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Production of ultrapure water for pharmaceutical industry using an integrated system textile ion exchanger – membrane processes

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ABSTRACT/RESUME

Abstract: *Water is a key element of all socioeconomic processes. Ultrapure water, with hardness less than 1 ppm, is currently widely employed in a variety of industries, including the semiconductor industry, the pharmaceutical industry, and electric power generation.To produce water with high-purity from well water, different purification methods such as thermal and membrane processes are performed. EDI is mainly used for ultrapure water production.Usually, this process is integrated with reverse osmosis (RO) to produce EDI feed water with a hardness of less than 1 ppm. In this study, ultrapure water was produced from a water well using a novel integrated UF- Ion Exchanger Textile (UF-IET)- electrodeionization (EDI) system.The UF IET-TEXTILE permeate with a conductivity of 248 µS/cm was fed into the EDI cell to generate the ultrapure water. It has been revealed that the product conductivity decreased as the EDI current density increased and the feed velocity increased.The results obtained revealed that the suggested hybrid separation process UF-IET/EDI system is an innovative solution for ultrapure water production with lower energy consumption and investment than the conventional RO/EDI system.*

I. Introduction

Ultrapure water, with conductivity less than 1 µS/cm, is widely employed in a variety of industrial applications [1], pharmaceutical manufacturing [2], and semiconductor production [3]. The production of ultrapure water according to international standards is recognized as a critical process.

Unfortunately, available water resources, such as groundwater (drilled water tables) and surface water (dams, lakes, and rivers), rarely satisfy the required quality standards.

At present, there is no doubt that membrane techniques are the most economical and ecological methods for water demineralization such as ultrafiltration,nanofiltration, and electrodeionization [4].

Membrane technology plays an important role in the production of pure water of various grades [5]. Additional membrane technologies, such as ultrafiltration (UF) or microfiltration, may be incorporated as pretreatment technologies depending on the feed water available [6].

Electrodeionization (EDI) is an environmentally friendly process that is mainly used to produce high-purity water [7]. It can only be used after pre-treatment by reverse osmosis to obtain very high-quality water with a resistance close to 18 megohms [8].

Electrodeionization (EDI) is an electrical purification process using a combination of ion-exchange resins and ion-selective membranes [7].

