

Design and Implementation of an ANN Based Intelligent System for Real-Time Monitoring and Fault Diagnosis in Pharmaceutical Reverse Osmosis Processes

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Abstract: This paper introduces a novel approach for real-time diagnosis of a purified water station designed for pharmaceutical applications. The water is produced using the reverse osmosis principle. Taking into account both the physicochemical properties required by international health regulations and the stringent standards of drug manufacturing, a diagnostic model based on artificial neural networks (ANN) is proposed. The developed intelligent monitoring system employs a multilayer ANN with gradient backpropagation (5-15-5). Its primary objective is to detect and localize potential faults within the water production process. The monitoring focuses on the physicochemical parameters of the purified water. Simulation results demonstrate effective fault detection, characterized by high accuracy, fast response time, and reliable performance.

Keywords: Pharmaceutical industry, Artificial intelligence, Artificial Neural Networks, Gradient back-Propagation Algorithm.

1. INTRODUCTION

Production of purified water occupies a prominent place in drugs manufacturing. Due to high quality with respect to water parameters rulebooks and technology purification systems following their physicochemical nature and their various complex parameters a model is developed to insure a high drugs quality production. The existing defect detection techniques are offline treatment. Knowing the importance of these requirements imposed on this vital source in pharmaceutical industry a model is proposed based on artificial neural network (ANN) monitoring the system in real time with high accuracy detection of any abnormality of the water station. The purified water station production is dedicated to Pharmaceutical Industry.

The monitoring [1], [6, 8] system of purified water [5, 7] has unique characteristics that is essential to be considered in designing complex system. Drugs quality must be guarantee with high performance. The monitoring and parameters control of purified water are insured online permanently. To respect these parameters, we have to follow

the pharmaceutical industry requirements given below:

- Guide FDA (Food and Drug Administration) pour les inspections des systèmes d'eau de haute pureté (07-93).
- Recommendations of PIC/S (Pharmaceutical Inspection Co-operation/Scheme), PE 008-4, Annex 1, 1 January 2011, Appendix 7 (Schematic drawings of water systems);
- Quality of water for pharmaceutical EMEA (The European Agency of the Evaluation of the Medicinal Products) 2002;
- Baseline guide Vol. 4 water and steam systems ISPE (International Society for Pharmaceutical Engineering), Published 15 December 2011.

In recent years, significant efforts have been used in developing new control methods and self-monitoring for such a system. Techniques of ANN that serve as a basic tool for decision support, present a more elaborated tool used by the designers. In the literature, we may find these technique of ANN [1, 2], [4], [7, 9]. They are chosen because of their ability of learning with high speed. They are used also in pattern recognition as a tool for classification or regression [1].

In this paper we present a new model-based on ANN integrating a monitoring system designed to control the quality of purified water [10] to meet the parameter rulebooks requirements and quality drugs in the production process.

2. PURIFIED WATER STATION

Drugs manufacturing technology is very severe in terms of quality, reliability and efficiency. Purified water station must fill all demands and provides high quality water during the process. Notice that the most important part of the process is the purified water which is crucial in drugs production. Define abbreviations and acronyms the first time they appear in the text, even after they have been defined in the abstract. Avoid using abbreviations in the title or heads unless it is unavoidable.

Purified water station is the strategic equipment in the drugs factory. This water station includes four principal parts, which are: mixing softening part, ultra filtering, osmoses stations and purified water feed forward loop for the factory.

Processing of reverse osmosis is given in Figure 1.

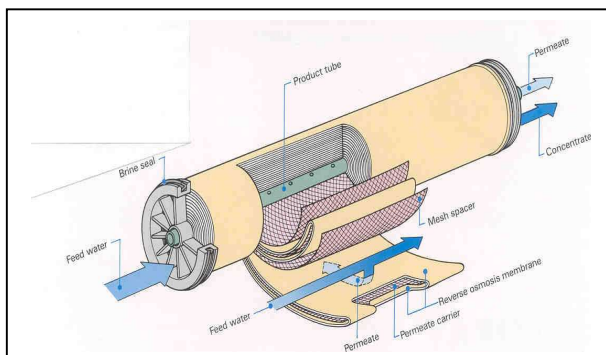


Fig. 1 Reverse osmosis.

3. STATION PARAMETERS

Table 1 shows the reverse osmosis parameters given by the membrane manufacturer.

