoes pretreatment to remove large particles, suspended solids, and insoluble impurities that could potentially interfere with the purification steps. Pretreatment methods may include filtration, sedimentation, and clarification.

I.7.2.1. Rapid sand filters:

The most common type of filter, Water moves vertically through sand which often has a layer of activated carbon or coal above the sand. The top layer removes organic compounds, which contribute to taste and odor. The space between sand particles is considered large, which leads to most particles being trapped in pore spaces.

I.7.2.2. Chemical treatment:

It consists of using some chemical reaction to improve the water quality.

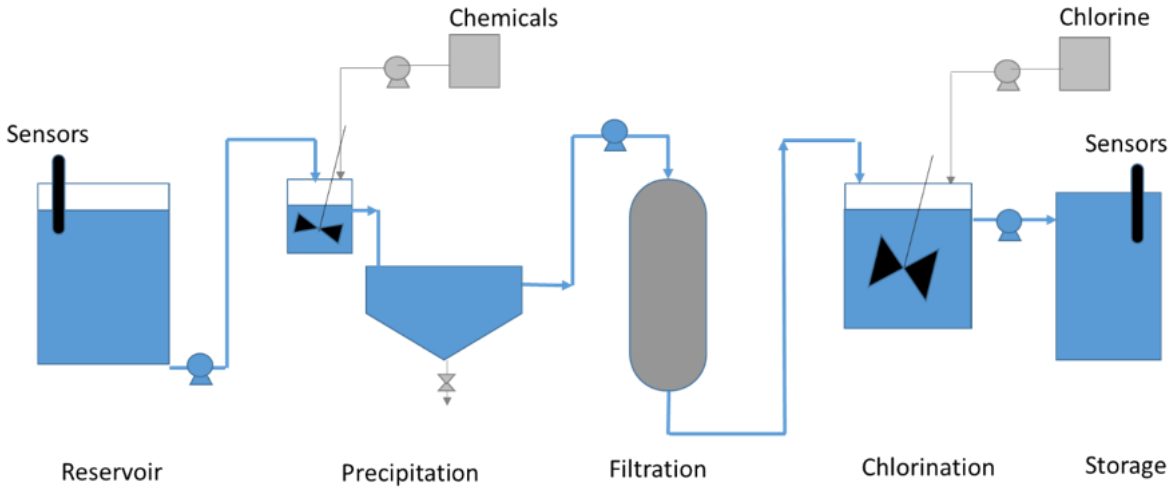


Figure 1.3: Chemical pretreatment process.

a. Chlorination:

Chlorination involves adding a measured amount of chlorine to water to produce a sufficient that manages to kill bacteria and viruses. The killing effect of chlorine depends on the pH of the water, temperature, chlorine level and contact time.

b. Dosing System:

To prevent the water's silica, sulphates, and other precipitates from eating the filter membranes, an anti-scalene dosage is used by adding sodium hexametaphosphates. After that, acids like hydrochloric acid HCL are added to the water to remove carbon dioxide.

c. The pH correction dosage (Neutralization):

To adjust pH levels back to neutrality the chlorine that was added during the chlorination process is additionally removed by adding sodium metabisulfite SMBS as a dechlorinating agent and NaOH to raise the PH.

I.7.2.3. Cartridge filters:

It is based on removing sediment and particles from the water supply. Since it can increase in concentration in all water sources and leave debris in the water.

I.7.2.4. Water softeners (Removal of metals):

Called Chemical precipitation it involves adding chemicals to water to form insoluble precipitates with metal ions, which can then be filtered out, designed to remove ions that are positively charged. Mainly calcium (Ca2+), iron (Fe3+) and magnesium (Mg2+).

After the water is suitably pre-treated with a PH between 6.5 and 8.5, a lower conductivity indicating fewer dissolved ions and impurities, Particle Removal (larger than 10 micrometers) and reduced Turbidity Less than 1 NTU (Nephelometric Turbidity Units) indicating clarity. The Different purified water generation systems in the pharmaceutical industry are undertaken for further purification.

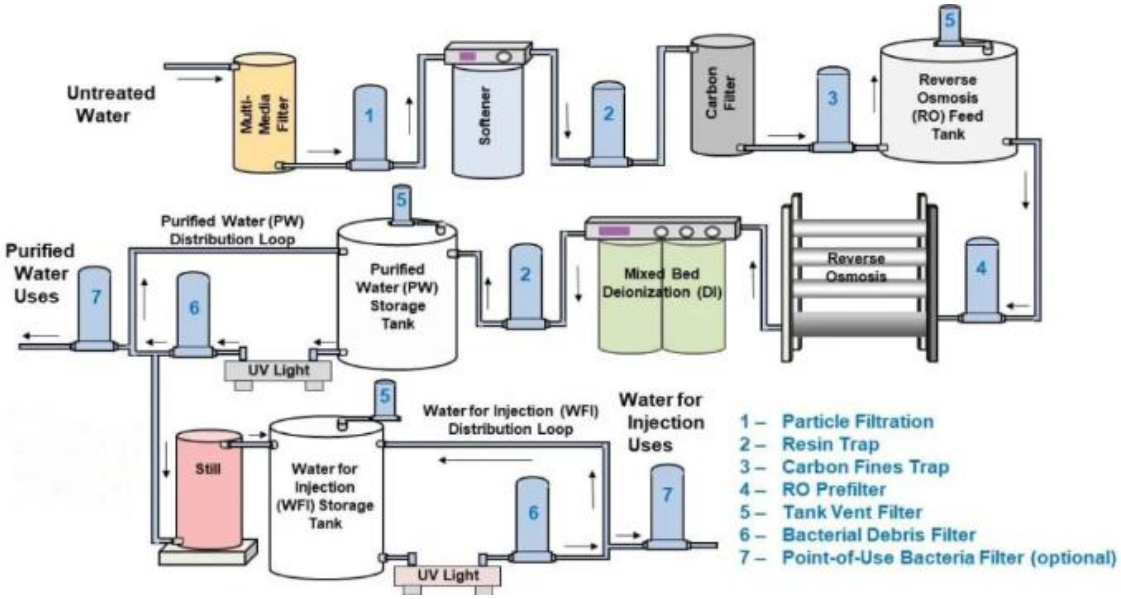


Figure 1.4: levels of water purification process.

I.7.3. Water Purification:

I.7.3.1. Reverse Osmosis (RO):

A high-pressure pump is installed to force the water to flow through a semi-permeable membrane which traps the microorganisms in the water and lets the ‘clean’ water flow by interrupting the water’s normal osmotic flow, these membranes have incredibly small pores that allow water to pass through while trapping particles, removing dissolved salts, minerals, and organic compounds, producing water with reduced conductivity and total dissolved solids (TDS).

I.7.3.2. Ultrafiltration (UF) or Nano-filtration (NF) :

UF and NF are membrane filtration processes that can remove particulates, bacteria, and macromolecules from water. Often used as additional barriers to ensure the removal of any remaining contaminants before the water is used in pharmaceutical manufacturing**.**

I.7.3.3. Electro-deionization (EDI):

EDI major goal is to get rid of dissolved particles such as salts, minerals, and organic contaminants from the water. It involves a DC current directing ion toward electrodes with opposite charges, this ion exchange resin then induces the water splitting and draws the ions into concentrating chambers. The water then splits from H2O into H+ and OH- to regenerate the resin again and again.

I.7.3.4. Ultra-violet Disinfection:

The UV radiation of particular wavelengths using a UV lamp in used in this procedure to inactivate pathogens such as bacteria, viruses, algae, molds, etc.

I.7.3.5. Common uses for purified water generation systems:

- Making pill-form and non-injectable drugs: used in the preparation of medications that are administered orally and absorbed in the human system, including topical ointments, and products administered through the ear, eye and nose.
- Pretreatment for water use: used as feed water in the preparation of WFI and pure steam.
- Cleaning laboratory equipment: Purified water is the best solution for washing process equipment for non-parenteral product preparation and other product-contact containers.
-

I.7.4. Water for Injection (WFI):

The purified water is made to pass through a heat exchanger, which transforms it into a gaseous state to then help it to get to the next separator. After the water passes through a setup that uses centrifugal force to trap the suspended particles resulting in sterile steam. That will go through the heating process again, it finally moves to the condensation process.

In the condenser, the steam is returned to its liquid state, tested for bacterial endotoxins and other pyrogens, and finally stored in tanks.

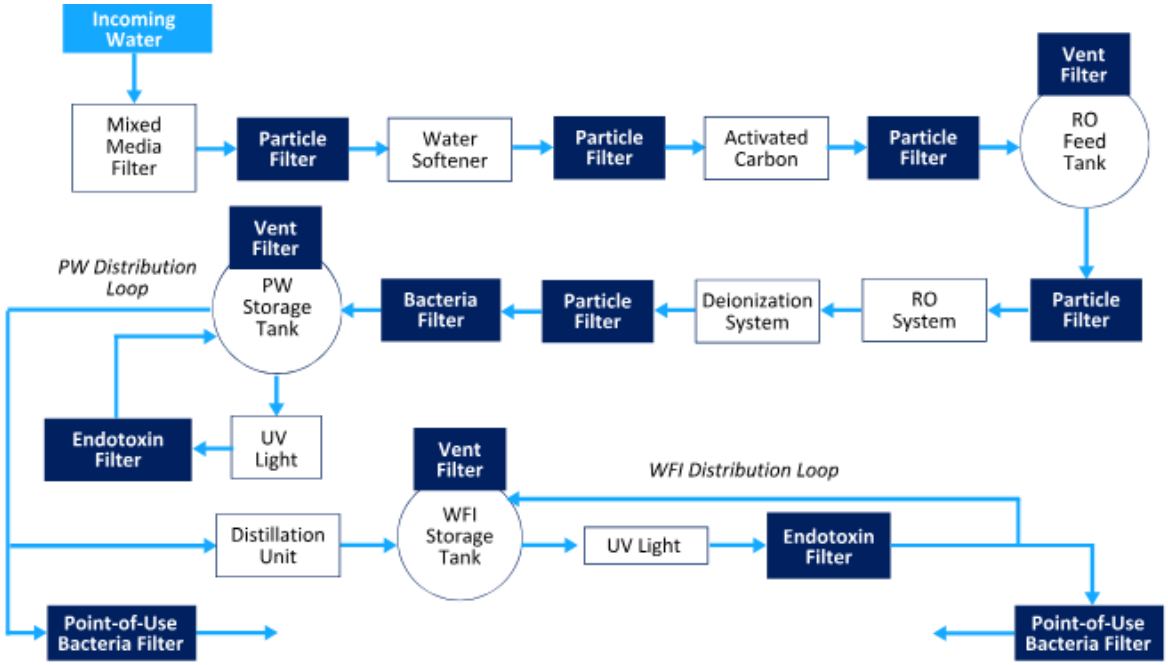


Figure 1.5: purified water /Water for injection system design.

I.7.4.1. Distillation:

Distillation makes use of the volatility (difference in vapor pressures) of the water and contaminants that are suspended in it, the water is boiled, and the vapors are condensed to obtain clean and sterile water.

I.7.4.2. Sterilization:

Once the water has been purified to the required quality, it undergoes final sterilization to ensure microbial control and eliminate any remaining microorganisms or endotoxins. Common sterilization methods include:

a. Membrane Filtration:

The Water is passed through sterile filters with pore sizes small enough to retain bacteria and other microorganisms.

b. Heat Sterilization:

Subjected to heat treatment, such as autoclaving or pasteurization, to kill microorganisms and achieve sterilization.

I.7.4.3. Continuous Sanitization Processes:

Implemented to maintain microbial control throughout the system. It may involve the continuous injection of sanitizing agents or the use of online monitoring systems.

I.7.4.4. Biopharmaceutical manufactures uses of WFI:

- Making parenteral drugs: mainly used for drugs injected directly into the human system. That includes the veins, layers of the skin, muscles...
- Diluting medicinal products: The purification of this kind of water makes it a sterile diluent for parenteral drugs.
- Cleaning laboratory equipment: necessary for maintaining sterile equipment and preserving the quality of products.
- Filtering the blood in hemofiltration: WFI is also used in the removal of waste products in the blood and the injection of sterile replacement fluids.

While there are certain minor differences in different pharmacopeia that are followed globally, WFI is usually checked for like, temperature (20°), Appearance (clear), Conductivity (1.1 Us/cm), and Heavy Metal (0.1 ppm).

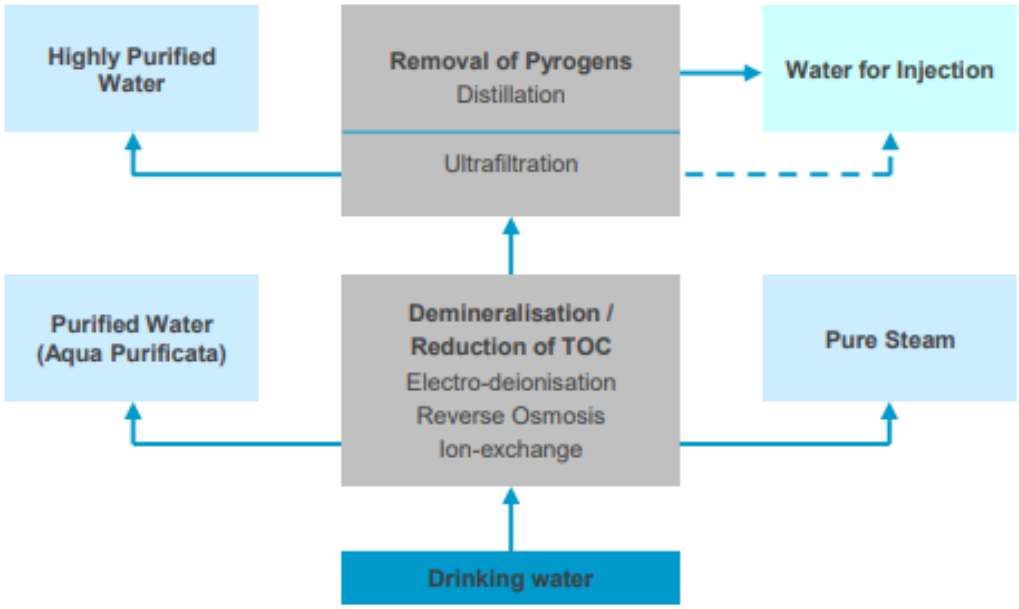


Figure 1.6: processed purified water design.

I.7.5. Pure Steam Generator:

Pure steam generator systems use a forced flow, to convert the incoming purified water to steam. During the single pass through the water coil, the heat from the hot gases is transferred to the water to convert it to steam.

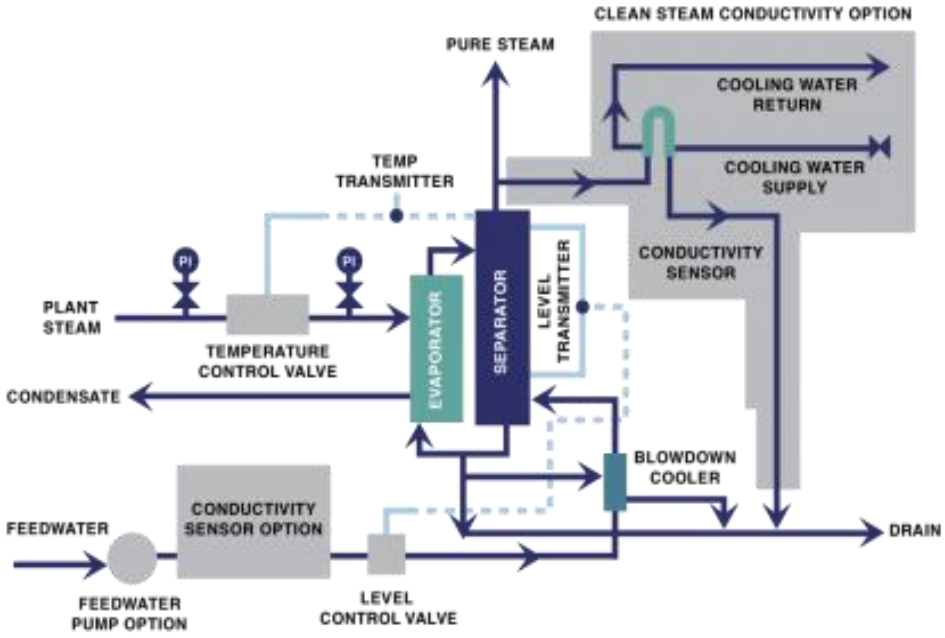


Figure 1.7: pure steam generator process.