Additionally, the continuous electrolysis of water in the module produces H^+ and OH^- ions. These ions maintain the resins at a high level of regeneration, eliminating the need for chemical regeneration [9].
EDI has the advantage of being a continuous process with stable product quality that can provide high-purity water without the necessity for acid or caustic regeneration, as opposed to traditional ion exchange systems [10].
EDI used an electrolytic cell in which two types of ion-selective membranes - cationic permeable membrane (CM) and anionic permeable membrane (AM) - have been placed between the electrodes [11].
When a constant electrical potential is applied to the cell's bornes, cations are drawn to the negatively charged cathode, while anions are drawn to the positively charged anode [7].
However, cations can pass through the cationic permeable membrane, but not into the anionic permeable membrane. Conversely, anions can pass through the anionic membrane, but not the cationic membrane. Thus, the water obtained in the dilution compartment is effectively deionized since the ions have migrated irreversibly to the electrodes under the influence of an electric field and concentrated on the adjacent parts [12].
However, electrodialyzers can only be used to produce low-quality deionized water with a conductivity of 200 µS/cm or less; more electrical power would be required to direct the ions through water of increasingly higher purity [13].
This problem is solved by filling the space between the two membranes with ion exchange resin. The resins provide a conductive flow for ion migration, which maximizes deionization, resulting in the production of high-purity water [14]. The continuous electrolysis of the water, acting in the module, produces H^+ and OH^- ions. These ions maintain the resins at a high level of regeneration eliminating the need for chemical regeneration [15].
The resins used in EDI systems can be a mixture of anionic and cationic beads (mixed beds) or separate beds of two types of resin [16].
The quality of water produced by this type of process is enhanced by multiple passes in which the "pre-purified" water is directed through two series of modules. In general, the produced water reaches a resistivity of 10 to 18 MW cm (at 25°C) with a total organic carbon content of less than 20 ppb [8].
Ultrafiltration (UF) is commonly used as a pre-treatment for Reverse Osmosis (RO) to prevent or minimize biofouling [17], obstruction, or damage the RO membrane [18]. Also, Reverse Osmosis requires relatively high working pressure [19], leading to considerable energy consumption and complexity instrumentation [20].
In this study, a new hybrid process was tested in order to produce water for pharmaceutical use from raw water. This innovative process consisted of a coupling of membrane filtration techniques (UF) with ion-exchange techniques with innovative materials (Textile ions exchangers).
These materials are obtained by grafting chemically active functional groups onto polymers [21]. On the one hand, they can perform the functions of a conventional textile as fabrics, filters, etc., on the other hand, they can function as chemical agents [22], such as ion exchangers, complexing agents, reducing or oxidizing agents [23], and catalysts [24].
The ion exchange process on active fibers has been strongly developed because of their multiple advantages over resins such as;
- Small diameter of their monofilaments (5-50 µm) and uniform thickness ensure a high rate and efficiency of the ion exchange process [25]. In this respect, they are similar to microspherical ion exchangers used for analytical properties. The application of resins in large-scale processes is hardly possible, due to the high resistance of the filter layers to the water flow.
This difficulty is eliminated when ion exchange fibrous materials are used because the resistance of this bed is easily controlled by the density of this fibrous exchanger according to the density of this fibrous exchanger in accordance with the technological requirements (conditions) in each specific case;
- Faster exchange kinetics due to their large specific surface area and non-cross-linked structure [26];
- Reduced consumption of regenerating solution;
The objective of this study is to examine the performance of a non-conventional hybrid process that uses ion exchange textiles instead of ion exchange resins. Ultrafiltration combined with ion exchange textiles and electrodeionization on ion exchange textiles has been studied.
This process has been evaluated in order to replace the use of the reverse osmosis (RO) process with the ultrafiltration (UF) - textile ion exchange (TEI) coupling. The integrated process (UF-TEI/EDI) has the advantage of using a lower working pressure, less than 2 bars, consuming less energy, and being less expensive than the RO/EDI system.

II. Materials and methods

- Experimental set-up

The objective of this work is to study the feasibility of obtaining water for pharmaceutical use from raw water by using membrane processes.
In this study, an experimental set-up of the UF-IET/EDI system was used to produce ultrapure water from well water (Figure 1).
The UF membrane employed was the Carbosep M2, which has a nominal MWCO of 15 kDa and consists of zirconium dioxide with porous carbon support. The tubes have an inner and outer diameter of 6.00 and 10 mm, respectively, a length of 170

mm, and a surface area of 0.074 m².
To produce EDI feed water, UF was used as a pre-treatment. This pre-treatment was used to remove hardness and organic contaminants before being fed to the EDI module.
The EDI stack was composed of one diluate compartment, two concentrate compartments, one anode compartment, and one cathode compartment (see Figure 1). Stainless steel electrodes were used in this study.
A cation-exchange membrane (CMS **Neosepta**) and an anion-exchange membrane (CMA **Asahi Glass**) were employed as the EDI stack's ionic selective barriers. Membrane properties have been reported in Table 1.

Table 1. *Characteristics of the membranes* [27].

Membrane	*Exchange capacity (Meq.g^{-1})*	*Humidity (%)*	*thickness (µm)*	*Recommanded field of application*	
				pH	*T (°C)*
CMS (CEM)	2.30	13.9	22	0- 14	≤ 60
CMA (AEM)	2.40	28	133	0-14	≤ 60

CME: Cation Exchange Membrane.
MEA: Anion Exchange Membrane.
The membranes used in EDI are washed before each use with demineralized water. Each membrane (anionic and cationic membranes) had an effective area of 37.4 cm^2. The characteristics of the cation (FIBAN K4) and anion (FIBAN A6) exchange textiles are summarized in Table 2 and Table 3, respectively. These ion exchange textiles are introduced into the UF membrane and the dilution and concentration compartments of the EDI.
The regeneration of the two textiles was done by the production of H^+ and OH^- which come from the extreme compartments which respectively contain HCl (0.1 N) and NaOH (0.1 N).