Table 1 Output Parameters of the Reverse Osmosis

Parameters	Specifications
PH	[5.5 7.5]
Conductivity	[0 2] $\mu\text{S}/\text{cm}$
Temperature	[13 15] $^{\circ}\text{C}$
Permeate pressure	[0 12] Kg
Concentrate pressure	[2 3] Kg

4. APPLIED APPROACH STRATEGY

The water treatment passes through several steps. The first is the softening step; the second is the ultra-filtration and finally the step of the reverse osmosis. Due to the complexity technologies of the membranes in both reverses' osmosis, we have to supervise rigorously their parameters. The supervised parameters in this purified water station are:

PH: The PH is the parameter of purified water quality, following the standards below:

- U. S. FDA Guide to Inspection of Highly Purified Water Systems, Annex 1, 35 and Annex 9, 10, 15.

- PIC/S Guide 3.10, PI 009-1, Aide Memoire: Inspection of Utilities.

Conductivity: the conductivity is the principal parameter of the purified water quality.

If this parameter is in the standards, dissolved matter (organic matter, gas, minerals ...) and living matter (viruses, bacteria ...) are neutralized.

European and American conductivity Standards in the pharmaceutical industry are:

- EP (European Pharmacopoeia), conductivity ($\mu\text{S}/\text{cm}$ at 20°C) ≤ 4.3 ;

- USP (U.S. Pharmacopeia), conductivity ($\mu\text{S}/\text{cm}$ at 25°C) ≤ 1.3 .

Temperature: the oxygen (O_2) varies in water from zero (0) to saturation, its maximum content decreases with temperature. Moreover, this physical parameter affects directly the chemical reactions (kinetics, solubility ...) and the development of living organisms.

Permeate/concentrate Pressure: This physical parameter is very important in the osmosis operation. This parameter is an indicator of several defects particularly the membrane fouling. It affects the rate (conversion rate = (permeate flow/feed flow rate).100) of the station (clogging of membranes). So we can monitor through pressures the state of membranes. Noting that, the permeate is the produced pure water; however the concentrate is the rejected.

Finally, the global strategy of our approach is given in Fig.2, which shows the various steps of the process in the purified water station. It shows clearly the membranes of the reverse osmosis, the supervised parameters within the model and finally decision to take in case of faulty which can occurs in the process.

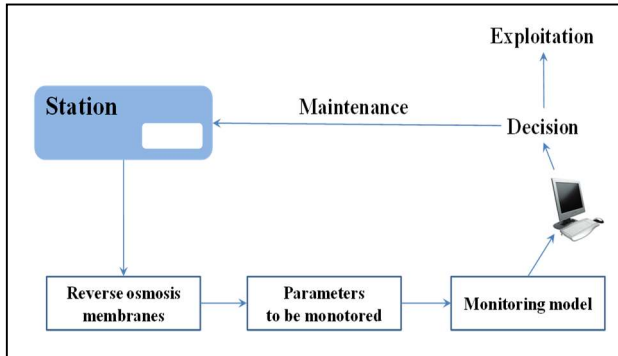


Fig. 2 Global Approach Strategy.

Figure 3 shows the proposed neural model placement which model the reverse osmosis given in Fig.1. This part constitutes the last element of the purified water station. The osmosis has four (04) semi-permeable membranes that work in series and equipped with several sensors placed in strategic points in the process as shown in Fig.3. The sensor (S1) is used to measure the PH, sensor (S2) for conductivity measurement, sensor (S3) for temperature measurement, sensor (S4) for the permeate pressure measurement, and sensor (S5) for the concentrate pressure measurement.

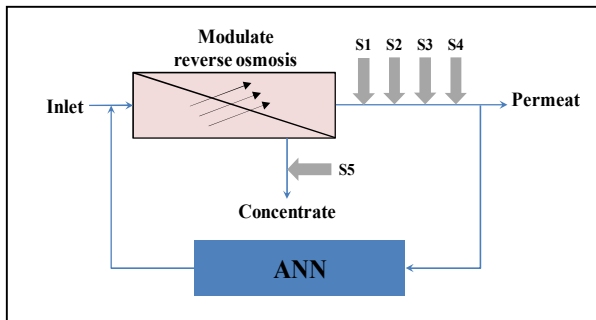


Fig. 3 Proposed Neural Model Placement of the Inverse Osmosis Station..

5. NEURAL MODEL OF THE MONITORING SYSTEM

To build the network you must follow the steps below.

Step 1: Network Inputs

- We must identify the functioning range values in normal condition for all the considered sensors. These values are given by the manufacturer (Table 1).
- Each parameter value given by the sensor is an input value of the neural network.
- The neural network should detect any values out of the range given in Table I. This detection will be considered as a fault of the

osmosis station. The sensibility detection has been chosen of the order of 10⁻³.