I.7.5.1. Sterilization:

Pure steam ensures the sterility of equipment surfaces, or parenteral solutions, and the manufacture of sterile solutions such as ophthalmic products.

I.7.5.2. Heat Transfer:

Steam is the most powerful and effective thermal energy transfer fluid. A steam pipe can transfer approximately four times the amount of thermal energy as an electrical cable with an equivalent diameter.

I.7.5.3. Prevention of Contamination:

Used to prevent the contamination of process vessels, piping networks, and other sterile ecosystems.

I.7.5.4. Cleaning and Humidification:

Used to clean and sterilize specific items. It is also used for the humidification of clean rooms where drug processing occurs like operation rooms...

I.7.5.5. Heating Prior to Clean-in-Place (CIP) Operations:

It may be injected into high purity water for heating prior to Clean-in-Place operations.

I.7.6. Storage and Distribution:

The purified water is stored in stainless steel or other suitable tanks equipped with ultraviolet (UV) sterilization to maintain its microbial quality during storage.

Throughout the purification process, critical parameters such as conductivity, pH, and endotoxin levels are monitored and controlled to ensure the water meets the required quality standards for pharmaceutical applications.

I.8. Validation and Qualification Steps:

Validating a water system in the pharmaceutical industry involves a system qualification Procedure, identified as a series of systematic steps to ensure that the system consistently produces water that meets the quality standards for its intended use.

I.8.1. Installation Qualification (IQ):

Verifies that the system is installed correctly such as the installation of components (filters, piping, valves, sensors...).

I.8.2. Operational Qualification (OQ):

Perform testing to ensure that the system meets specified performance criteria repeatedly and reliably (flow rates, pressure, temperature).

I.8.3. Performance Qualification (PQ):

Conduct testing over a defined period under simulated or operating conditions, and document key parameters such as conductivity, TOC (total organic carbon), microbial content, pH, and temperature.

The purpose of this qualification protocol documentation package is to identify the minimum acceptance requirements to assure the complete and proper specification, design and acceptance of this system.

I.9. Conclusion:

We can conclude that the water purification system process is high quality and very critical, made to ensure the efficacy of pharmaceutical products, following different regularity standards to uphold.

Many validation steps need to be checked and approved for this series of operations to be qualified as a functional manufacturing environment, from the staff to raw materials to

packaging. After the procedure conditions being approved the water purification steps are to be held, starting by the pretreatment of the water removing large particles and impurities using sand filters as its name suggests and chlorination to regulate the water pH, to water purification with smaller particles like bacteria and total dissolved solids (TDS). Using Reverse Osmosis (RO) trapping the microorganisms in the water, Electro-deionization (EDI) to get rid of dissolved particles and organic contaminants, and Ultra-violet Disinfection to inactivate viruses and bacteria.

The third operation is called water for injection (WFI), where the water is more thoroughly checked, distilled and sterilized to eliminate any remaining microorganisms. Taken to the fourth level, the pure steam generator converting the purified water into steam.

CHAPTER II

Functional analysis of the water treatment system

I.

II.

II.1. Introduction:

Purifying potable water sufficiently for use in the pharmaceutical industry usually requires a series of purification stages. The overall objective is to remove the impurities in the feed water while minimizing additional contamination from the components of the purification system and bacterial growth.

Based on very sensitive materials and with a high technology to ensure good quality demanding on pharmaceutical uses. In this chapter we will present the deferential materials and methods of production of suitable water for pharmaceutical production.

II.2. General information on water treatment and process:

II.2.1. Energy supply:

After the water has been pretreated with the right chemicals and filtration units and thus accepted for further treatment. It then reaches a feed tank accompanied with (Temperature transmitter, level sensor, an actuated valve) where it would pass a strainer leading the water to the first pump ROFP (RO Feed Pump) ≃ 25.6 bar pushing the liquid into its way, passing by a no return valve and a flow transmitter, where it goes through a ball valve, passing into a pressure gauge for the pressure to be measured and displayed.

Figure 2.1: Water storage tank.

II.2.2. Heat exchanger:

The water has to be at a certain temperature (between 20 and 23°C), before passing to the next procedure that's where we find the heat exchanger, in point of letting the cool either- or hot water as needed inside the water tube, If the temperature needed is met the loop will continue, and an actuated valve will open if not the water returns once again inside the exchanger for a second treatment.

Figure 2.2: Heat exchanger.

When the treatment ends the cooled and heated water will eventually leave, sending the heated steam to a condenser to be recycled as water again. As the water reaches $(20 - 23°C)$, it goes straight to the pH treatment.

II.2.3. PH Treatment and dosing pumps:

The pH value of water may need to be adjusted during treatment, to ensure that the pH value meets the water quality standards.

As the water keeps its course ,it passes by a pH sensor ,where it meets a 3 different way pumps tubes ,coming from 3 different chemicals referred to as a multiple dosing system to

neutralize the pH level from usually a higher pH 11-8 to a lower level of 7-5 (NaOH to raise it in case , SMBS for dechlorinating and Antiscalants like Calcium Sulphate ($CaSO_4$) and Barium Sulphate ($BaSO_4$) as a method of adding acid to the feed water and lowering its pH, dissolving scale-forming salts and preventing scale on the membrane surface).

Next to the dosing line, a sampling point is located, to confirm once more the pH level. This second pH sensor will determine if the water passes through or be sent to drain by a flow diverting valve if not neutralized.

Figure 2.3: pH chemical dosing pumps treatment.

The water then falls through a low-level pressure sensor, for the pressure to be monitored once again, meeting the second pump ROHP1, followed directly by a high-level pressure switch, facing afterwards a two-level membrane set.

The first level contains two membranes, the first membrane is responsible for the reverse osmosis (RO).

II.2.4. Reverse osmosis:

Reverse osmosis involves the passage of water through a semipermeable membrane that blocks contaminants but allows water molecules to pass through.

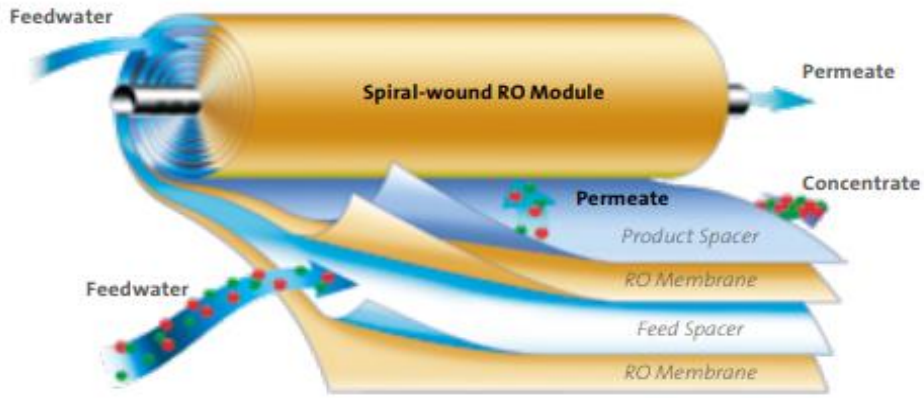


Figure 2.4: reverse osmosis membrane schematic of operation.

II.2.5. Membrane processes:

The membrane processes are significant in water treatment reverse osmosis, ultrafiltration, and microfiltration and Nano filtration.

The Membrane Types is Thin-film and composite membranes, the acceptable type of flow would go straight to the second level for the process to continue, the not approved water contrarily would go to the first level's second membrane to repeat the process once more.

RO membranes are used to remove contaminants that are less than 1 nm nominal diameter. Approximately removing 90% to 99% of ionic, organic and particulate contamination, from water. Their characteristics are illustrated in the Figure (2.5) below.

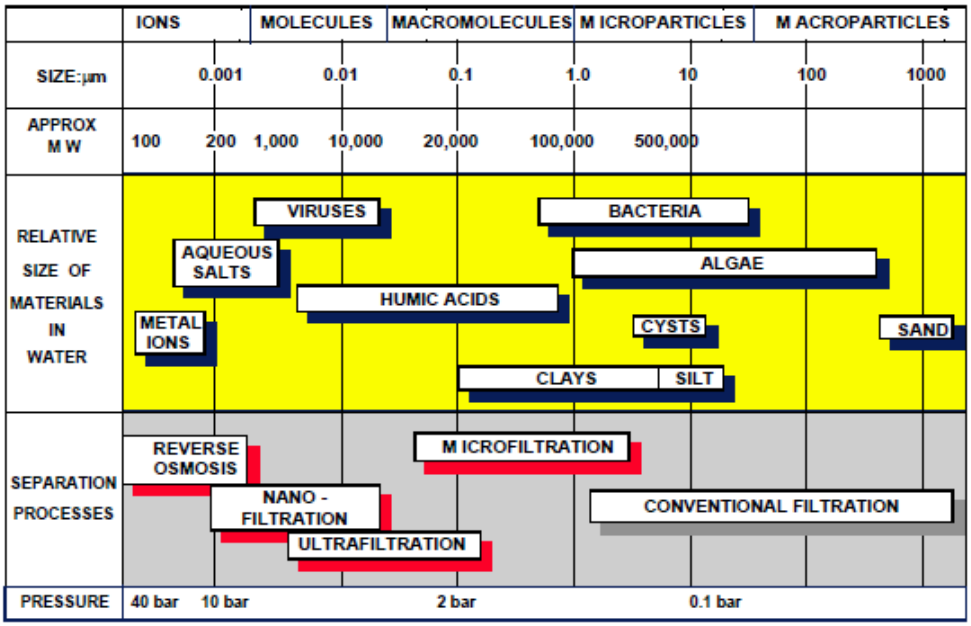


Figure 2.5: Characteristics of membrane processes.

The water then is checked for its conductivity and ORP levels, and passes through a second three-way valve, if the conductivity level is higher than 50 µs/cm the water is sent straight to drain, if it's between 50-5 µs/cm the process continues.

II.2.6. ORP Sensor:

On the side, the Oxidation Reduction Potential (ORP) steps as a dynamic indicator of system activity. Measuring the potential for oxidation and reduction reactions, as a crucial metric, usually between 60-195 mv offering insights into the activity of oxidizers within the system in the RO environment.

Up to 10-25 bar are then generated by the third and final pump ROHP2, once again tied to a low-level pressure switch a step before the activation, and a high-level switch after it, to lastly send the water into the second level membrane (ultrafiltration).

II.2.7. Ultrafiltration and conductivity:

On the second level of the membranes the ultrafiltration starts (UF). Similar to RO but uses slightly larger pores that can remove particles to 0.1-micron range, including some viruses and large molecules, the pressure is typically high, used as a post-RO step to enhance purity by removing endotoxins and other biological contaminants.

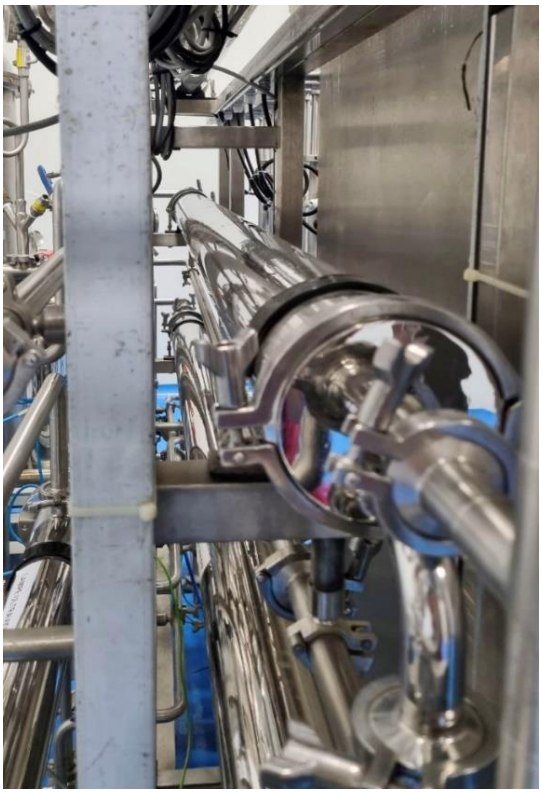


Figure 2.6: two level membranes.

II.2.8. Electrode ionization (EDI):

After being checked by a flow transmitter, the process reaches the step before last Electrode ionization (EDI), it combines semi-permeable membrane technology with ion-exchange media to remove ionized species from water, and to polish demineralized water. Typically, EDI product water has a conductivity of 0.5 to 10 µs-cm (at 20°C) and a total organic carbon content below 20 ppb. Bacterial levels are minimized because the electrical conditions within the system inhibit the growth of microorganisms.

Like any other step of the process the water is either send back to the feed tank to repeat the cycle once more or move on to the next step, the UV radiation.

Figure 2.7: EDI module.

II.2.9. Ultraviolet (UV) Irradiation:

To finally be passed to the last step Ultraviolet (UV) Irradiation. It is used to kill and deactivate bacteria and other microorganisms through damage to nucleic acids typically at 254nm, also Used for disinfection and to reduce TOC (Total Organic Carbon). The UV breaks large organic molecules into smaller ionized components, which can then be removed by downstream leading to another 3 ways valve with a final conductivity check then into a storage tank, or return to the previous feed tank.

Figure 2.8: Ultraviolet lamp tube.

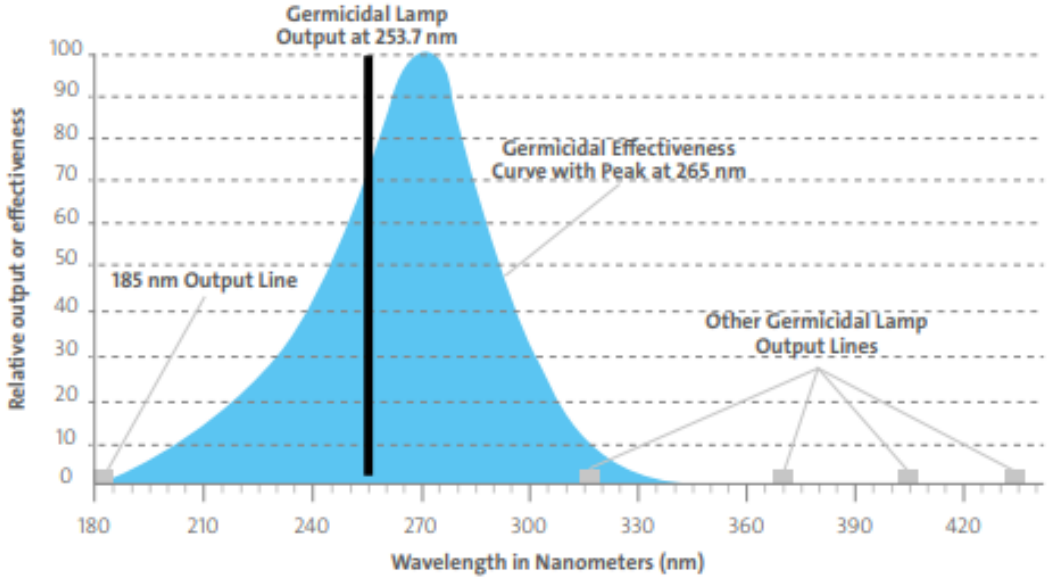


Figure 2.9: Germicidal lamp output verses effectiveness.