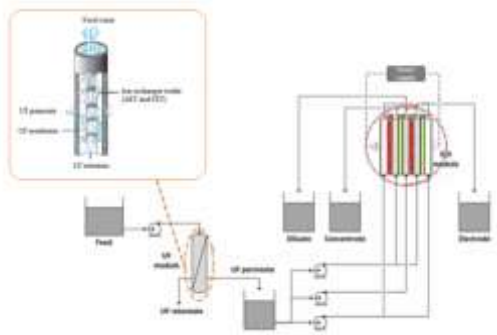
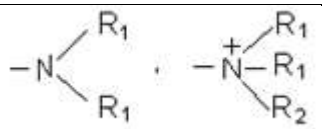


Figure 1. *Experimental set-up of the UF-IET/EDI system.*

Table 2. *Properties of FIBAN K4 textile* [28].

Functional group	-COOH
Matrix	Polypropylene fiber.
Capacity optimum meq/g	3.5-6.0 (H).
Water uptake, g H_2O/g fiber	0.4-1.0
pH	5 – 13
Temperature range	0 - 80° C
Stability against aggressive agents	Stable in the presence of concentrated acids, alkalis, oxidizing agents, and organic solvents.

Table 3. *Properties of FIBAN A6 textile* [28].

Functional group	
Matrix	Acrylic
Capacity optimum meq/g	Not less than 1.8 - for strong bases, 1.0 - for weak bases. the material can be produced with high or low exchange capacity
Water uptake, g H_2O/g fiber	1.3
pH	0 - 12
Temperature range	> 70°C (Cl^- form), > 40°C (OH^- form).
Stability against aggressive agents	Stable in aqueous, alkaline solutions. Relatively stable against oxidizing agents.

- **Analysis methods**
- **Limiting Current Density**

Different tests were carried out to determine the limiting current imposed on the electrodes. The current intensity applied must not exceed a critical value called limit current [29].
The curves I = f (V) obtained allow us to define the diffusion level. This method is very practical to determine the effective working areas, beyond which the yield of the process drops, which has as a global consequence a bad demineralization of the solution to be treated.

- **Conductivity**

Electrical conductivity is one of the most important characteristics of ultrapure water **[30]**. Conductivity was measured by a Crison conductivity meter. The conductivity was measured at a regular time interval in the dilution compartment.

- **pH**

The pH in the feed and concentration compartments was monitored with a HANNA pH meter.

- **Physico-chemical and microbiological analysis of purified water**

The calcium hardness was determined using a potentiometric method with EDTA. As well as the tests of physico-chemical and microbiological analyses that the pharmacopeia requires to qualify the water as being water for pharmaceutical use.

- **Physico-chemical control of purified water**

The quality control of pharmaceutical products is a step and an indispensable operation that requires precautions and precision **[31]** . This explains the importance of developing the most appropriate methods of analysis.

In this context, we have carried out the various physico-chemical controls carried out on purified water.

- **Microbiological control**

The microbiological tests concern the study of the effectiveness of antimicrobial conservation or the "Challenge test". This was done by a control of microbial contamination and counting germs. These tests are intended to determine whether a product subject to a pharmacopoeia monograph meets the microbiological requirements, by counting germs such as total viable germs, enterobacteria. The effectiveness of these tests can be used to monitor the quality of raw materials, as well as pharmaceutical preparations [32].

The purpose of this test was to determine the presence or absence of a type of bacteria such as fecal Coliforms and Pseudomonas Aerogenusa, which tend to proliferate in water environments.

III. Results and discussion

In order to obtain water for pharmaceutical use from well water, we used membrane filtration techniques that we coupled with ion-exchange techniques with innovative materials.

Knowing the hardness of natural water, and in order to preserve the membranes which represent a key element of each membrane process, an integrated UF-IET/EDI process was developed in order to produce high quality ultrapure water.

III.1. Pre-treatment of well water by ultrafiltration

In order to maintain the efficiency of a membrane process installation, a pre-treatment of the water is necessary.This pre-treatment will prevent or minimize biofouling and obstruction of the membranes **[33]**

. The type of pre-treatment depends strongly on the quality of the water used:

- Origin of the feed water.
- Composition.

This is an important step in the design of the pre-treatment system and the overall membrane system to determine the type of pre-treatment.