Step 2: Network Construction

- The neural network is a multilayer network (feed-forward) with gradient back propagation [3]. The best neural configuration is: first layer contains (05) neurons, hidden layer contains (15) neurons and the output layer contains (01) neuron.

- The used activation function is the bipolar sigmoid function.

- The neural network receives all settings values from the input of the osmosis station.

- Fault detection depends on the measured values given by sensors from S1 up to S5. The network output is in state '1' if and only if all sensors values are within the acceptable ranges. Otherwise the network output will be in state '-1' to indicate a faulty in the system.

-Detection is generated with respect to Table 2.

Table 2 Matrix of detection of neuronal network

Input values of the ANN					Output values of ANN
S1	S2	S3	S4	S4	
1	1	1	1	1	1
-1	-1	-1	-1	-1	-1
-1	1	1	1	1	-1
1	-1	1	1	1	-1
1	1	-1	1	1	-1
1	1	1	-1	1	-1
1	1	1	1	-1	-1

Step 3: Network Learning [3], [4]

- Building the learning matrix from the input vectors

- Preparing the learning samples so that the network learns all possible combination parameters of the osmosis station.

- Normalizing the input matrix with the desired output vector (each input value of the learning matrix should correspond to the desired output).

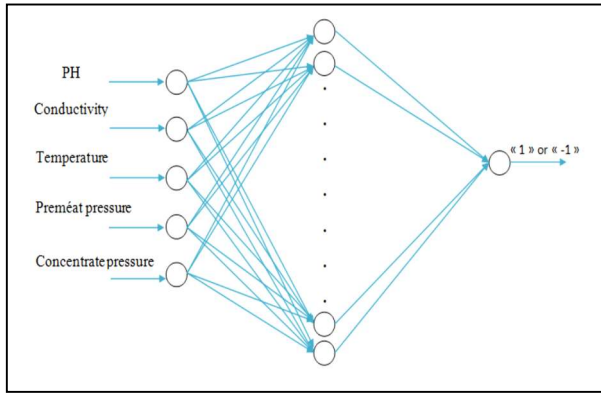


Fig. 4 Proposed Neural Model (5-15-1).

- Network training using the gradient back-propagation algorithm given by Fig.5.
- Network parameters are summarized in Table 3.

Table 3 Learning Parameters

Chosen parameters	Neuronal model (5-15-1)
Network type	Multilayer network (feed-forward)
Learning type	Supervised learning
Activation function	$F(x) = \frac{1 - e^{-x}}{1 + e^{-x}}$
Used algorithm	Gradient back-propagation algorithm
Error (goal) learning G	G= 0.001
Learning step	$\mu= 0.1$
Iteration number NB	NB= 500

Step 4: Network Simulation

Based on the proposed learning algorithm given in Fig.5 of the neural model given in Fig.4, we minimize the mean square error until it reaches the desired value (10⁻³) within the iteration number

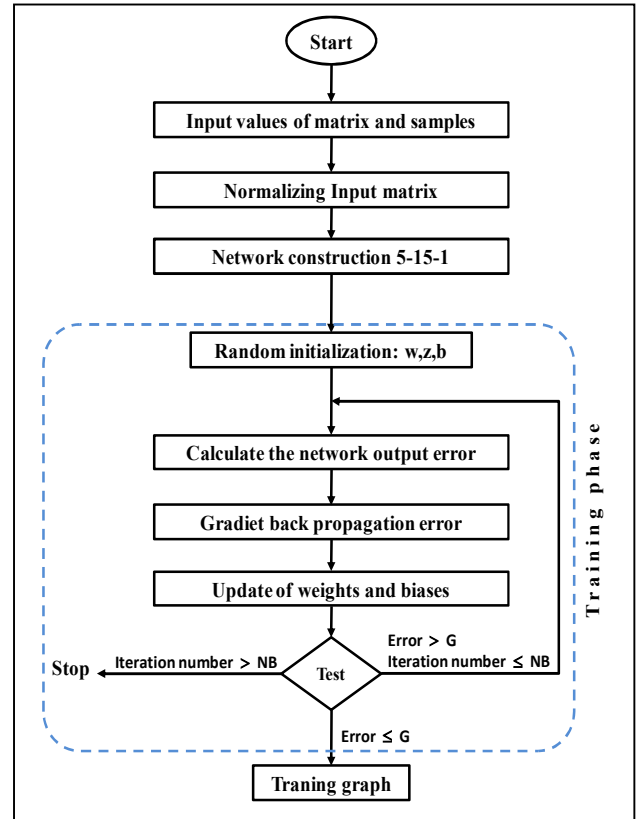


Fig. 5 Flowchart of the Learning Algorithm.