The selection of water purification technologies is typically based on the quality requirements of the end product, cost considerations, and operational efficiencies. The combination of multiple technologies in a water purification system helps ensure compliance with stringent requirements, ensuring that the produced water is safe for its intended use in pharmaceutical formulations.

All of this process can be summarized in the next diagram (2.10).

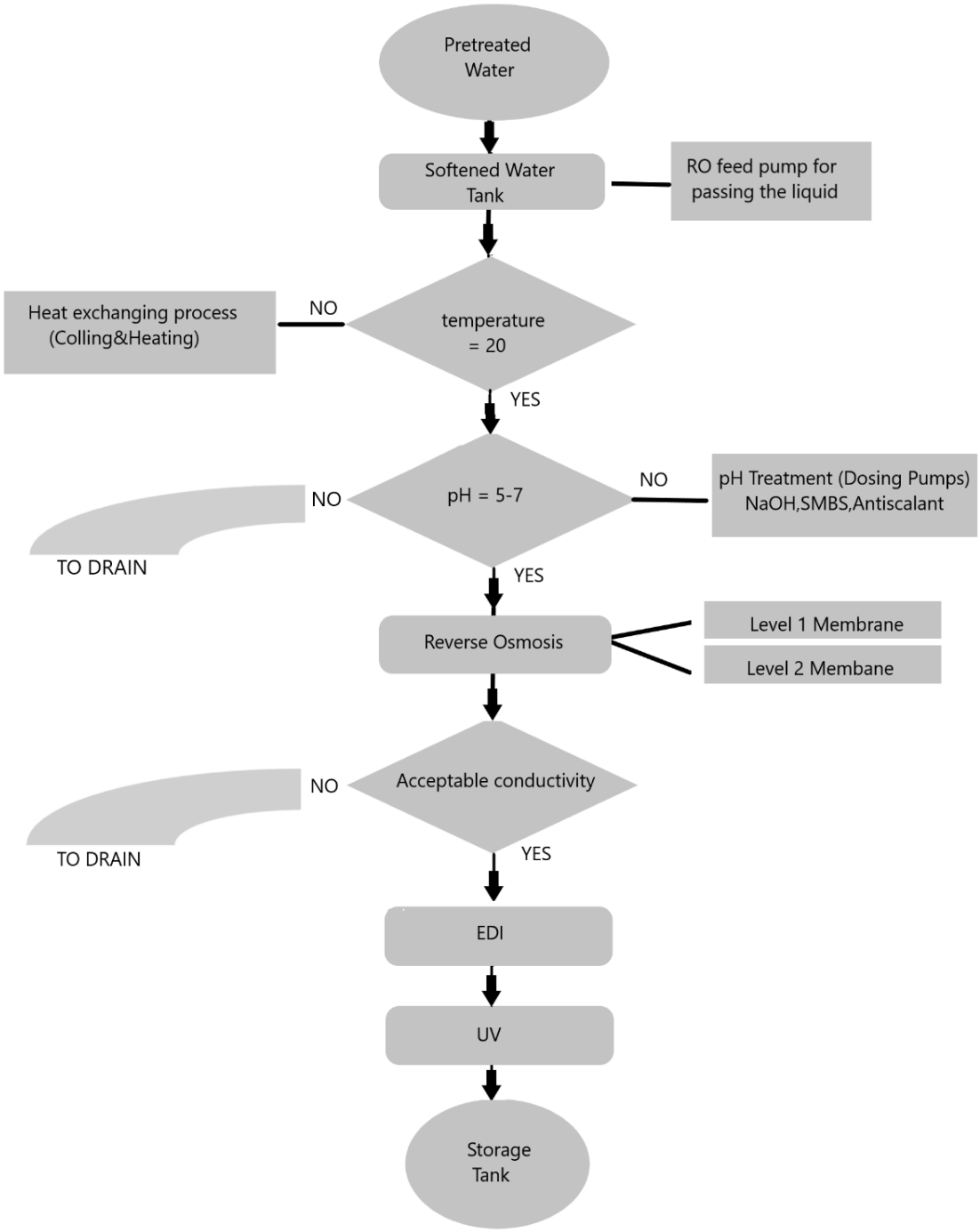


Figure 2.10: Water purification brief process diagram.

Remark: inside the Reverse osmosis process:

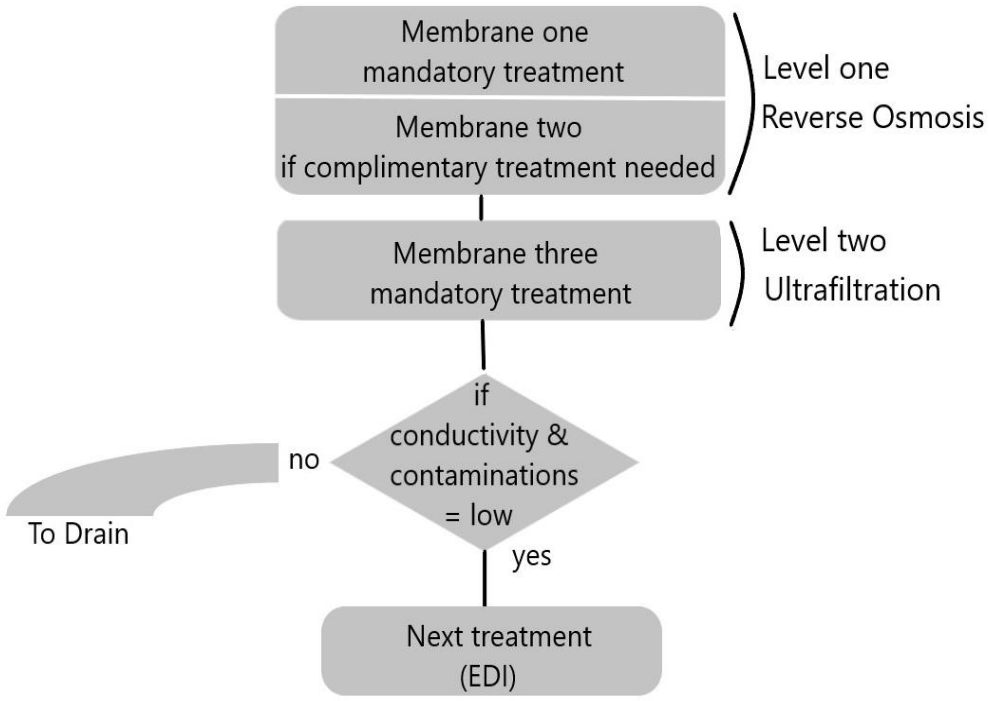


Figure 2.11 : Membrane filtration diagram.

II.3. Good design system:

We can find several design and control strategies in water generation systems to minimize microbiological risks in pharmaceutical production. These include using:

a) Continuous Water Movement: Water should flow continuously, ideally between 1–2 meters per second, to prevent biofilm formation and microbial adherence.

b) Avoid Stagnation: Design systems to minimize dead legs and use hygienic valves at points of use, while ensuring proper drainage.

c) High-Temperature Control: Maintain water temperatures above 20°C to control biofilms, with provisions for cooling at points of use.

II.4. The automatic system:

II.4.1. Definition and Structure of Automated Systems:

An automated system is a device capable of taking into account signals and consequently producing predefined actions autonomously.

The goals of the system are to perform complex or dangerous tasks for humans, perform repetitive tasks and gain in efficiency and precision.Composed of two parts:

- **Command part:**

The control part ,It is able to process the information it receives from humans and give orders through a plc to the operative party,with a digital or analog signal .

- **Operative part:**

The operative part executes the orders of the command part (work, action) by producing a physical phenomenon,with the help of sensors and actuators .

II.5. Programmable logic controller:

An industrial programmable logic controller is an electronic device programmable by Personnel. It is intended to control processes in industrial environments and in real time or Operational parties. It allows to process incoming information to issue orders of Output based on a program.

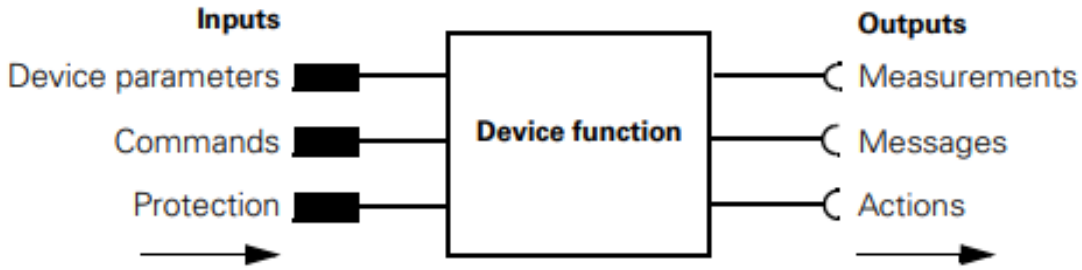


Figure 2.12: inputs /outputs of a programmable logic controller.

II.5.1. Why the water purification system works with SIMATIC ET 200SP:

Working with ET 200SP has its own advantages and functions that go well with water purification system, mostly main features like Remote I/O stations, that can be easily integrated into various industrial automation applications, with IP20 degree of protection, and can be networked via PROFINET IO and PROFIBUS DP. Here's how it could be utilized:

1) **Remote I/O and Modularity:**

Up to 64 modules, it allows for distributed I/O, meaning you can place input and output modules close to the process they are controlling or monitoring, this could mean placing and modifying sensors directly in the water tanks or pipelines to monitor parameters like pH levels, turbidity, or flow rates.

2) **Integration with PLC**:

The ET 200SP can be seamlessly integrated with a programmable logic controller (PLC) such as Simatic S7-1200 and S7-300. This allows for centralized control of the entire water purification process, from filtering to disinfection.

3) **Reliability**:

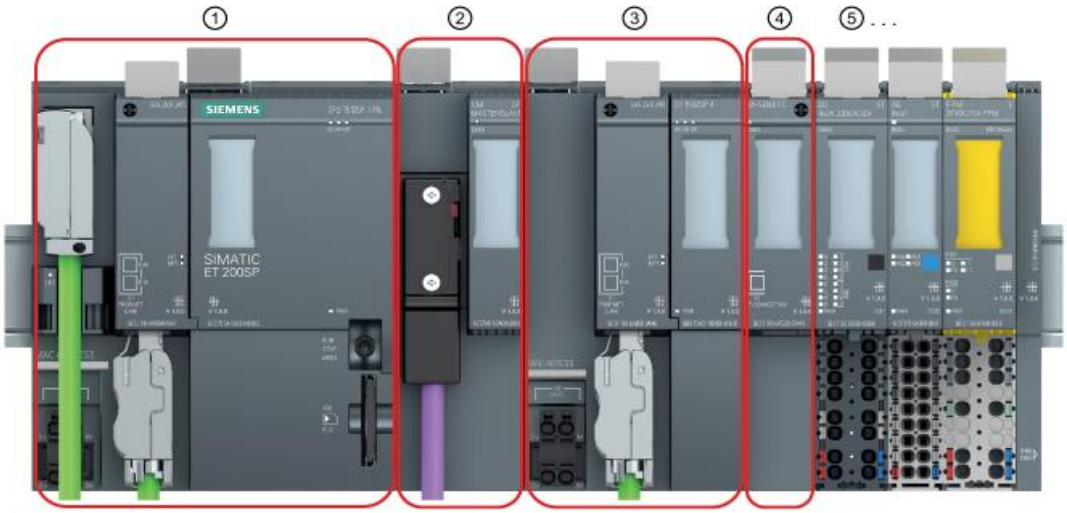
Designed to withstand harsh conditions, making it suitable for use in water treatment plants where there may be exposure to moisture, chemicals, or varying temperatures.

4) **Diagnostic Features**:

Offering diagnostic features that allow for quick identification of faults or errors in the system, is crucial for maintaining uptime in a water purification system where any downtime could affect water quality or production schedules.

Overall, using Simatic ET 200SP into a water purification system can enhance control, monitoring, and reliability, ultimately contributing to the efficiency and effectiveness of the purification process.

In addition to its features that allow to have a flexible control. It also provides multiple communication options, including a web server and S7 (s7-1200) that will be used for the programming part with ease. Remembering that selecting the right PLC involves a balance between functionality, reliability, and cost.



- Slot1 only permitted for the CPU.
- Slot2 for CM/CP/Bus adapter send.
- Slot3 for CM/CP bus adapter send.
- Slot4 for CM/CP bus adapter send.
- Slot5 ff for IO modules.

Figure 2.13: Slots of a programmable logic controller.

II.6. Actuators in the water purification system:

II.6.1. Actuator:

An actuator is a device capable of producing a physical action such as displacement, heat release, light emission or sound from the energy it receives, converting one energy into another. While transforming the information received from the computer program into actions.

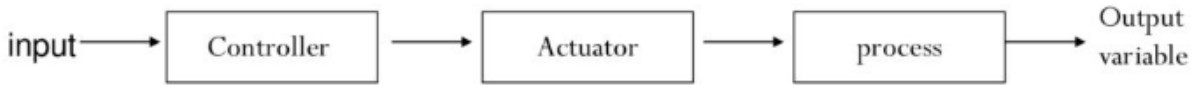


Figure 2.14: Open loop control system.

II.6.2. Types of actuators and security criteria if needed:

At the station level, there are several types of actuators depending on the use. It is composed of motors, pumps and valves.

II.6.2.1. The engines:

Industrial manufacturing uses a wide variety of machines powered by energy. However, electrical energy is predominant because, for reasons Most of the mechanical devices used in industry are drive by electric motors.

1) Siemens Inverter Drive

The SINAMICS V20 is a compact and cost-effective frequency converter (also known as an inverter drive) manufactured by Siemens.

Designed for simple motion sequences in various applications. With Short Commissioning Times, easy handling, user-friendly interface and helps optimize energy consumption, covering a power range from 0.12 kW to 30 kW.

Figure 2.15: Siemens Inverter Drive installer SINAMICS V20 Series.

II.6.2.2. The valves:

Like any actuator it acts on a magnitude that will always be for a two-way valve, the regulated quantity will be pressure, flow rate, level, temperature, a concentration ratio. Usually its work principle can be described in the following figure (2.16).

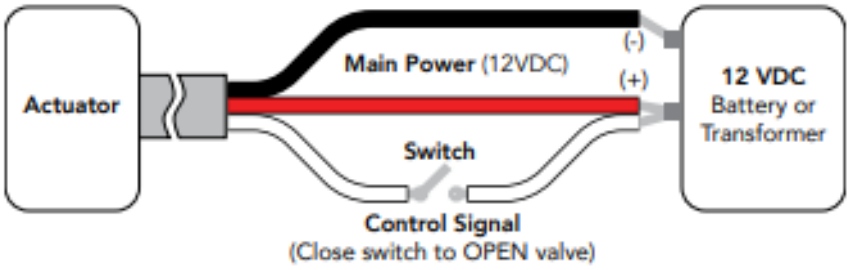


Figure 2.16: working principle of a valve.

1) Ball valve:

A ball valve is a rotational motion valve that controls the flow of a liquid by rotating. When the ball is rotated (90 degrees) around its axis, it either allows the medium to flow through or blocks it completely.

Figure 2.17: Ball valve.

2) Angled body valves:

Like standard angle valves, automated angled body valves have an L-shaped design with an inlet and an outlet oriented at a 90° angle to each other. It is also equipped with a pneumatic actuator, allowing for remote control and automation.

❖ They can divert flow, shut off specific lines, or direct fluid to different treatment stage.

Figure 2.18: Angled body valve.

3) 3-Way seat valve:

The three-way valve or The Flo-Diversion Valve, is a pneumatic seat valves used to shut off or change product flow by controlling its direction. It is positioned in the product stream at the discharge of the holding tube and will not forward the product until the system conditions are met.

Figure 2.19: 3-Way seat valve.

4) Water strainers:

Water strainers protect water, valves and other sensitive components from dirt, rust, and other damaging debris, by filtering the pipeline, and separating solids and larger particles from flow lines.