In this work, hybrid UF-IET process was used to pre-treat raw water which consisted of ion-exchange performed by the ion exchanger textiles (FIBAN K4 and FIBAN A6) introduced inside the Carbosep ultrafiltration membrane.

III.2. Control of the hydraulic permeability of the membrane

Figure 2 shows that the permeate flux grows linearly with the membrane pressure, therefore DARCY's law was verified.

The hydraulic permeability of the membrane is derived from the straight line Jv = Lp *P which represents the slope.

Lp = 260.081 (l/h m² bar). The equation of the line was then written : Jv = 260.0817P - 49.177.

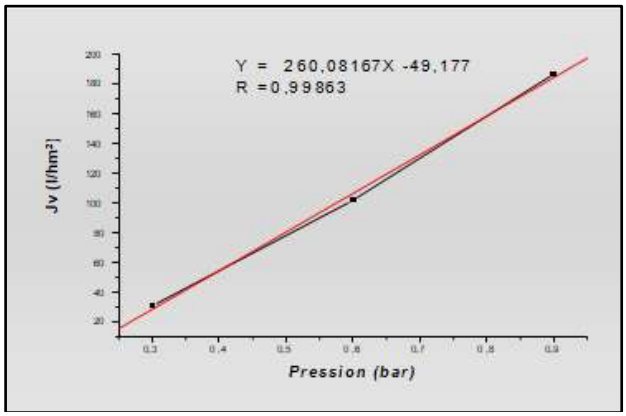


Figure 2. *Effect of the membrane pressure on the flux of permeation.*

III.3. Evolution of the permeate flux Jv as a function of the ultrafiltration time

The evolution of the permeate flux as a function of time for different pressures was shown in figure 3.

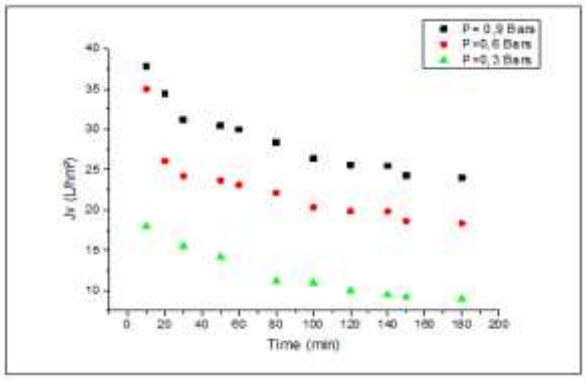


Figure 3. *Effect of the pressure on the flux of permeation*

Figures 3 represent the evolution of the permeate flux as a function of the ultrafiltration time. According to this figure we can see a decrease in the flux [34]

which was mainly caused by the fouling and concentration polarization phenomena but we can also see that the potting time has also increased. This was due to the presence of the textile inside the membrane. This increased the time for water to pass through the membrane, and this favors the ionic exchange between the water to be treated and the ion exchange textile [35-37].

In order to verify this hypothesis, pH and conductivity measurements were made on the pre-treated water and on the permeate. These results are shown in Table 4.

Table 4. *Physico-chemical parameters of the ultra-filtered water.*

Parameter	Groundwater	Ultrafiltered water
pH	7.56	7.5
Conductivity (µS/cm)	987	583

According to the conductivity values, a clear decrease of the conductivity can be noticed in a very short time interval (after 30 min of UF) and with only 1 gram of textile (anionic+cationic). This reflects the efficiency of the ultrafiltration/ion exchange coupling (with textile).

Nevertheless, in order to further demineralize the pre-treated water, two other ultrafiltration passages are performed to deplete it in ions and preserve the cation and anion exchange membranes which are a part of the electrodeionization cell (EDI). This represents a finishing process to reach completely ultrapure water [38]. The results obtained are represented in the figure 4.