6. SIMULATION AND RESULTS

Figure 6 shows the simulation results of the learning phase of the neural network (5-15-1). This graph shows the mean square error function cost convergence. This cost function converges rapidly in only 32 iterations by considering an error of 10⁻³. This shows the learning speed of the neural network. Furthermore, we remark the absence of local convergence (local minimum) obtained in Fig.6. This confirms the learning parameters choice. Also, we observe two small perturbations at 2 and 20 iterations which are due to the instability of the measured values. But, they have no influence on the reliability of the obtained results.

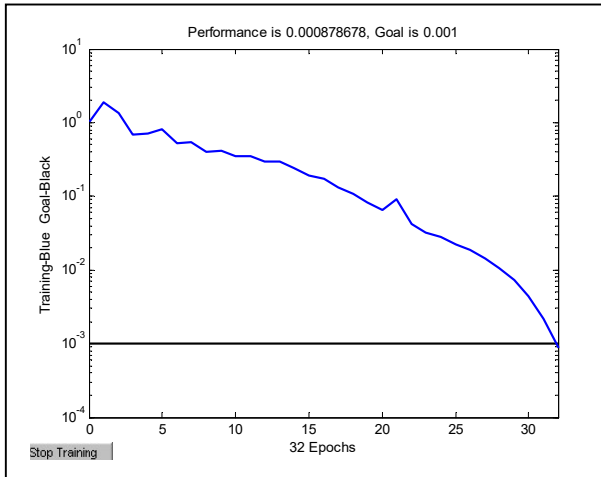


Fig. 6 Learning Curve.

After the learning phase, it is useful to simulate the trained network outputs to show its detection capability for unknown values. The obtained results are given in Fig.7. This figure shows clearly the normal functioning values which are all concentrated at symbol '1', where as the abnormal values are concentrated at symbol '-1'. We can conclude that the network has efficiently recognized the desired outputs to differentiate between normal and faulty functioning.

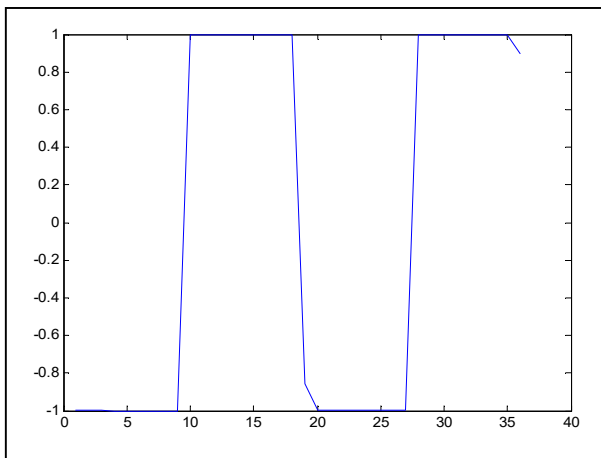


Fig. 7 Simulation Network Outputs.

To evaluate the network performance, Fig.8 is used to show the correlation between the network output values and the desired values (target). The dashed blue line is the linear equation which is of the form $(A = aT+b)$, this equation represents the target. The continuous red line is also the linear equation obtained from the simulation results using the sensor values within the tolerated range ($A = 0.993T + 0.00122$). The target equation and the obtained equation are closely similar. In fact the slope of the equation is 0.993 which is closely to 1 and 0.00122 is also closely to

0. Moreover, the obtained correlation coefficient, R is approximately equal to 1.

All the obtained results are concentrated in the range of $[-1, -0.8]$, indicating default in the osmosis station or concentration in the range of $[0.8, 1]$ indicating normal functioning, as shown in Fig.8.

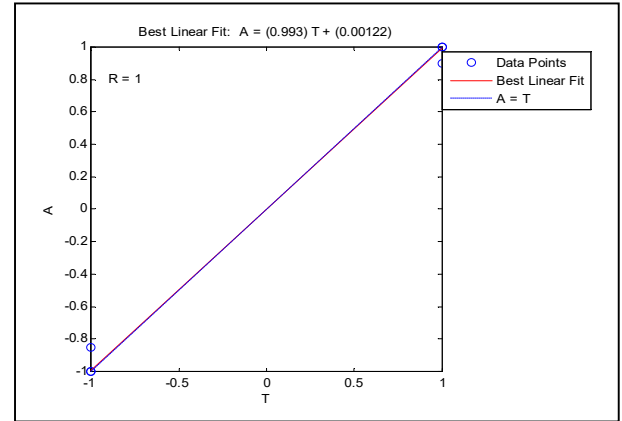


Fig. 8 Network Performance.