II.6.2.3. The pumps:

To discharge the different existing liquids, different pumps are used which are quoted the following types:

1) Feed pump of a RO System:

A feed pump is required to drive raw water through the system and on to the inlet of the high-pressure pump. The pump type and material are selected based on the type and source of water.

While the sizing is dependent on the water flow and pressure of the filtration system.

Figure 2.20: Feed pump of a RO System.

2) High Pressure Pumps (HP):

High Pressure Supply Pumps for Modules reverse osmosis are intended to send water under high pressure from filtered water pumps to the membrane, and from after the membranes to the rest of the system (EDI, UV…).

Figure 2.21: High pressure pump of a RO system.

In case one of the pumps gets electrically tripped the system will immediately shut it down, leading the flow to stop circulating.

3) Dosing pump:

The CC3 0407 PP pump is a type of electronic dosing pump, controlled electronically.

These pumps consume minimum power and it can be controlled automatically through pulse signals or 4-20 mA signal, with a capacity of 24 l/hr.

Designed to be maintenance-free, accurate, and consume a minimum amount of power. It's used in the system for water pH treatment, NaOH, Antiscalant, and SMBS dosing**.**

Figure 2.22: Electromagnetic dosing pump.

If one of the pumps chemicals is at a low level the pumping will stop, leading to the rest of the loop being cut, until it is filled again and the pH is balanced.

II.6.2.4. Other:

1) Heat exchanger (shell & Tube heat exchanger):

Figure 2.23: Exergy Shell & tube heat exchanger.

a) Operating Principles:

A heat exchanger is a device used to transfer heat from one process stream to another, without having the two streams mix. Typically made of stainless steel.

A hot liquid would be going through the shell (outer chamber), and the cold liquid would be passing through the inner chamber. With using steam as the heat source, and chilled water as the cooling source. As shown in the following figure (2.24).

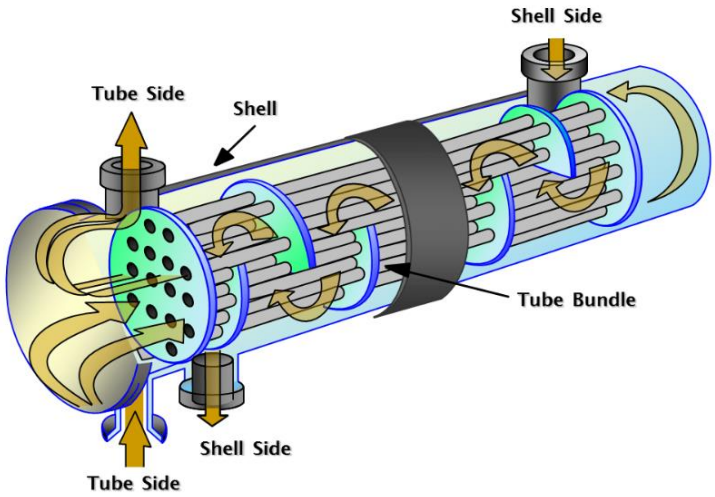


Figure 2.24: Description of Configuration Heat Exchanger Parts.

b) Cooling Mode:

When the cooling mode is turned on, it closes the recirculation valve (the pumping power builds up heat in the water as it circulates), and opens the cooling water valve.

❖ **Clean-In-Place (CIP):**

Heat exchangers deliver and maintain the water at a high temperature, for initial and final rinses.

❖ **To sanitize a distribution loop with hot water:**

Purified water distribution loop and storage tank must be sanitized to kill bacteria. With hot water at (80°C) minimum.

2) Reverse osmosis (RO) membranes:

Reverse osmosis (RO) membranes work by selectively allowing water molecules to pass through while blocking contaminants like salts, ions, and particles. This is achieved through a pressure-driven process that forces water through a semi-permeable small membrane.

Figure 2.25: Semi-permeable steel membrane.

If the membranes get clogged, or the flow is highly contaminated, the system will stop the reverse osmosis treatment, shutting the pump ROHP1, stopping the flow from going any further.

3) Electrode ionization (EDI):

While most traditional water purification technologies and equipment utilize chemicals to complete the ion exchange process. This water purification modules use resin, electricity and ion-exchange membranes to deionize water by separating the impurities from it.

Figure 2.26: Electro deionization EDI, Make-Ion Pure

If the conductivity rate or even the temperature (in case of sanitization) are higher than a given number the EDI unit will shut, while waiting a certain delay, if the numbers aren't fixed,

the last third of the system (third pump ROHP2) will decline sending any further flow into that line.

4) High intensity Ultra violet Unit:

These lamps emit UV-C light, within the wavelength range of 200nm to 280nm. The light is germicidal, meaning it effectively kills microorganisms such as bacteria and viruses.

Figure 2.27: High intensity Ultra violet Unit API Series by AlfaaUV.

If the conductivity or toc rate are higher than a given number the UV unit will shut, then following the same steps as the EDI unit alarm protocol.

II.7. Sensors and security protocol in water purification system:

II.7.1. Sensor:

A sensor is an element of the operative part that detects a physical phenomenon (temperature, sound, light, displacement, position) in its environment. Allows to collect information and transmit it to the control part.

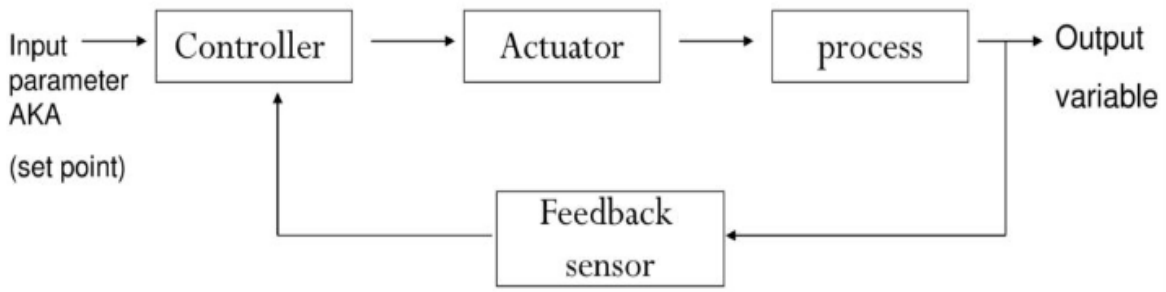


Figure 2.28: feedback control system.

II.7.2. Types of sensors and security criteria if needed:

II.7.2.1. Low level switch:

It's a device used to measure the level of a liquid, it detects whether the level has reached a specific point and activates an alarm or performs a control action.

Low level switches are commonly used in various applications like Tank Level Monitoring: Pump Control, Valve Actuation and Safety Alarms.

II.7.2.2. Flow transmitter:

A flow transmitter is an instrument designed for measuring the rate of fluid flow when it passes through a confined water transmission system.

Figure 2.29: Flow Transmitter H250 M40.

II.7.2.3. Level Switch:

It is sensor that detects the presence of liquids. The device would be usually mounted or floating on the media to be sensed at a specific location

Figure 2.30: Magnetic Float Guided Level Switch.

If the level is too high the tank is closed and no further liquid can reach. If it's too low on the other hand the system pumps will shut down, leading to the liquid flow to stop thus the loop ending.

II.7.2.4. PH Sensor:

It is a sensor that is used to detect the hydrogen ions concentration within the solution and changes it into an equivalent usable signal, to measure alkalinity & acidity within water.

Figure 2.31: Digital pH sensor CPS11D.

If the pH is outside the interval (usually too high pH>=12), the three-way valve is open letting the water drain for a certain delay, while the dosing pumps send the right amount of chemicals to balance this PH, all of that while the next in line pumps (ROHP1) are shut down.

II.7.2.5. Pressure switches:

A pressure switch is a device that controls an electrical contact when a preset fluid pressure is reached whether it's rising or falling from a certain pressure level. Adjustable with five different ranges (3 up to 2000 PSI).

Figure 2.32: Pressure switch.

When reading an acceptable pressure, the set point of the switches is open letting the pump pressure pass, if the pressure is too low, the low-level switch point is deactivated forcing the pump to generate a higher pressure, if it's too high then the high-level switch also deactivates and the pump shuts down temporarily.

II.7.2.6. Temperature transmitter:

A Temperature Transmitter is a device that converts the signal produced by a temperature sensor into a standard instrumentation signal. Followed with a temperature gauge for the reading of temperature gradient.

Figure 2.33: Wire PT100 Temperature Sensor Model 8060A.

II.7.2.7. Conductivity sensors:

The Model 400/400VP sensors is designed to measure electrolytic conductivity in various applications, from high purity water to clean cooling water. They are best suited for use in clean, non-corrosive liquids with conductivity less than about 20,000 µS/cm.

Figure 2.34: contacting conductivity sensors.

If the conductivity level is high the system will open the nearest drain flow diverter valve to get rid of the access unfiltered liquid and wait a certain delay until the conductivity level is neutralized.

II.7.2.8. Total Organic Carbon (TOC) Analyzer:

TOC analyzers measure the number of organic compounds contained in a water sample. That can either be dissolved in water or undissolved, suspended material, or liquid.

Figure 2.35: TOC Analyzer.

If the toc level is high the system will open the nearest drain flow diverter valve similar to the conductivity, also waiting for its level to be neutralized.

II.8. Identification of other station instruments:

1) No return valve:

A non-return valve, also known as a check valve, clack valve, one-way valve or retention valve, is a manual valve designed to allow fluid to flow in one direction only, therefore preventing the liquid or gas from flowing back upstream of the valve.

Figure 2.36: no return valve.

2) Sampling valve:

The sampling valve allows the operator to extract a sample of the product from the production line to safely be analyzed. This ensures that water of suitable quality is used for manufacturing or other designated purposes.

Figure 2.37: Sampling point.

3) Heated water condenser:

A condenser is an equipment that makes it possible to pass water from the gaseous state to the liquid state by condensation. A heat exchanger is very well suited to this function.

Figure 2.38: Stainless steel Water condenser.

4) Display:

Display screens are spread all over the system to display various rates, from flow to pressure to conductivity etc...

Figure 2.39: Rosemount Analytical Model 1056 Dual Input Analyzer.

II.

II.1.

II.2.

II.3.

II.4.

II.5.

II.6.

II.7.

II.8.

II.9. Our problematic:

We had the pleasure to work with a pretty neat, trouble free system. Made in the last few years, equipped with the latest actuators and sensors, yet it still lacks one important aspect to be installed, an accessible supervision gadget, an HMI (human machine interface).

There is only One HMI to be found, and it is not easily reachable, located in a distant central room in a higher level from the work stations.

Reaching this room, will take time and effort, leading the staff to leave their office, which is not very practical in case of an emergency.

II.9.1. The proposed solution:

In order to make the station a better work environment, we recommend a series of more attainable HMIS.

The first interface, is crucial, it would be placed on the electrical cabinet, making it possible for the engineer to monitor the system's characteristics and sensor's value directly on site.

Other workstation HMIS are still indispensable, the idea is to place a few distant HMI connection to a number of engineers in charge of the system production wellness. For them to be able to check any missed or changing details in the manufacturing process, while still being able to focus on multiple different tasks.

In the next chapter we will be presenting this interface and its different components.

II.10. Conclusion:

The automation of the water treatment plant improves operator safety, reduces physical effort, and significantly increases accuracy, with it being the most delicate part of the process, also insuring the alarm system functionality and reliability when needed. Over the entire speed of tasks, a description of the automated systems and functional analysis, the Grafcet of the installation, and program on the SIEMENS TIA portal software, as well as the supervision will be easy to achieve in the next chapter.

CHAPTER III

Programming and Supervision

I.

II.

III.

III.1. Introduction:

A PLC, is a very important aspect of initiating and managing a process as it serves as the brain of industrial automation systems. Meanwhile, the HMI (Human-Machine Interface) provides an intuitive visual interface of the said process for operators to monitor and interact with.

In this tightly integrated duo, the PLC handles the underlying logic, while the HMI ensures seamless outside communication between operators and the machinery. Bridging Logic and Control Whether it's managing a manufacturing line, water treatment plant, or an assembly process, mastering PLC and HMI programming is a must to create an efficient, reliable, and responsive systems.

In this chapter we will be showing our program for the water treatment system and its newly fabricated interface placed on site.

III.2. Automation objective:

Apart from financial objectives we have:

- Eliminate repetitive tasks.
- Simplifying the human work.
- Increase safety and productivity.
- Saving raw materials and energy.
- Adapt to specific contexts.
- Maintain quality.

III.3. Choice of an automaton:

Since we are working with a pretty modern system the ET 200SP is not enough to maintain a thorough control over every part of the production, thus the necessity for a second plc the S7 1215.

In principle the choice is made according to the specifications of the system such as the number of inputs/outputs and their nature (digital, analog). The nature and time of the processing. Communication with other systems. Reliability and robustness etc...

III.3.1. Why we chose SIMATIC S7-1215 DC/DC/DC?

SIMATIC S7-1215 is our automation solution for the requirements of the system. Very effortless to install and extremely user-friendly, due to its reliability and safety and easy setup. And since it's already connected to the ET 200SP, allowing a centered and more profound control.

Citing few of these factors to explain why we chose the SIMATIC S7-1215:

- A comprehensive range of modules for optimum adaptation to the task.
- Flexible use through simple implementation of distributed structures.
- Can be expanded without problems when the tasks increase.
- Powerful thanks to a range of integrated functions.

III.3.1.1. Environmental Requirements:

The operating environment: not very harsh conditions but withstanding temperature variations, humidity, and dust, are important on site.

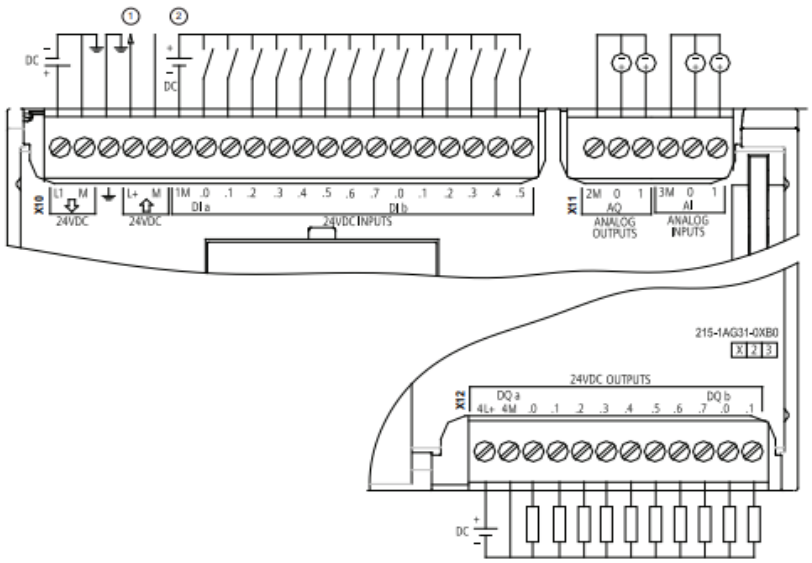
Figure 3.1: Water purification system electrical cabinet.

III.3.1.2. Power supplies PS and Installation:

The S7-1215 uses primary-clocked power supplies from 20.4 to 28.8 VDCV DC, with an input current of 500Ma.

The power supply is stabilized, and the output of the device is isolated, no-load proof, and short-circuit proof. Extremely flat in design, making it suitable for installation in control cabinets with a depth of 130 mm and a 100mm height.

Table A- 79 CPU 1215C DC/DC/DC (6ES7 215-1AG31-0XB0)



1- 24V DC Sensors input.

2- For sinking inputs.

Figure 3.2: CPU 1215C power diagram.

III.3.1.3. Inputs and Outputs (I/Os):

The S7-1215 supports a wide range of digital and analog I/O modules, allowing users to interface with various sensors, actuators, and other devices in the control system.

These modules can be easily added or removed to adapt to changing requirements. It has:

- an interface module, which communicates with all of the controllers.