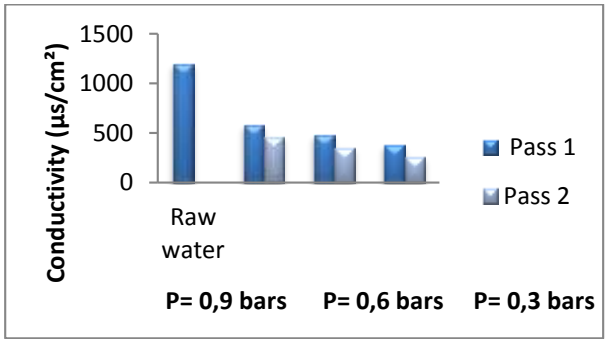


Figure 4. *Effect of the number of pass in UF on the conductivity of ultrafiltered water.*

III.4. UF- EDI

In this study, the feed solution was UF permeate with a conductivity of 237 µS/cm.

III.4.1. Voltage-current density characteristics

Different tests have been carried out to determine the limiting current imposed on the electrodes. The current intensity applied must not exceed a critical value called the limit current.

The curve I = f (V) (Figure 5) recorded allows us to define the level of diffusion. This method is very practical to determine the effective working areas, beyond which the yield of the process falls, which has as a global consequence a bad demineralization of the solution to be treated [39].

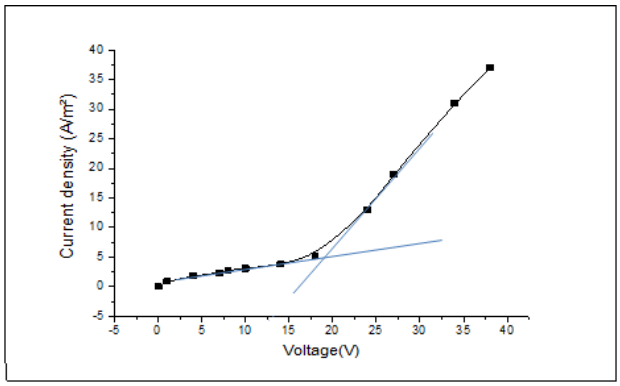


Figure 5. *Variation of current density with voltage in EDI process.*

As shown in figure 5, the current density increased more than the voltage, as seen in the UF permeate curves. The reason for this was that even at low voltage, the diluate compartment produced a considerable quantity of H^+ and OH^- ions.

Due to the increased conductivity of textile in H^+ and OH^- forms, the resistance of the stack decreased as more H^+ and OH^- are generated at higher voltage.

The voltage-current density curve for this study fell into two segments:

Segment 1 (0-18 V): As the voltage was increased,

the current density increased linearly. This section's voltage-current density curve follows Ohm's law.
Segment 2 (18-38 V): The same as the first segment, the current density increased linearly as the voltage increased, but at a faster rate. Water dissociation occurred in this segment, resulting in a considerable number of H^+ and OH^- ions being generated. As a result, there are more conductors present, resulting in a higher current density.
From Figure 5, the limiting current density can be calculated using the voltage-current density curve. It represented the cross-point of the tangents obtained from the first and second segments, which is approximately 1.38 A/m².
In order to preserve the optimal performance of the EDI cell, it was preferable not to exceed this current density limit [40].

III.4.2. Effect of current density on produced water quality

a) On the diluate compartment

As presented in Figure 6, The electrical conductivity of the diluate compartment decreased when the current density was increased. These results suggest that ultrapure water for pharmaceutical can be obtained by using current density from 0.5 A/m² to 1.3 A/m².

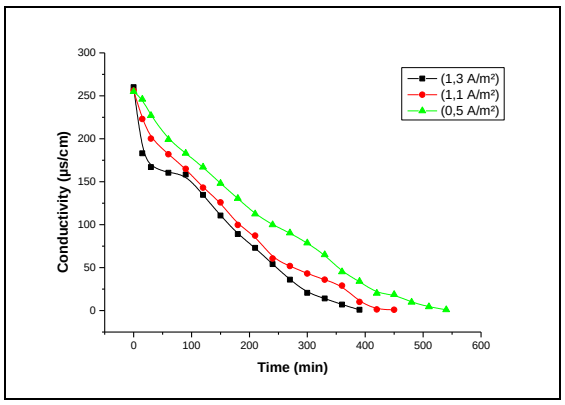


Figure 6. *Effect of current density on the conductivity of the dilution compartment (pH $_{ultrafiltred\ water}$=7.4).*