Figure 9 shows the capability of the network to detect any fault in the osmosis station for any unknown values. This is due to the capacity network regeneration (associative memory network).

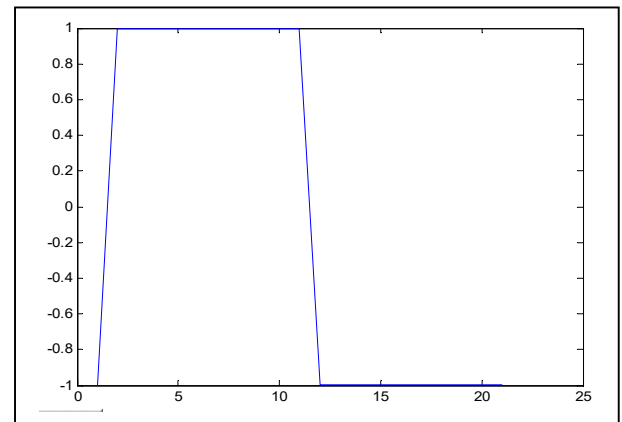


Fig. 9 Simulation with Unknown Values without Learning Phase.

By introducing some measured known values in normal functioning mode, as recommended by the manufacturer during the starting of the osmosis station, the obtained simulation results are shown in Fig.10, which shows the detected outputs are all in the neighborhood of '1'.

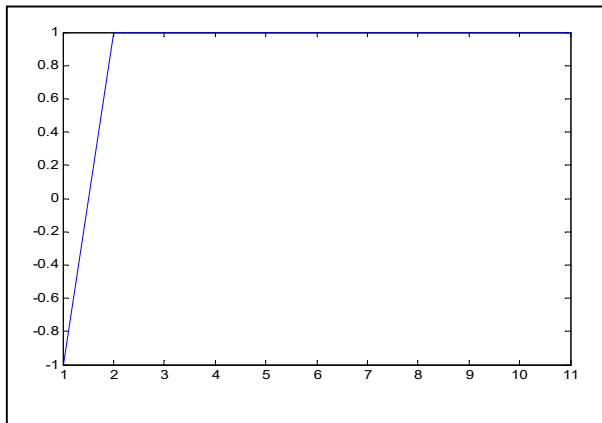


Fig. 10 Obtained Results in Normal Functioning Mode.

On the other hand, when we introduce some measured out of range values in the neural network, the default is automatically detected. Fig.11 shows the obtained simulation results where the outputs are all in the neighborhood of '-1'.

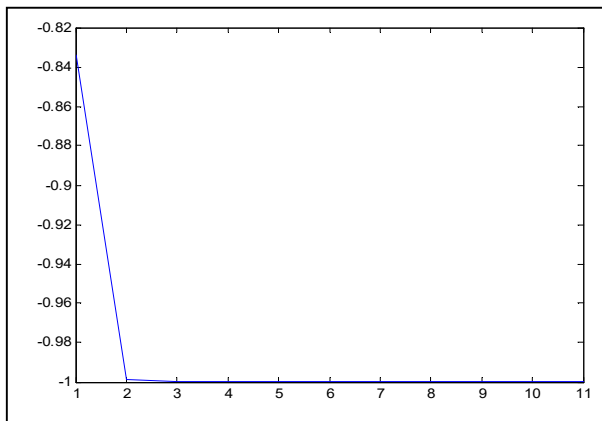


Fig. 11 Obtained Results in Failing Mode.

7. CONCLUSION

This contribution presents a diagnosis study in real time of the reverse osmosis of the purified water station used in Pharmaceutical Industry. The neural model is based on the multilayer gradient back-propagation network (5-15-1). The neural network inputs are the physicochemical parameters of the outputs of the osmosis system. These parameters are the permeate pressure, concentrate pressure, temperature, PH and conductivity. The neuronal network outputs are normalized in such a way to have two states, either state '1' which symbolize a normal functioning and state '-1' which symbolize default in the osmosis purified station. The convergence of the proposed neural network is obtained in only 32 iterations which seems to us that the network have a rapid learning.

We notice that in the learning phase, the phenomena of over-learning and local minima

didn't appear in the obtained results given in Fig.6. This means that the choice of the parameters introduced in the gradient back-propagation algorithm are suited for this application. Moreover the detection calibration error accuracy of 0.001 is largely sufficient.

All the obtained results are concentrated in the range [-1, -0.8], indicating default in the inverse osmosis station or in the range [0.8, 1] indicating normal functioning, which were given in Fig.8. The accuracy of the results allows us to assess the sensibility of the network to detect any faults that can occur in the purified water station. This insures the quality of the water as depicted by the requirement rulebooks.

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