- 14 integrated digital inputs and 10 integrated digital outputs up to 32 modules with the integrated analog I/O.

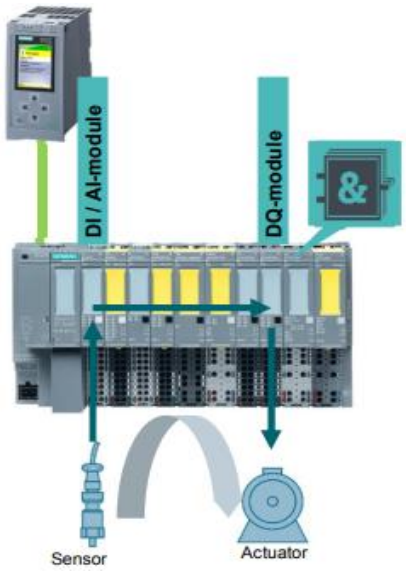


Figure 3.3: input/output modules of a PLC.

III.3.1.4. CPU and Speed:

The CPU 315-2pn/dp is the brain of the S7-1215 system. It processes the data from the I/O modules and executes the control program.

The processor achieves an execution time of approximately 0.08 µs for bit operations, With a 125 KB RAM.

Capable of executing complex control tasks efficiently and offers sufficient space for user programs, combining compactness and flexibility. A perfect solution for standard applications.

III.3.1.5. Communication Protocol Types:

This CPU communicates via PROFINET PG/OP communication based on Ethernet TCP/IP. Plus, an extra Isochronous Real-Time (IRT), a protocol to exchange data between controllers and devices in less than 1 µs. Ensuring significantly greater performance than any other conventional system.

It is also compatible with PROFIBUS Multi point interface, using the protocol (RS485/232). Letting it communicate with other devices, such as HMIs (Human-Machine Interfaces), SCADA (Supervisory Control and Data Acquisition) systems, and other PLCs.

Remark:

- The PG Connection is made for loading PLC Blocks of going online.
- An OP Connection is made for communication issues like HMI Communication.

III.3.1.6. Programming:

Programming of the CPU 1215 is typically done using Siemens' TIA PORTAL software. This software provides a comprehensive development environment for creating, testing, and debugging control programs.

All these criteria led us to choose “SIMATIC S7-1215”, given the availability of this product at the laboratory level, and the training on its software programming (Tia portal V17).

III.4. PLC Programming

Programming a PLC is an incredibly important aspect of any position in industrial automation. To program the PLC, we can use:

- A programming console with the advantage of portability.
- A PC with which programming is more user-friendly, communicating with the PLC by an RS232 serial link or field network, following the next steps:

Step 1: Finding a Wiring Diagram and wiring. ...
Step 2: Install Programs. ...
Step 3: Networking. ...
Step 4: Programming. ...
Step 5: Wiring Outputs. ...

III.4.1. The Totally Integrated Automation Portal (TIA Portal):

Developed by Siemens, TIA provides unrestricted access to a comprehensive range of digitalized automation services, it seamlessly connects digital planning, integrated engineering, and transparent operation for your installations. Components Included:

1) **Tia portal main programming tool:** This software allows you to configure, program, test, and diagnose Basic, Advanced, and Distributed Controllers.
2) **PLCSIM Flexible:** Used for creating Human-Machine Interfaces (HMIs) to visualize and control industrial processes.

III.4.2. PLC Programming languages used in the system:

Each automaton has its own language. But on the other hand, the manufacturers offer all a software interface that defines five usable programming languages, which are block diagram (BD), Relay scheme (LADDER), Structured Text (ST), GRAFCET (SFC), Instruction list (IL), but we are only using two of them:

- **GRAFCET (SFC):**

Sequential Function Charts or Grafcet provides a visual representation of how an automation system operates. It consists of steps, transitions, and directed links connecting them.

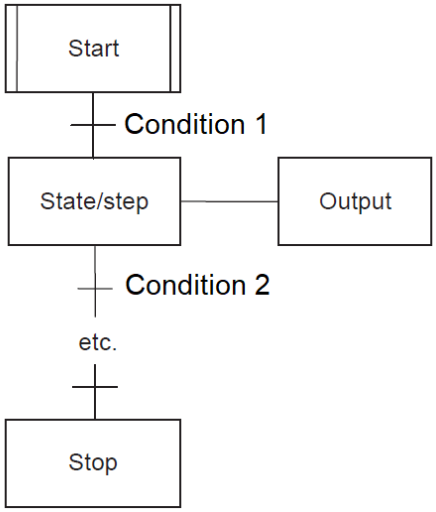


Figure 3.4: GRAFCET basic example.

- **Grafcet and software AUTOMGEN 7.1:**

AUTOMGEN is a tool for algorithm control, design and simulation, and PLC programming. It is especially suited for developing controllers using GRAFCET.

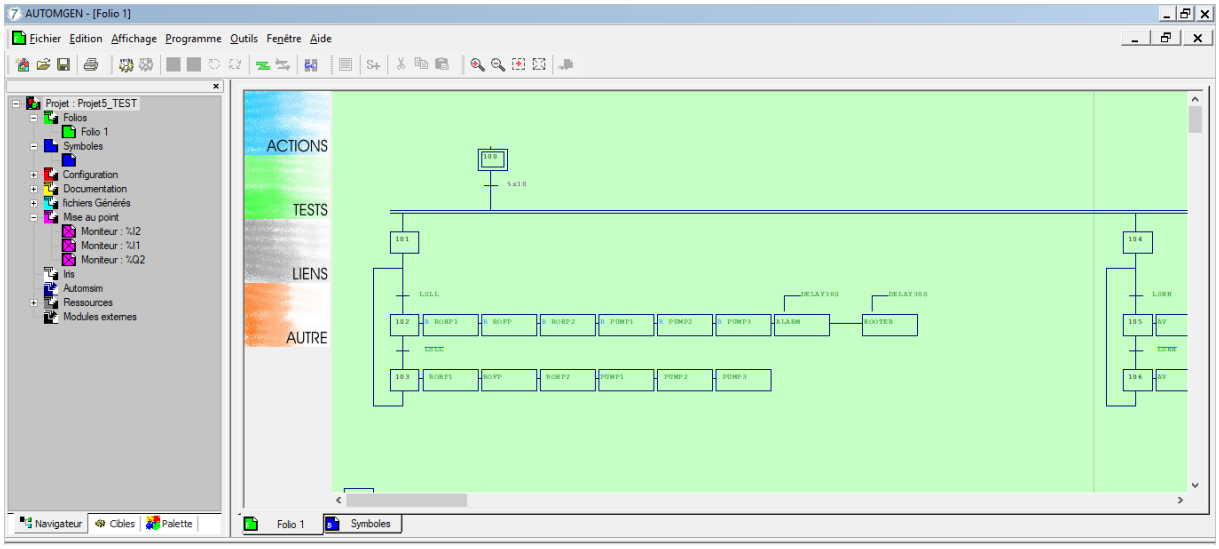


Figure 3.5: AUTOMGEN's main execution page.

- **Relay scheme (LADDER):**

the term "Ladder" comes from its visual similarity to electrical ladder diagrams. Originally, this Logic represented logical functions using physical wiring. Since Before PLCs existed, functions were achieved through manual wiring.

III.4.3. Creating the program:

A program can consist of one or several blocks. These blocks include all functions that are necessary for processing specific automation tasks. Based on I/O identification there are:

- 18 Analogue Inputs (AI).
- 33 Digital Inputs (DI).
- 22 Digital Outputs (DO).

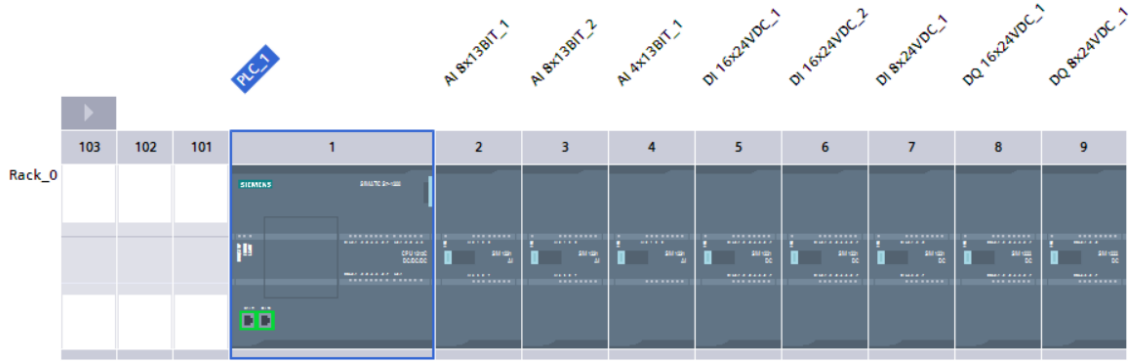


Figure 3.6: device and networks.

III.4.4. Creating the variable table:

Before any program we must define the list of variables that will be used during the programming. We edit the table of variables according to our specifications, for the inputs and outputs.

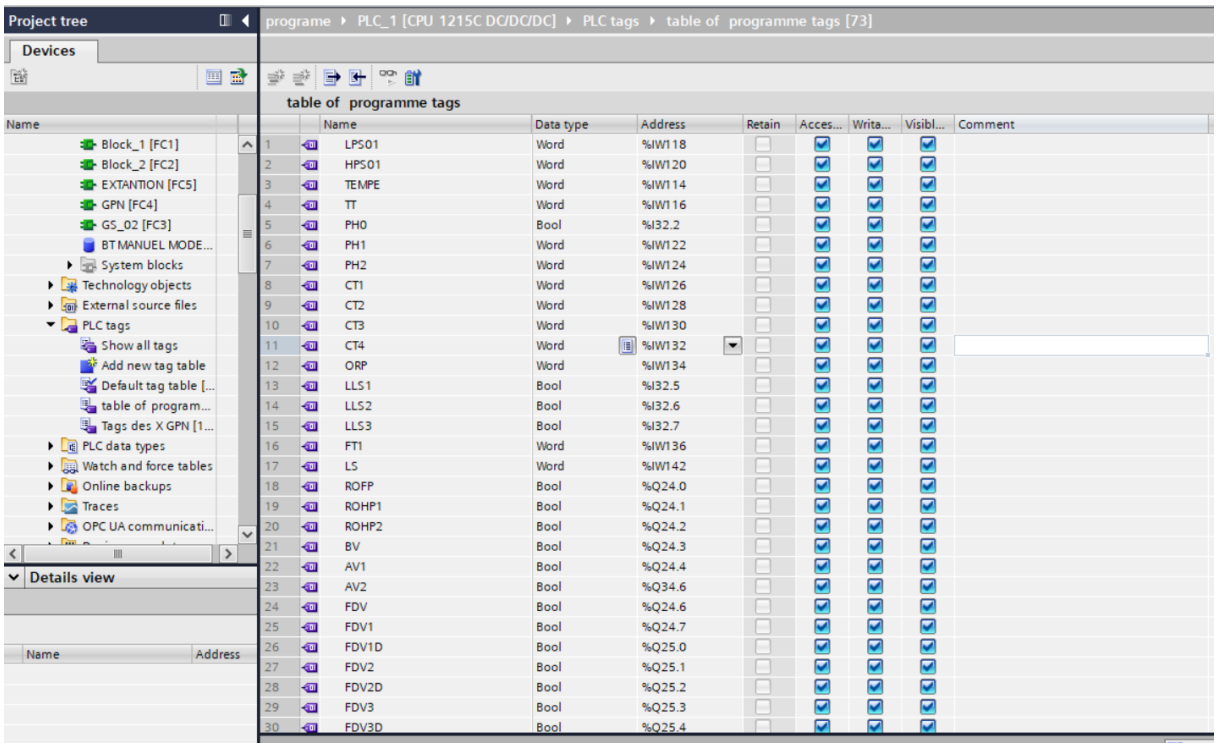


Figure 3.7: Mnemonic table.

III.4.5. Blocks in the User Program Tia Portal:

programming software allows us to structure and break down the program into individual, self-contained sections. This has the following advantages:

- easier and simpler program organization to understand.
- Individual program sections can be standardized.
- easier modifications to the program.
- Debugging is simplified since we can test separate sections.

There are several different types of blocks used within the program. Which are:

Table 3.1: Description of the block's functions.

Block	Brief Description of Function
Organization blocks (OB)	Determine the structure of the program.
System function blocks (SFB) and system functions (SFC)	SFBs and SFCs are integrated in the CPU and can access to some important system functions.
Function blocks (FB)	FBs are blocks with a "memory" which are programmed individually.
Functions (FC)	Contain program routines for frequently used functions.
Instance data blocks (instance DB)	Associated with the block when an FB/SFB is called. They are created automatically during compilation.
Data blocks (DB)	DBs are areas for storing data. They are also assigned to a function block, and can be defined and used by it.

III.4.6. The water purification process via Tia Portal program:

FC3 FC4 FC5 are three blocks titles programmed to introduce us about the systems' following GPN (normal production) and GS (security).

We created these blocks in order to process the analog/digital values. Measurement provided by the sensors and actuators, converted from an electrical signal to a digital value.

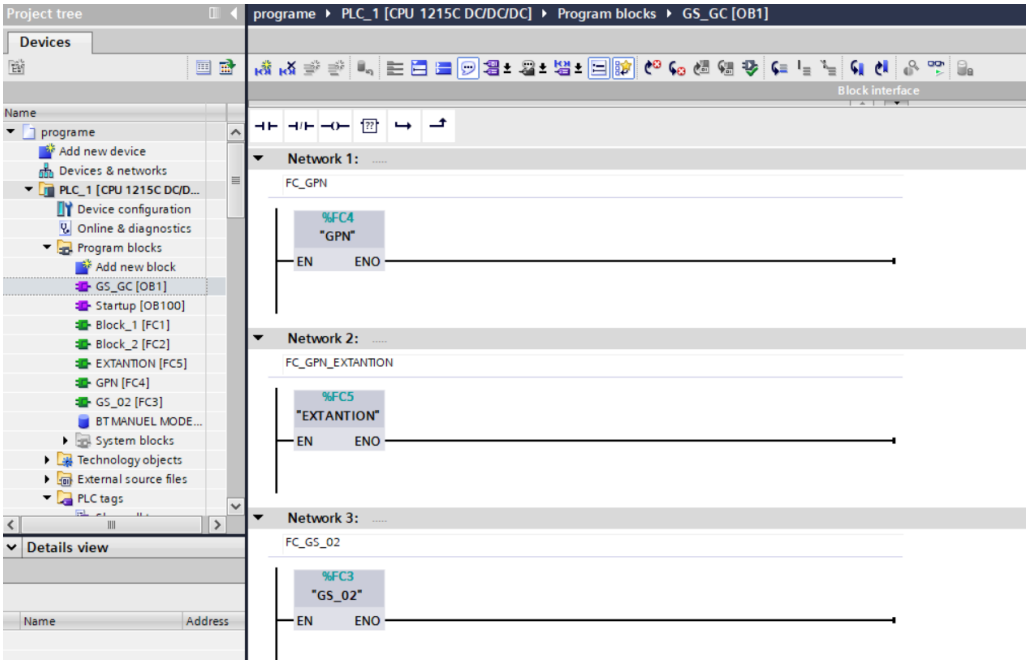


Figure 3.8: Main ladder program example.