By examining the evolution of the conductivity as a function of time for the different intensities considered, it can be observed that the results are very significant and this is reflected by a demineralization of the water as a function of time and therefore the depletion of the solution to be purified in the dilution compartment.
The results show that for different current densities, the conductivity varies. They are lower for high densities, it can be shown that the conductivity decreases with time and more rapidly with the increase of the current density [41].
In fact, the increase in current density is favorable for the migration of the ions. It can be concluded that the increase of the density leads to a better deionization for a shorter time [16].

b) On the concentration compartment

In order to investigate the influence of the current intensity on the electrodeionization, a study of the evolution of the conductivity as a function of time for the different current densities considered revealed that the conductivity varies proportionally with the applied current density (Figure 7). It can be concluded that there was a better demineralization for a current density I=1.3 A/m².

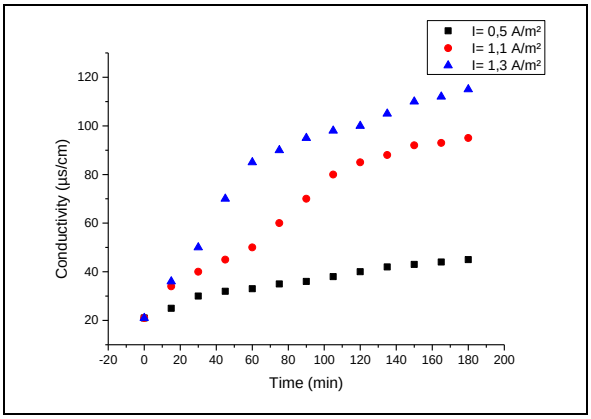


Figure 7. *Effect of current density on the conductivity of concentration compartment pH (Conductivity of distilled water = 20 µS/cm).*

III.4.3. Effect of current on pH

a) On the diluate compartment

As illustrated in Figure 8, the application of different current densities caused changes in pH from 7 to 6.8 in the diluate compartment. As known, the pH of ultrapure water must be between 6.6 and 7.6 [41].The diminution of pH can be explained by the mixed effects of electromigration and ion convection in the EDI - IET system. In this integrated process, ions can be transported through the textile by convection and at the membrane surface by electromigration.
When a high current density was applied, a strong electric field was induced in the diluate compartment. The high electric charge caused significant migration of all ions within the diluate compartment. At last, the increase of the proton migration rates caused the removal of protons in the diluate compartment, indicated by the decreased pH [42].

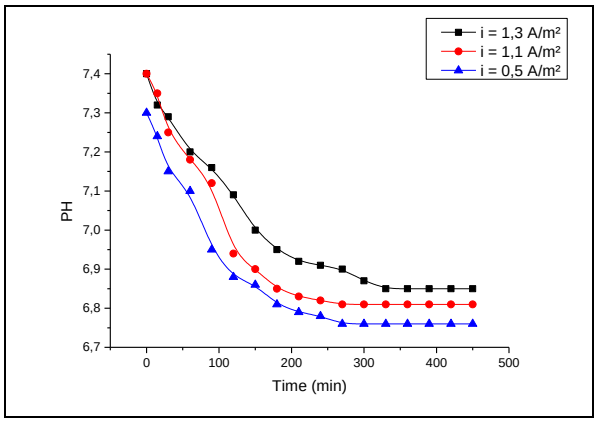


Figure 8. *Effect of densities of current on pH (Conductivity= 237 µS/cm)*

b) On the concentration compartment

As illustrated in the figure 9, the decrease of the pH in the concentration compartment as a function of time for different intensities used during the electrodeionization on textile can be attributed to the migration of the ions which are removed from the solution to be purified (UF permeate) and the H^+ protons produced at the electrodes under the effect of an imposed electric current from the dilution compartment into the concentration compartment [43].

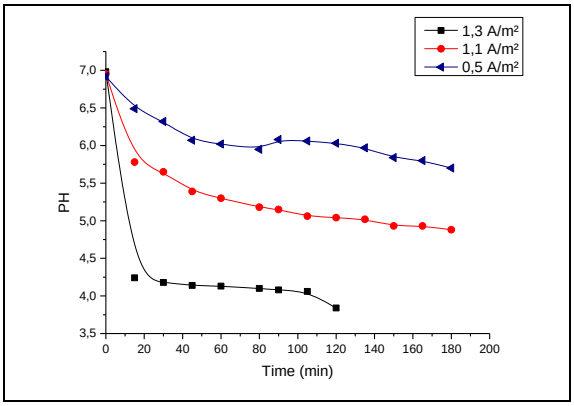


Figure 9. *Effect of density of current on the pH of the concentration compartment pH (Conductivity of distilled water = 20 µS/cm).*

III.4.4. Physico-chemical and microbiological analysis of ultrapure water

III.4.4.1. Physico-chemical analysis of ultrapure water

Various tests were carried out to control the quality of the ultrapure water obtained. The results of the different physico-chemical controls carried out are summarized in table 5.

Table 5. *Physico-chemical controls of purified water*

Test	Norme pharmacopoeia	Result
1. Aspect **a. Color** **b. flavor**	clear liquid colorless tasteless	conform
2. pH	[5-7]	6.3
3. Conductivity [µS/cm]	< 1	0.9
4. Test :		
Oxidizable substances	Persistent pink coloring	Conform
Chlorides	no change for 15 min	Conform
Nitrates	Maximum 0.2 ppm	Conform
Sulfates	Maximum 0.2 ppm	Conform
Ammonium	Maximum 0.2 ppm	Conform
Calcium and magnesium	Maximum 0.2 ppm	Conform
Residue on evaporation	Persistent pink coloring	Conform
Heavy metals	< 1 PPM	conform

According to the results presented in Table 5, it can be seen that the ultrapure water produced meets the standards required by the pharmacopoeia and could be used for the preparation of pharmaceutical products [32].

III.4.4.2. Microbiological test of ultrapure water

Microbiological control is a fundamental element of successful water treatment. in order to verify the microbiological quality of the water, various tests described in different pharmacopoeias are necessary [44]. After the EDI process a final pass through ultrafiltration was recommended in order to eliminate any possibility of bacterial contamination of the purified water. The results of the tests carried out are shown in Table 6.

Table 6. *Results of microbiological tests.*

Test	Norme pharmacopoeia	Result
Enumeration of aerobic bacteria	< 20 UFC ml	Absence
Enumeration of yeasts and molds	<100 UFC	Absence
Fecal coliforms	Absence	Absence
Total coliforms	Absence	Absence
Fecal Streptococci	Absence	Absence
CSR (Chlostridium sulfito reducer)	Absence	Absence
Pseudomonas Aerugenusa	Absence	Absence

According to the results presented in Table 6 there was an absence of microbial proliferation, reflecting the purity of the ultrapure water produced. It can be observed that UV disinfection is no longer necessary to remove any microbial contamination, and this will reduce the number of operations required to produce ultrapure water and also reduce the energetic consumption of the treatment process.

IV. Conclusion

In this study, the possibility of using a more sustainable process to produce ultrapure water for pharmaceutical use was successfull. In a conventional process, raw water was first treated by reverse osmosis, then by ozone injection or irradiation with ultraviolet rays to eliminate bacteria and viruses, and finally by electrodeionization where membranes and ion exchange resins are combined to produce ultrapure water with a conductivity less than 1µs/cm.

In this work, a new hybrid UF-IET/EDI process has been implemented to produce ultrapure water.

The first step is represented by an ultrafiltration coupled to an ionic exchange accomplished by the FIBAN ion exchange textile. Two passages at the UF-IET were sufficient to have a demineralization of more than 80% with a conductivity of 237 µS/cm.

The second step was the electrodeionization process which represents a finishing process characterized by an alternation between ion exchange membranes and fiban ion exchange textiles, which allowed to have an ultrapure water with a conductivity lower than 1µs/cm.

These findings demonstrate that this hybrid process with novel ion exchanger materials exhibit higher efficacy (more than 98%) while using less energy and lower investment, making it ideal for industrial scale-up in a variety of applications around the world.

In conclusion, the use of the hybrid process UF-IET/EDI has made it possible to obtain ultrapure water that meets the requirements of the pharmacopoeia while using a process that consumes less energy and has a reduced treatment chain than the conventional treatment requiring the use of a UV disinfection step.

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