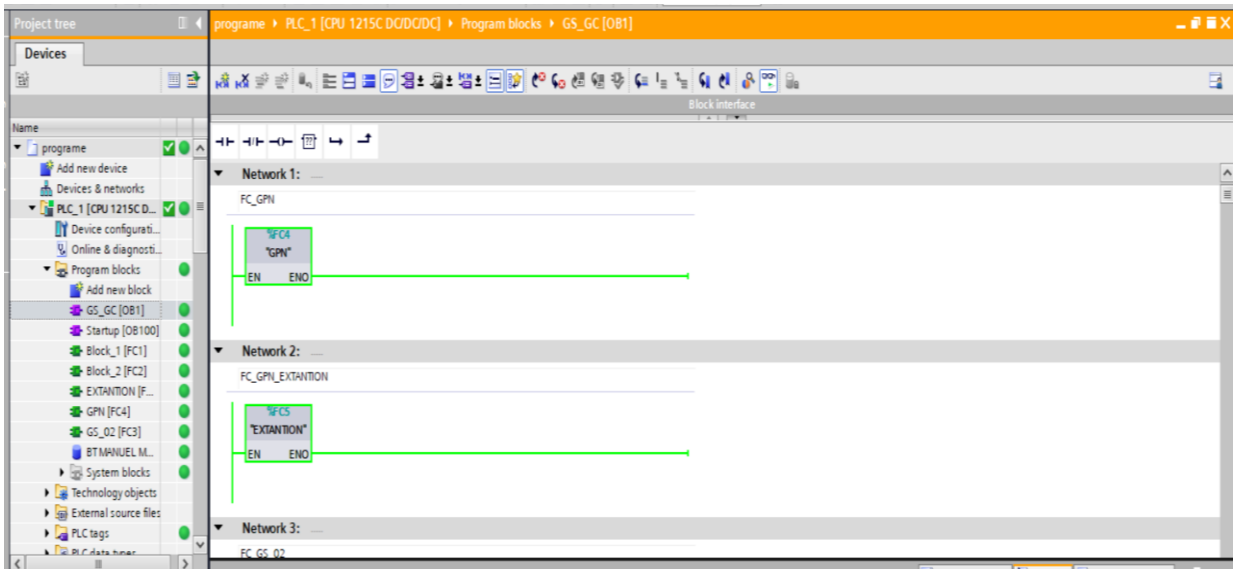


Figure 3.9: Main ladder program example activated.

III.5. Supervision and security:

When the process is operational, it can meet a certain level of complexity, leading the operator to need maximum transparency and control over the system. This transparency is obtained through the Human Interface Machine (HMI).

III.5.1. Definition of Human-Machine Interface (HMI):

An HMI acts as a visual bridge between humans and machines within industrial settings. It provides real-time data visualization, process monitoring, and control options.

Operators rely on HMIs to optimize processes, track performance, and manage alarms. By centralizing information, HMIs enhance efficiency and safety across various industries, from manufacturing to energy and transportation.

III.5.1.1. Creating an HMI (Human Machine Interface):

To create a Man/Machine interface, you must have first the program checked for any minor error. While always using Siemens TIA Portal, following the next several steps:

1) **Connecting PLC and HMI Hardware**:

A. We choose the appropriate HMI device (e.g., TP1500).

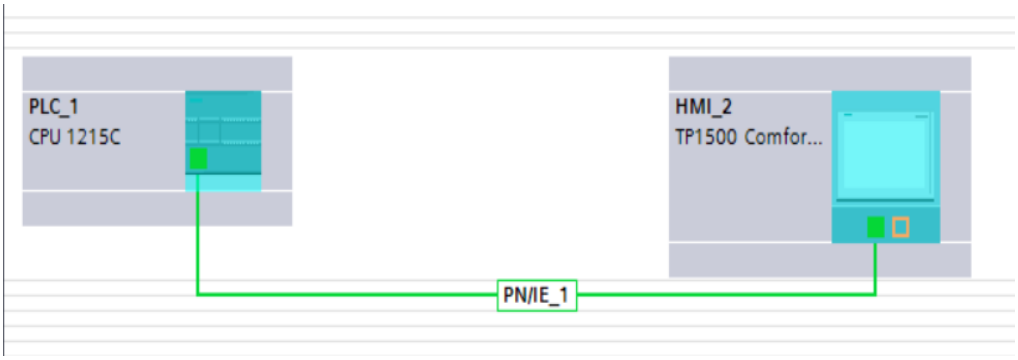


Figure 3.10: network view of connection line between the PLC and HMI.

B. Add the PLC hardware (CPU 1215C DC/DC/DC):

The most important thing to do is to create a direct link between TIA PORTAL V17 and the CPU, so that the software can read the data that are in the memory of the automation.

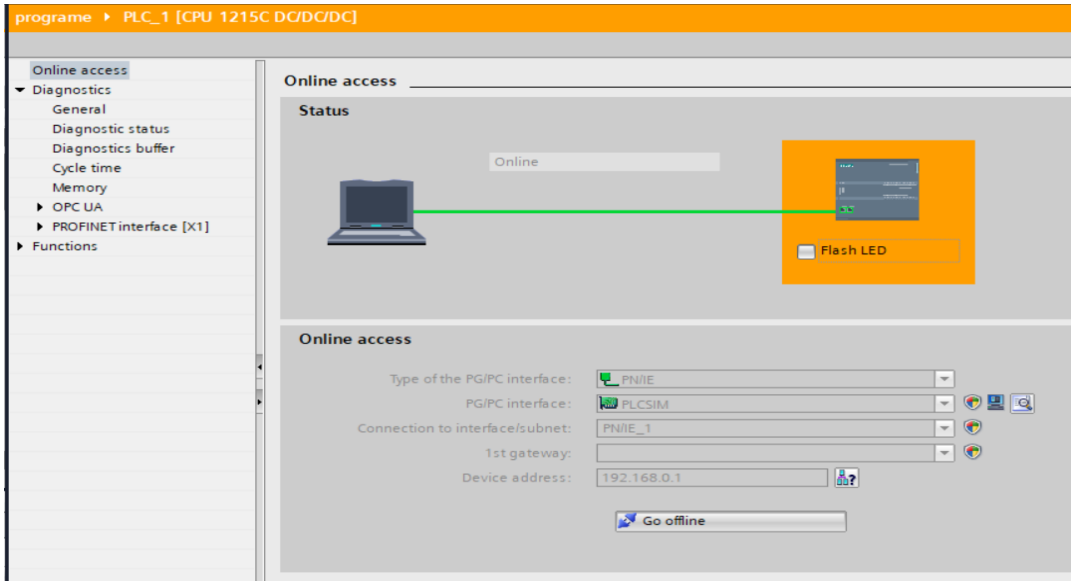


Figure 3.11: Online access from the PC to PLC.

C. Creating the variables table:

The variables allow to communicate and exchange data between the HMI and the Machines.

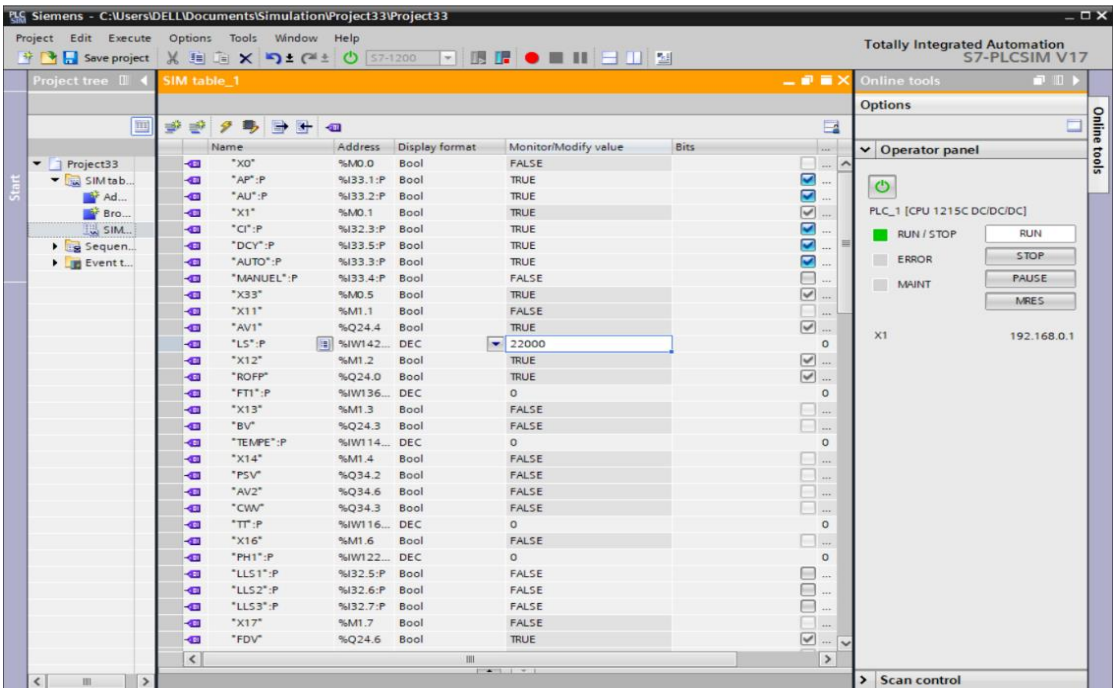


Figure 3.12: Variable table in PLCSIM.

2) **Design the HMI Screen** :

A. Select “Basic Objects.”

B. Drag and drop elements (buttons, text, pipes, and motors) onto the screen.

In the following we will detail all the views that constitute our solution of supervision:

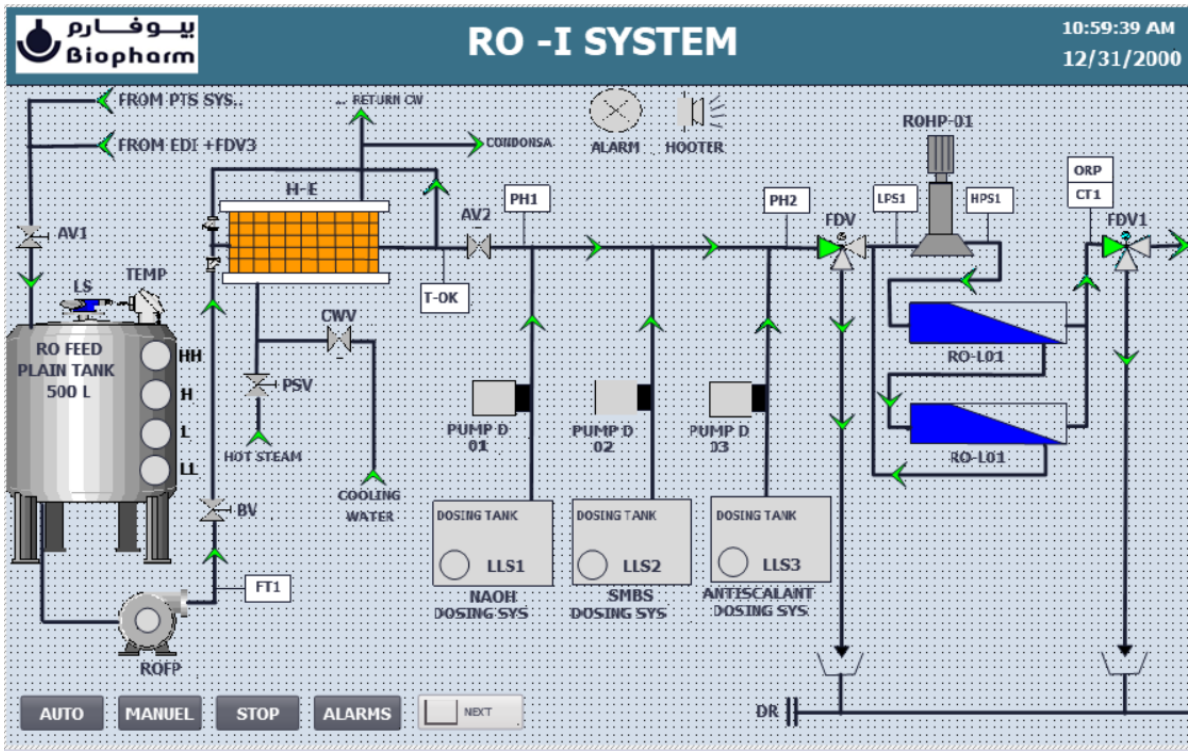


Figure 3.13 : Screen 01 of HMI.

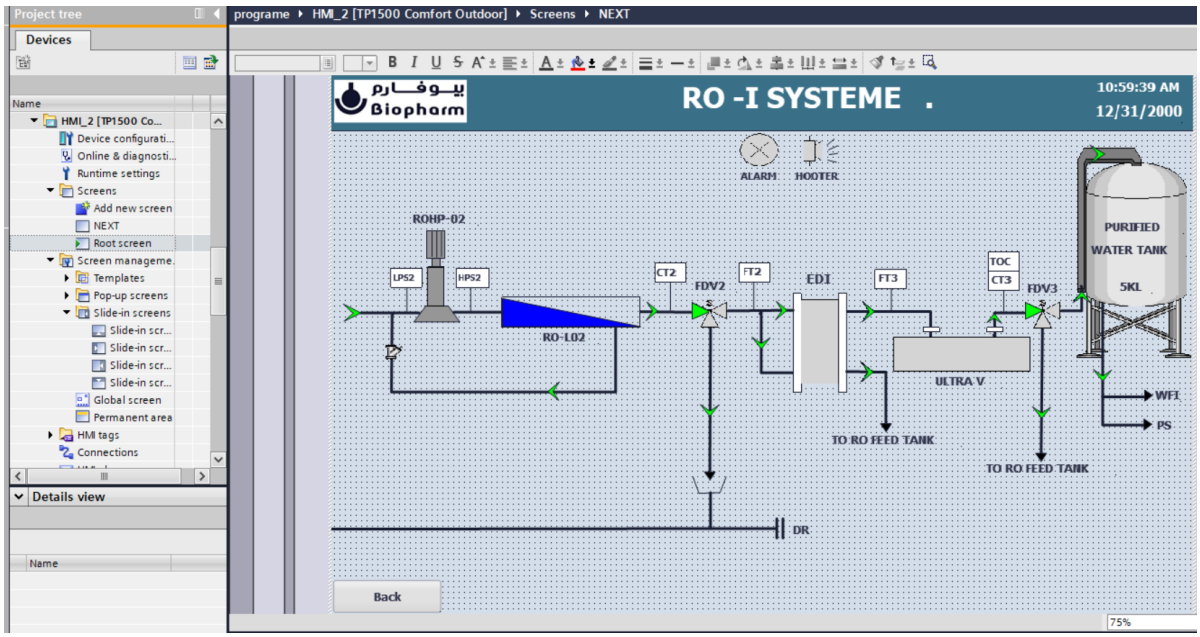


Figure 3 .14 : Screen 02 of HMI.

3) **Create Animations and Events** :

A. Define animations for visual representation (e.g., the two parts of the purification process).

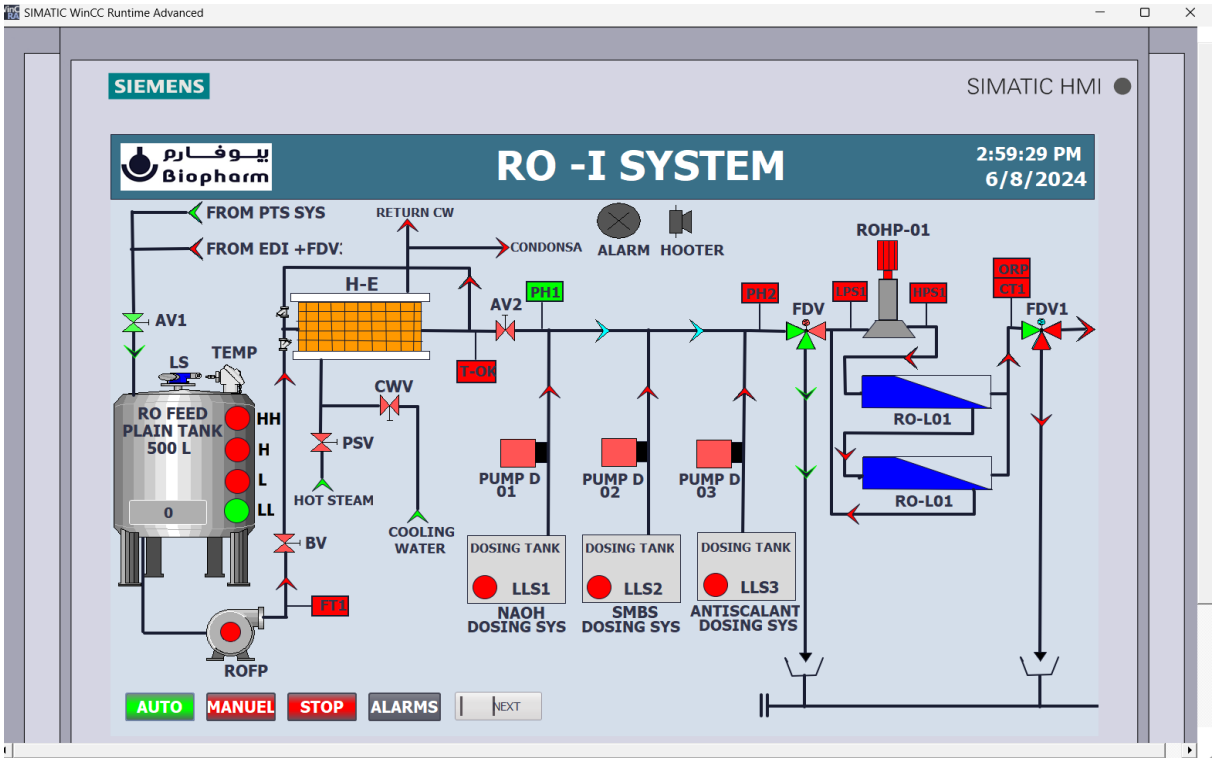


Figure 3.15: simulation part 01.

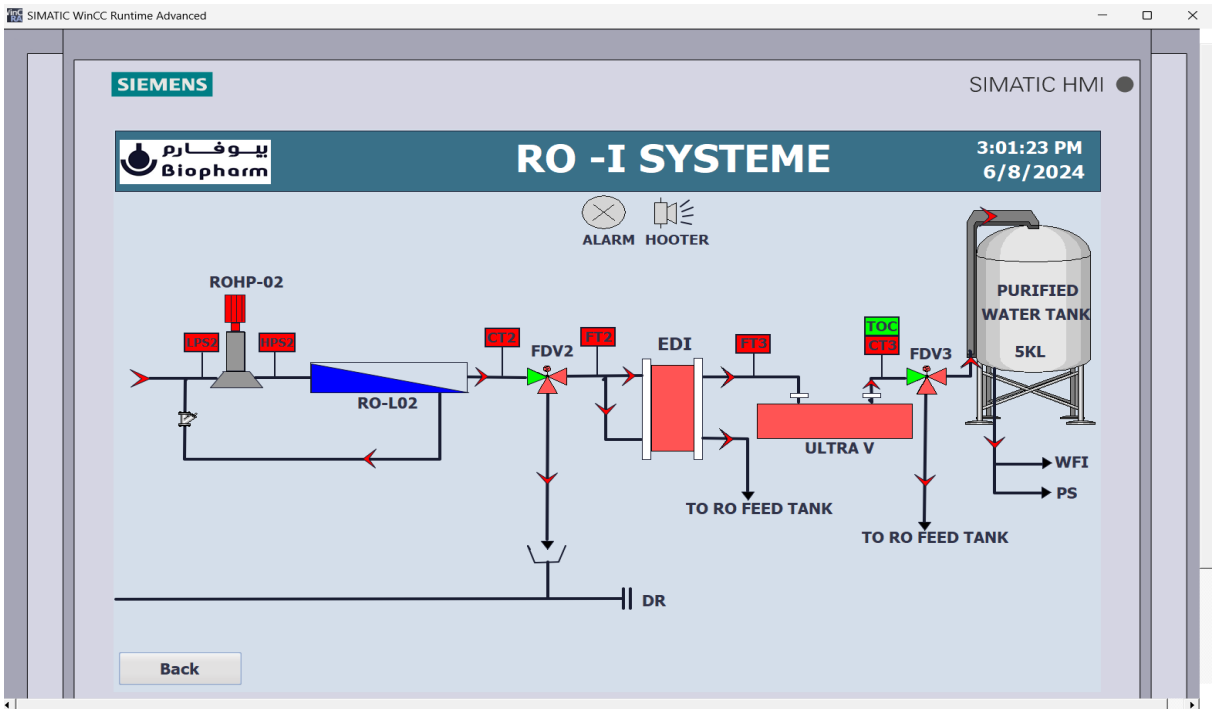


Figure 3.16: Simulation part 02.

III.6. Conclusion:

By achieving the integration of PLCs and HMIs, we can unlock the full potential of the water purification system industrial automation, driving efficiency, safety, and innovation to the top.

In this chapter, we have presented the different stages of the creation of our program TIA PORTAL V18 and its implementation. We also presented the procedure to follow for the creation of a Human Machine Interface for the distant control of the station.

GENERAL CONCLUSION

GENERAL CONCLUSION

Water is the main component in any pharmaceutical industry, specifically during the preparation of the vast majority of drugs, water is used as an excipient, to reconstitute a drug, during the production or as a main element for cleaning tanks, equipment and or primary packaging.

Different qualities of water are necessary, depending on the use that would be made of it (Purified Water, Water for injection or pure steam). The difference in quality would be distinguished by their characteristics, and microbiological purity.

Our time in BIOPHARM's laboratory first gave us the pleasure to be part of the first ever Algerian facility to start producing oncology medications, thus it allowed us to understand the need of such detailed process and its proactive approach of qualification.

This qualification process is part of a global process stretched from the design of the facilities and equipment, to the personnel. This manuscript allowed us to know all about the techniques of water treatment in the facility.

We were able to approach quality from a practical and operational point of view, by participating in the operational qualification of one of the HMIs (human machine interface), with the equipment and station, while daily monitoring the regulatory requirements specific for the water purification process to keep going. From (pressure conductivity, pH, and temperature etc.).

Starting from the pretreatment station, to the further water purification treatment (reverse osmosis, electro-ionization etc.), noting that it is not a small nor direct treatment, which will be later the problem, after studying the automation of it, programming every detailed action as well as the introduction of a supervision dedicated to this process. We couldn't help but conclude that a near and accessible HMI is needed. As technology continues to evolve, and no matter how much the system is developed, the water treatment system showcased a glimpse into the future of industrial automation, where HMIs will drive even greater efficiency, reliability, and innovation.

Since the system can continuously change, adjust, and optimize its processes, adapting to changing and monitoring it is a constant demand.

Therefor we proposed and presented an interface of this last one to be accessible and hopefully distributed all over the areas needed.

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Appendix A

References of the actuators and sensors in the water purification system

Table1: References of Actuators in purified water system.

References	Description	Signal	power supply	Figure
CM3-4A-R-G-V-AQQV	RO Feed Pump • Rated flow :3.1m³/h • Rated power: 0.46 kW • Rated speed :2770-2820 rpm	NMRQ (from inverter drive)	3x240D/415Y V & 2/1,2 A	Figure 2.20
CRN 1-23 A-P- A-V-HQQV	ROHP • Rated flow :1.8 m³/h • Rated power: 1.1 Kw • Temperature range:-20 to 90 °C • Maximum pressure: 25 bar • Rated speed: 2840-2870 rpm	NMRQ (from inverter drive)	voltage: 3 x 220-240D/380-415Y V	Figure 2.21
6SL3210-5BE27-5UV0	Siemens Inverter Drive • Rate power : 7.5 KW/10000hp • Rated current 16.50A	NMRQ	line voltage: 3AC 380- 480v	Figure 2.15
370419298/Api20	High intensity Ultra violet Unit • DC Voltage 0 – 600 • DC Amperage 0 - 6.0 • Maximum Temperature:45°C • Pressure Range : 1.4 to 2.1 bar • Flowrate: 0.5 m³/h	NMRQ : MODBUS (RS485) protocol	230V/50HZ	Figure 2.27
IP-LXM4HI-3	Electrodeonization module • Max Temperature : 60°C • Max Pressure : 7 bar • Sanitization temperature:80°C • pH range : 4-11 • Flowrate: 0.5 m³/h	NMRQ	380VDC/ 10 A	Figure 2.26

CC3 0407 PP	Electromagnetic dosing pump • Capacity: 6.3 L/H • Max Pressure: 3.5 Bar • Power: 12 W	NMRQ	230V /50HZ	Figure 2.22
04125-31, exergy	Shell & tube heat exchanger • Flow rate : 2.5 m^3/h • Max Temperature : 425°C • Tube Side Pressure: 25 bar • Shell Side Pressure: 20 bar • Steam Pressure: 8.6 bar	/	/	Figure 2.23
ROHO0089 WWH-4040 Housing	Reverse Osmosis Membrane •Temperature range : 1 to 48°C • Pressure range : 6 to 20 Bar • Diameter: 170mm • Length: 1086mm	/	/	Figure 2.6
1056-01-20-30-AN	Display Analytical Model • Dual Input Analyzer	NMRQ	115/230V AC ,50HZ	Figure 2.39
Inoxpawakh1 00652025110	Single Seat Valve (Flow diverter valve Fdv) • Temp range: -10 to 121ºC • pressure : 6 to 8 bar	Digital	24V DC	Figure 2.19
6812M217/CF8M/S 6/T/ONF	Angled Body Valve • Pilot Pressure : 3.5 to 6 bar	NMRQ	Pneumatique control	Figure 2.18
KZ-2B-PVC-100	Ball valve • Temp range : -40° to 85°C • Max pressure : 17 bar	Digital	12 V 5A	Figure 2.17

Table2: References of sensors in purified water system.

References	Description	Signal	power supply	Figure
H250/RR/M40/ESK 4A	Flow transmitter • Max temp : -196 to 400°C • Max pressure: 1000 bar	Analogue 4-20 mA	Without auxiliary alimentation	Figure 2.29
FGSO-J14DSH1WWW	level switch • Max Temp : 150°C • Max Pressure : 10 bar • Liquid Density : ≥0.6 g/cm3	Analogue	5A	Figure 2.30
RHS612-S-W3-A3-A-25-6R-50-A-200-C2P Model 8060A	Temperature Sensor with transmitter type : pt100 • Temp Range : -100 to 200 °C	Analogue	4 to 20 mA.	Figure 2.33
00825-0100-3400, Rev AA	Conductivity sensors • 0-3000 µs/cm & 0 -5000 µs/cm (Model-400-13) • 0-200 µs/cm & 0 -500 µs/cm (Model-400-11/400-12) • 0-100 µs/cm & 0 -10 µs/cm (Sensor Model-400-11) • Max Temp: 105°C • Max pressure : 18 bar	Analogue	4 to 20 mA.	Figure 2.34
CPS11D Transmitter model :CM14-AAK	pH sensor • Temp Range : 0 to 135 °C • PH Range: 0–14. • Pressure Range: 1 to 17 bar	4-20mA MODBUS /RS485 Digital	24V DC	Figure 2.31
CPS12D Transmitter model :CM14-AAK	ORP sensor • Measurement range : -1500 mV to +1500 mV • Temp range: -15 to 135 °C • pressure range: 0 to 16 bar	Analogue	4 to 20 mA.	/

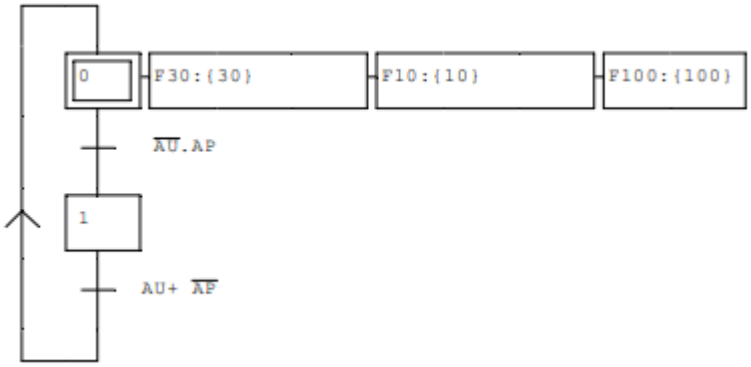
RT200017-523766/RT5	**Pressure switches** • **Low level: 0.2 to 6 bar** • **High level :4 to 17 bar** • **Temp range : -50° to 70°C** • **max pressure : 22bar**	**Analogue**	**28A 400V**	**Figure 2.32**
CYK10-A051	**Digital PH/Conductivity/temp measuring cable** • **Length : 10m up to 100m** • **Diameter : 6.3mm** • **Temp range: -25°C to135°C** • **Max pressure : 50 bar**	**Digital**	**5.1V 130Ma**	**/**
Model: UV80 with UV254	**Toc analyzer** • **Temp range: (5 to 45°C)** • **Low Range Configuration : up to 370 ppm (mg/L)** • **High Range Configuration: up to 1000 ppm(mg/L)**	**Modbus RTU**	**4 to 20 mA Internal from T80 Transmitter**	**Figure 2.35**

Appendix B

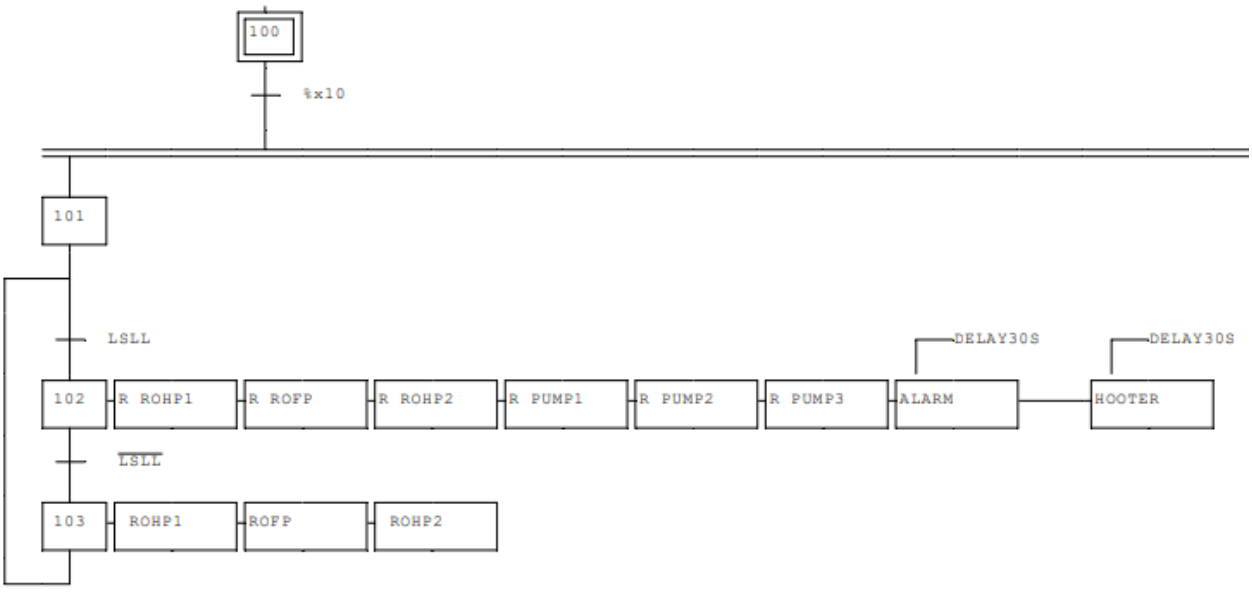
Sequential Function Charts (Grafcet) of the water purification system:

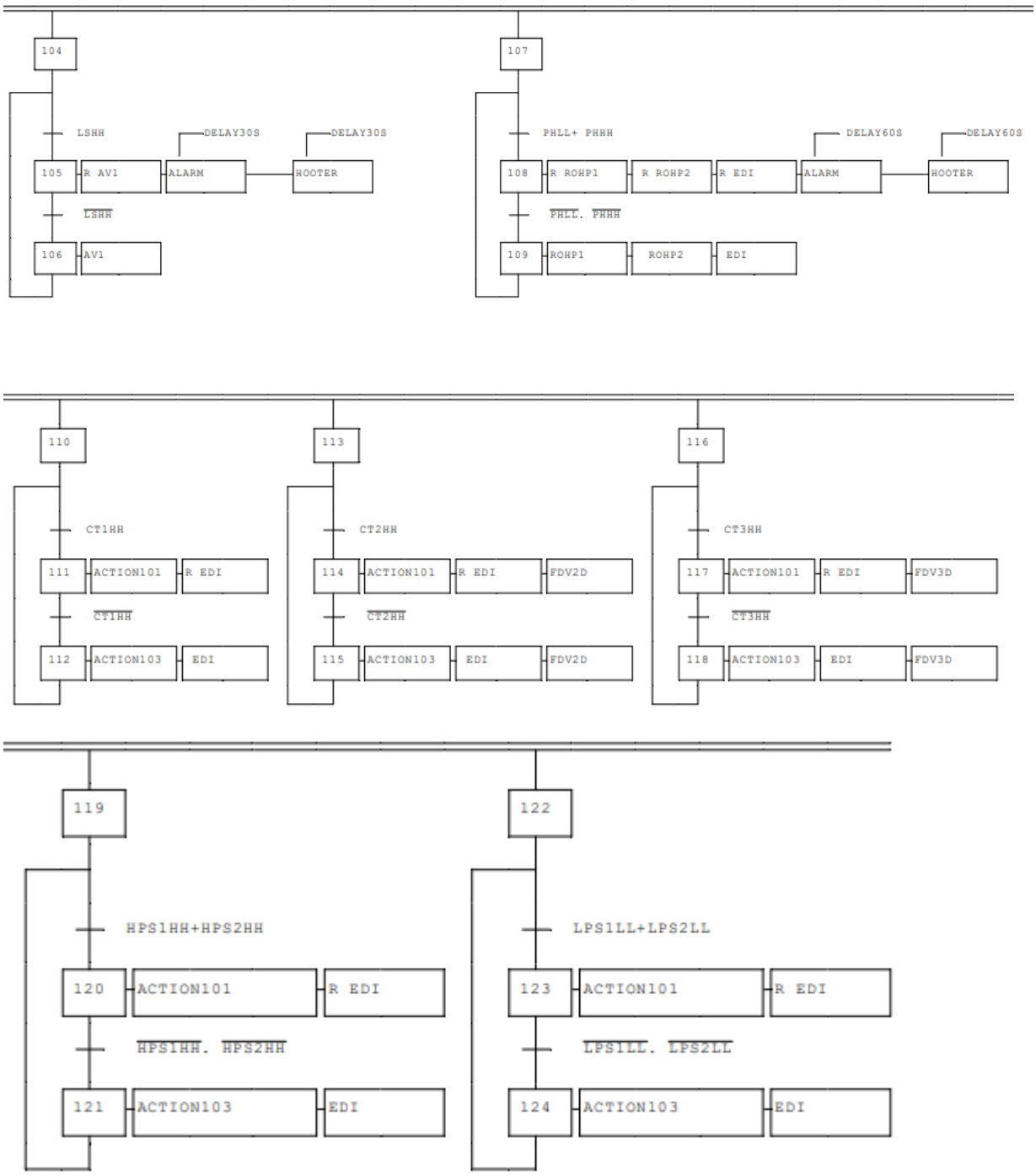
I. Security Grafcet :

- **GS1**

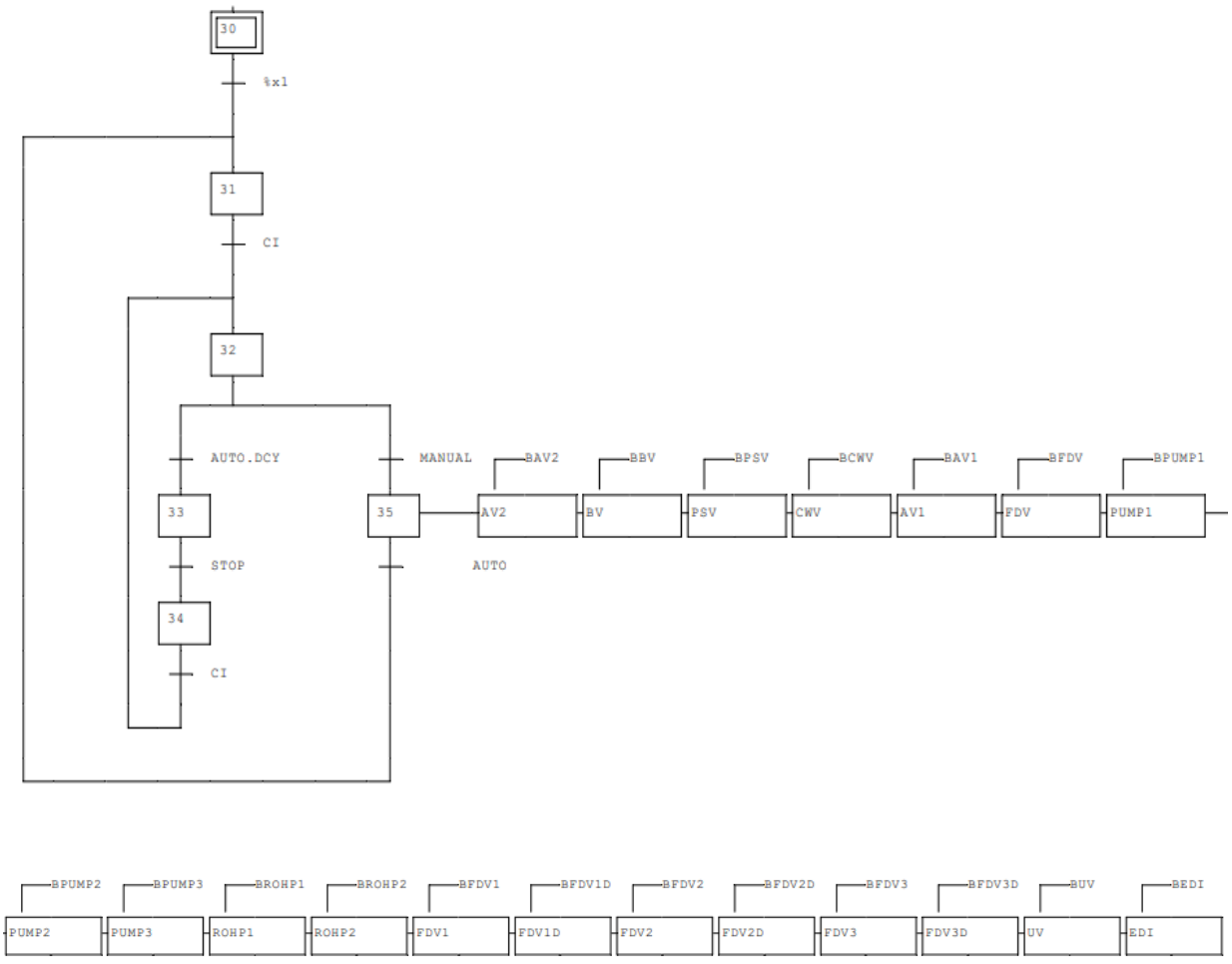


- **GS2**

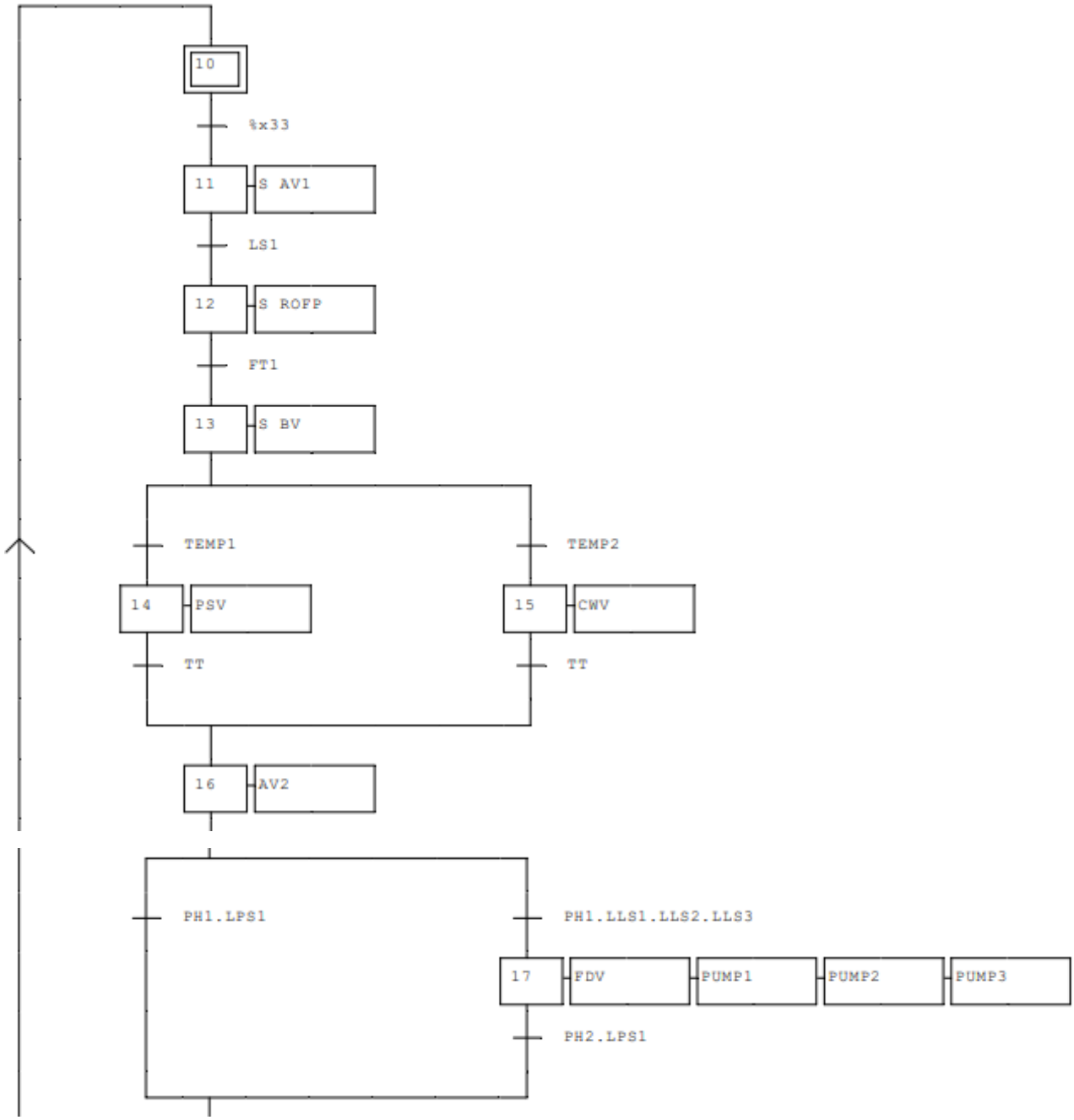


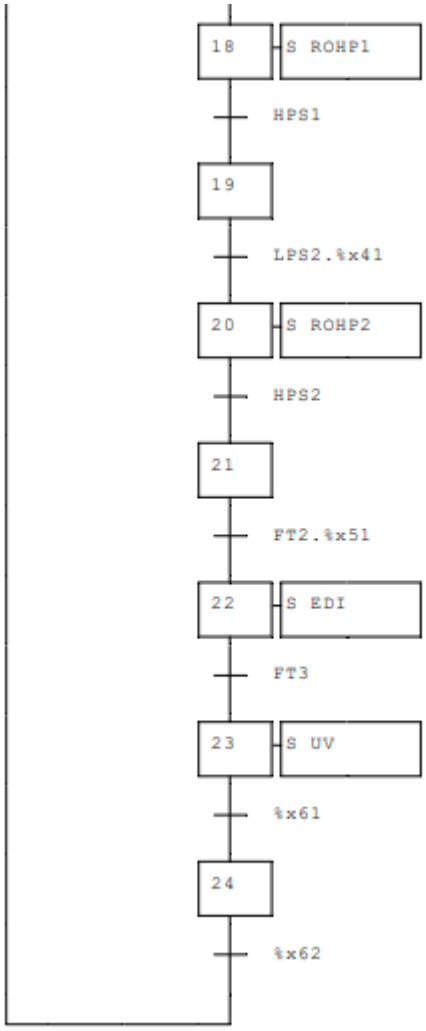

104
LSHH
105
R AV1
ALARM
DELAY30S
HOOTER
DELAY30S
LSHH
106
AV1
107
PHLL+ PHHH
108
R ROHP1
R ROHP2
R EDI
ALARM
DELAY60S
HOOTER
DELAY60S
PHLL. PHHH
109
ROHP1
ROHP2
EDI
110
CT1HH
111
ACTION101
R EDI
CT1HH
112
ACTION103
EDI
113
CT2HH
114
ACTION101
R EDI
FDV2D
CT2HH
115
ACTION103
EDI
FDV2D
116
CT3HH
117
ACTION101
R EDI
FDV3D
CT3HH
118
ACTION103
EDI
FDV3D
119
HPS1HH+HPS2HH
120
ACTION101
R EDI
HPS1HH. HPS2HH
121
ACTION103
EDI
122
LPS1LL+LPS2LL
123
ACTION101
R EDI
LPS1LL. LPS2LL
124
ACTION103
EDI

Conduct Grafcet (GC):

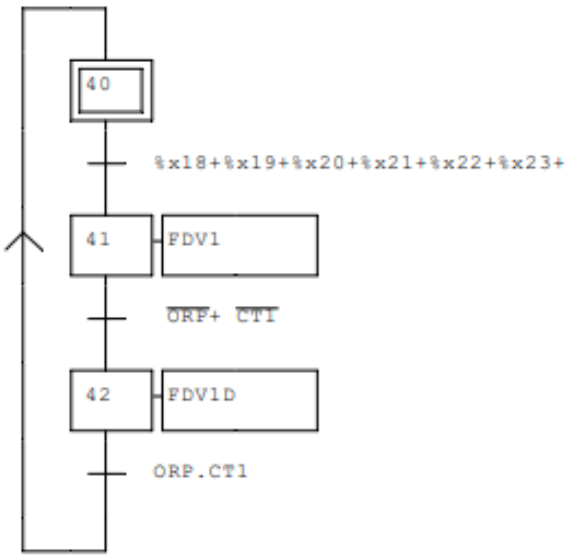


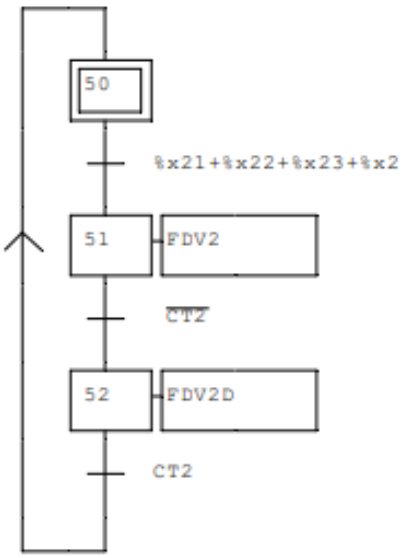
Normal production Grafcet (GPN):

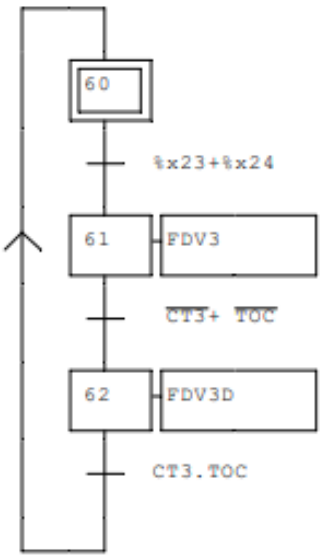




Conductivity and draining:







PH treatment: