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Effectivness of Automation in Drug Production Pipelines

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1 INTRODUCTION

The automation, in manufacturing, is a system or a method in which most or all processes of production, inspection of parts and materials are done automatically or operated by self-operating machinery, electronic devices or controlled by any other method to replace human interference to control the system need to be controlled [2]. Computer is indispensable where equipment requires microprocessor or microcontrollers control for diagnostics or operation. A picture that comes readily when dealing with automation is of fully automated systems. In these systems, unit automation is integrated with most commonly device (the robot or robotic arm) for running activities such as transferring containers, filling, labeling and so on. The complexity of the systems range from feeding drug containers to large systems capable of performing complicated processes even diagnosing the system's errors or maintains them. Many equipment manufacturers have develop these control systems with variety of architectures. The introduction of robotic fingers for existing an industrial arms that are capable of griping or moving bottles or containers in manufacturing pipelines are made feasible integration of modular units automation. Many systems are now can be designed by professional integrators whose business is the creation and assembly of systems rather than manufacturing equipment. While staffing will be reduced by using automated systems, still the throughput will greatly increase and the total cost will be reduced. This is due to reduction of man power and the increment of working hours by automated systems. Automated system with computer can easily be modified by changing software to add new features to this system [2].

2. SYSTEM LAYOUT

The aim of the hardware and software design is to automate the syrup powder filling operations. The electronic devices required to construct the system are a personnel computer, micro-controller, sensors, and solenoid valves, plus interconnection links and lab link cables.

3. PROBLEM STATEMENT

Pharmaceutical industries control one of the processes that need a highly and fully automated control system; this is because the traditional control of those systems by using classical control will make many problems. One of the greatest problems is the human interference in the processes of controlling production of medical drugs, this includes the contamination of drugs by handling them by persons or human factor faults.

Another problem using classical control systems; they have low production speed and time consuming compared to fully automated systems. This will be added to the human factor where humans are working in shifts not in full day like automated systems.

4. THE PAPER METHODOLOGY

The research is dealing with syrup and powders automated system filling bottles, and their flow and safety control and capping closing, packing and storing. Initially the containers are fed through the chain to be controlled the microcontroller and the count is displayed in the screen. The bottles are moved in a sequence of processes through a production line. Then the bottle is transferred to the filling station, when it is located, the filling hoper will be released, and the bottle will be filled to the required amount. When the filling level is reached, then the powder or tablets or syrup flow filling will be stopped by closing the hoper valve and the bottle is transferred to the closing station .When the cap is put on it and labeled, the bottle will be transferred to packing. The packing process will be done by robotic manipulator which transfers the drug bottles into the packing box. And this is well controlled by using forward and inverse kinematics and their effect in robotic manipulator movement error control is analyzed by math lab software. The production of syrup filling include bottling (feeding), cap closing, labeling, packing and storing operations. Figure (1) shows a sketch of block diagram for the different stages of the drug production processes summery.

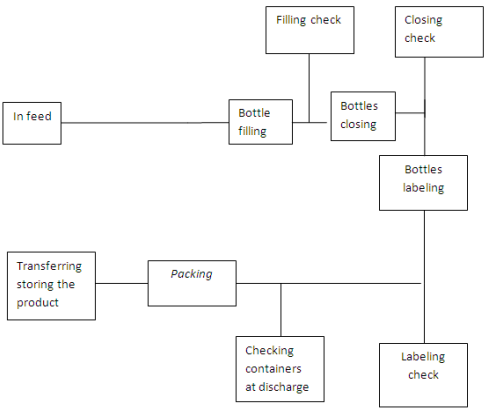

Figure (1) General outline drug production pipeline

5. TECHNOLOGY AND AUTOMATION IN PHARMACY OPERATIONS

Technology is an increasingly important element in operations management. It may be defined as "anything that replaces routine or repetitive tasks that were previously performed by people or which extends (or enhances) the capability of people to do their work" (Rough, 2001).

Merriam-Webster (2009) defines technology as "the practical application of knowledge especially in a particular area" and "a capability given by the practical application of knowledge".

On the other hand, automation refers to 'any technology, device or machine that is linked to or controlled by a computer and used to actually do work that was previously done by humans' (Rough, 2001). In essence, all automation is technology, but the reverse is not necessarily true.

Automation is a trend in technological development, which seeks to eliminate direct manual involvement in control procedures; whereas, mechanization is a component part of automation and it is concerned with replacement of manual labor with machine (Encyclopedia Britannica, 2010). the use of technology and automation is paramount in the focus of operations management on improvements of business support services. Technology as an enabling factor has an indirect impact on work and it should be considered whenever quality and efficiency is low, particularly in processes such as dispensing of medicines in a pharmacy. These activities are repetitive in nature but amenable to some basic technology. The decision to substitute technology for labor in such support services is the only way to reduce processing and transactional costs over the long run.

The Local Enterprise Authority (2009) identified three types of technology; these are product, process and support technologies. Product technology is embodied in the organization's product and it is often an important element of the product. It provides the products innovative features, improved performance, and the very materials that goods are made from.

Scientific knowledge is applied in development and production of medicines by pharmaceutical manufacturers and other healthcare researchers for the purpose of improving health and wellbeing. For this reason, medicines and other pharmaceutical products can be regarded as technology. Examples are drug delivery systems such as transdermal patches and implantable computer incorporated drug administration devices. These are classified as product technologies covered in the area of pharmaceutical technology (Bozzette et al., 2001).

Process technology is employed in the production process and refers to the actual method used to transform inputs into outputs or finished goods and services. It concerns the equipment used, the operations performed on materials or customers in the service systems and such technology could be manual, or automatic. In most cases, a range of technologies is available for defining a specific process and each one has advantages and disadvantages, which must be weighed in the light of a firm's competitive priorities. Technology is also often a crucial part of the process to produce and/ or deliver the product, for example digital technology to produce and deliver published medicine information materials for use in patient care. On the other hand, support technologies are used to perform certain other activities that are not embodied in the product or production process of an organization. Among such technologies are information and communication tools such as software packages, computer networks, and quality assessment technology.

The goal of operations management is effective and efficient use of resources which is enabled by technology; hence its need in the management of pharmacy operations. The benefits of technology to support pharmacy operations include improvement in safety, efficacy and economy of medicines (Slee *et al.*, 2002). The compelling need for technology and automation is partly the result of innovations in creation and design of new technologies and increased labor costs which call for more cost effective production systems and operations (Garsombke and Garsombke, 1989). Developments in technology can be seen as developments in the innovation process and technological innovation is the first commercial introduction of a new technology, which may take the form of a product, process or service (Ilori, 2006).

The use of technology in pharmacy operations improves medication safety in patient care and also enhances efficiency of the medical process. Furthermore, it improves the documentation of care (Kelly, 2006). Nevertheless, it is believed that the application of sophisticated technology in operations management poses its own challenge; while technology improves medication safety and processes in terms of reduced medication errors, there is little evidence to suggest that any single technology has the potential to radically reduce adverse events.

However, there are incremental benefits to be derived from each and full benefits may only be realized when several technologies are used and integrated [8].

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Technology could be manual, automatic or mental. In most cases, a range of technologies is available for defining a specific process and each one has advantages and disadvantages, which must be weighed in the light of a firm's competitive priorities. Technology is also often a crucial part of the process to produce and/or deliver the product, for example digital technology to produce and deliver published medicine information materials for use in patient care. On the other hand, support technologies are used to perform certain other activities that are not embodied in the product or production process of an organization. Among such technologies are information and communication tools such as software packages, computer networks, and quality assessment technology.

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7. PHARMACEUTICAL PROCESS CONTROL

Pharmaceutical products are produced under carefully controlled conditions to ensure product quality. Each process is different and requires close attention to detailed steps. Sterilization, fermentation, extraction, neutralization, filtering, freeze drying, and centrifuging are typical processes found in this industry. The development of new medicines requires a variety of measurements in different processes. The control system must be accurate enough and flexible to accommodate these demands. In some

cases the control system needs to control a portion of the process while it measures the results. The monitoring and precise control ensures that new processes are tested thoroughly. By Operator interfacing with computer can be developed to offer the operator, data analysis, and storage and reports generation. [5] The main processes parameters that need to be measured are shown by the following:

8. PROCESS TEMPERATURES

The temperature measurement and control is important in most pharmaceutical processes. The temperature is often used to control the speed of chemical reactions. The thermo-couple or thermostats are used with data acquisition systems to measure process temperatures. Those data acquisition systems can control heaters or chillers to adjust temperature in processes.

9. PRESSURE PROCESS CONTROL (PUMP AND VALVE CONTROL)

In some pharmaceutical processes maintaining pressure is crucial for obtaining the correct chemical reaction. Pressure transducers usually output a voltage or a current proportional to pressure value. Pressure can be controlled by actuating pumps and valves through automatic control system [5].

Some processes are continuous and require a certain flow rate control for one or more chemicals entering the reactor vessels. Flow monitoring of control systems needs sensors flow meters with digital display and the control of flow also needs automatic control system to adjust the flow rate by adjusting certain valves automatically [5].

10. CHEMICAL COMPOSITION

The density of ions like Bromide, Fluoride, Nitrate, Sodium, and Sulfide can be measured with transducers. The acidity (PH) value measuring may also be in managing chemical process. With carefully monitoring and controlling over the amounts of chemicals entering the process the correct chemical composition can be obtained.[5]

Process tanks level control will reduce cost. This is done by proper liquid levels in tanks control throughout the process. High levels (over flow) require extra chemicals flow control while low levels needs control for chemicals not to diminished (empty tanks) and this may result in improper chemicals composition. Both digital (point levels sense) and analogue (continuous level sense) techniques are commonly used [5].

An agitator is used to mix solids, liquids, or gases thoroughly. Shaft encoders can be used to monitor the speed of the agitator while torque transducers can be used to monitor the consistency of the product being agitated [5].

Solids can be accurately by using weight load cells which provide a linear voltage output or bridge output that can be measured by the data acquisition system [5].

11. REVIEW OF PHARMACEUTICAL COMPOUNDING

The history of pharmacy and pharmacology dates back to medieval times with priests who ministered to the sick with religious rites as well. In 9th century specialization in

drugs production accrued in Baghdad and gradually was spreading to Europe as alchemy that prepares medicines and prescribes them then pharmacist who compounded prescription and manufacture them appears in 19th century of civilized world.

Pharmacy is the art of preparing dispensing drugs .the word is related to Greek pharmakon (Remedy) or the Egyptian term Pharmaki [10].

Representation of the process and the associated constraints mean modeling of both process and constrains in an autonomous fashion with sufficient accuracy. Additionally, these models need to be updated continuously in order to be valid over the life span of the industrial process.

Without an autonomous scheme, the human user will fail to keep these models updated in the long run timeless factories drugs factories with mechanical machinery.

Selection of the method and tools that are used to adapt and optimize the process automation is usually conducted in a priory fashion by the human user. In this selection the expert knowledge of the user grantees that the methods or tools will be applicable to the case at hand which is a combination of the cost function and the process and constraints?

Autonomous selection would require a scheme that can quantify the applicability for a certain type of cost functions, processes and constraints.

Fault tolerance and safety is a necessary prerequisite, since hardware failures will inevitably occur during the life cycle an industrial process [5].

Pharmaceutical companies are the ones of the most strictly regulated companies where precise control of the end product quality is highly desired to satisfy the standard set system governed by the regulatory authorities to ensure the efficiency of the drug products.

Continuous pharmaceutical manufacturing enables the implementation of efficient automatic real time monitoring and control of critical process parameters and critical quality attributes as desired for quality by design rather than quality testing based manufacturing. There are many factors that can affect the end products involving dosage forms. For example, the raw materials and process variability and any other non-measurable process disturbances can up-set the process and thereby the product quality.

An automatic feedback control system, though essential to ensure the end product quality in real time, can take action only after the disturbances affect the product quality. Therefore, a feedback standalone strategy is insufficient to provide near perfect control of the process which is often needed for the manufacturers of pharmaceutical products.

A feed-forward control strategy takes action before process disturbances can affect the product quality. However a feed-forward only control strategy does not take into account the feedback signal of the control of control variables and, as a result of unmeasured process disturbances, the control variables or the end product quality can deviate from the desired values [10].

It is a quality assurance system that ensures the consistency of product production according to standards of usage an d marketing authorization. GMP is aimed primarily at diminishing the risk inherent in any pharmaceutical production. Such risks are essentially of two types: cross-contamination, (unexpected contamination) and mix-ups (confusion) caused by false labels put on the container as an example.

Under GMB:

(i) All manufactures are clearly defined, systematically reviewed, and shown to be capable of consistently manufacturing pharmaceutical products of required quality that comply with their specifications.

(ii) Qualification and validation are performed.

(iii) All necessary resources are provided, including appropriately qualified and trained personnel, adequate premises and space, and suitable equipment and services, appropriate materials, containers and labels, approved procedures and instructions, suitable storage and transport [15]

12. Electronic Circuit Design And Process Simulation

The project contains some electrical, electronic, mechatronic components, and sensors and actuators. The design contains some electronic circuits for building the control circuit. This includes drivers, amplifiers, and microcontrollers, assist in providing consistent product quality.

For the robotic arm movement three servomotors are used for the manipulator for picking up and placing down the objects, upward and downward of the arm and for the circular movement at the base. This is to control robot arm movement from its start position to assigned place to the bottle and move it to its desired place at the packing box.

The processes operations are controlled by the microcontroller from the start command from the operator then the bottles filling up to the labeling process. The control of the robotic manipulator is done through the proportional, integral and derivative controller (PID). For the drug production pipeline the conveyor is moved by a stepper motor for filling, capping labeling or packing. [11].

The design begins at the start of the pipe line when the bottles are moved to feed station by a motor. Then the valve at the nozzle is activated open to start filling of the bottle. When the powder, tablets or syrup in the bottle reached the level needed this is checked to stop filling.. After that, the bottle is closed by the capping system, then it will be carried by the robotic manipulator to container and packed and then to be transferred to be storing area. The complete block diagram is shown in fig (2) below.

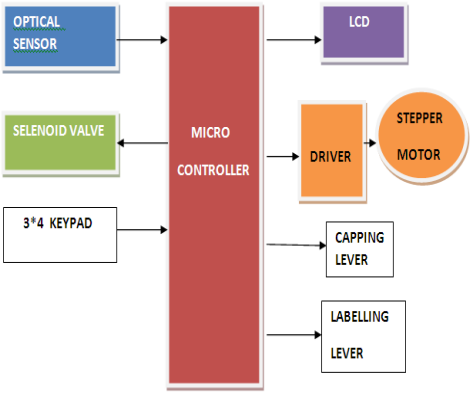


Figure (2) Block diagram of the drug system

13. ELECTRONIC & ELECTRICAL COMPONENTS:-

1 the motors

For this research motors are the race horses in this project since all the actions and movements of the pipeline and the robotic manipulator are done by these motors. Here mainly, servo motors and stepper are used.

2. DC motors

The idea of DC motor is that; when a current carrying conductor is placed in magnetic field a mechanical movement can be produced, as shown in figure below.

3. AC Motors

The basic operating principle of an ac motor also involves the interaction between two magnetic fields. In this case however, both fields are varying in consonance with the ac excitation voltage. Therefore, the force between the fields is the function of angles of rotor and the phase of current passing through the coils. There are two basic types of AC motors, synchronous and induction motor. The primary motor for application to the control industry is the induction motor [1].

4. The Stepper motor

Stepper motor is an electronic device that can transfer movement to its attached object and derives it towards a particular direction in stipulated steps when it is controlled by microcontroller to give precise useful actions depending on the control input signals from the controller, the stepper motor can be caused to exhibit various effects through specified mode of operation. It is applied in electromechanical devices were precise or specific angular movement is addressed.

5. Programming Language software for drug production pipeline

To achieve the automation procedure for the syrup-powder production pipe line it is need to go through the following steps:-

Step one is developing a Mikroc program in Microcontroller.

The program algorithm is: These production pipeline steps are seen in the following diagram shown below.

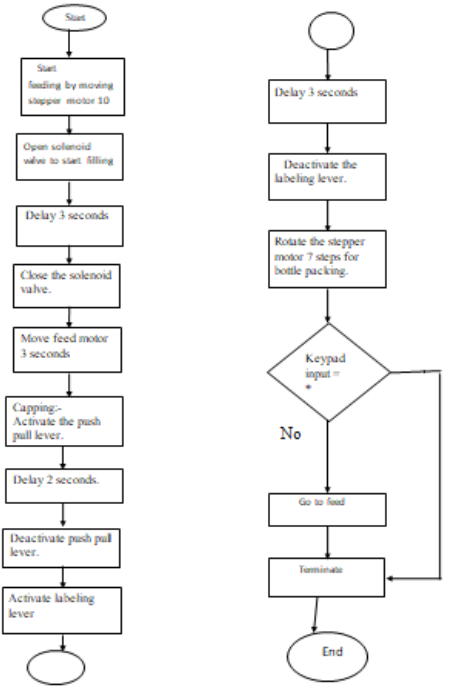


Figure 3 showing software program sequence flow chart

14. THE PACKING SYSTEM

1. Introduction

Moving from trend to tradition, more and more manufacturers are adding robotics to increase productivity, increase uptime and assist in providing consistent product quality. Here robotic arm system is developed to control the functions of process. The system software is designed and analyzed by Mathlab to control drug bottle packaging operation in the pharmaceutical pipeline**.**

Running conditions are shown by motors through their kinematics modeling of the robotic arm which is used as packager. This system is developed to study the implementation of kinematics in automation of packaging of drug bottles as in figure (4).

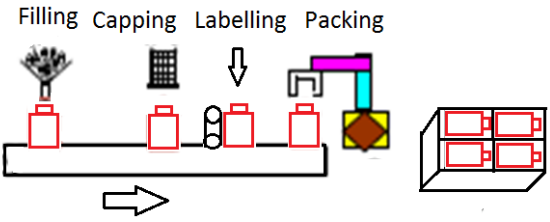


Figure (4) showing the drug production pipe line and the packing system.

The packaging system is composed of robotic hand with three joints, three links and three degrees freedom. Research is focused on drug production and considers integration with robotic hand packaging system to streamline the drug production process in the pharmaceutical industries.

The robot arm is flexible with 90 swiveling range that allow it for free positioning of bottles within working area. Moreover it is connected to drug production processes and worked together with filling and capping machines on the same conveyor. The simulation of robot systems is becoming very popular, especially with the lowering of the cost of computers, and it can be used for layout evaluation, feasibility studies, presentations with animation and offline programming.

Modeling and simulation of robots could be achieved using either of the following models: the geometrical model (positions, postures), the kinematic model and the dynamic model

2. Modeling and simulation of robot manipulator

Modeling and simulation of robot manipulator could be achieved using either of the following models: the geometrical model (positions, postures), or the kinematic model. To do so, the modelization RPP of a robot type is implemented r. Our main task is to control the trajectory of the manipulator. This is done by giving reference trajectory to be tracked by the manipulator end-effector, and establishing a computing code to obtain the kinematic by MATLAB software which is used to check the accuracy of robot manipulator motion.

The simulation of robot systems is becoming very popular, especially with the lowering of the cost of computers, and it can be used for layout evaluation, feasibility studies, presentations with animation and offline programming.

The possibility to perform real time simulations becomes particularly important in the later stages of the design process. The final design can be verified before one embarks on the costly and time consuming process of building a prototype.

The need for accurate and computationally efficient manipulator dynamics has been extensively emphasized in recent years. The modeling and simulation of robot systems by using various programming software will facilitate the process of designing, constructing and inspecting the robots in the real world. A simulation is important for robot programmers in allowing them to evaluate and predict the behavior of a robot, and in addition to verify and optimize the path planning of the process [21]. Moreover, this will save time and money, and play an important role in the evaluation of manufacturing automation. Being able to simulate opens up a wide range of options, helping to solve many problems creatively. One can investigate, design, visualize and test an object before making it a reality [22].

15. RESULTS AND CONCLUSION

15.1 Results

Equation (2) below gives the total time (T total) taken for filling a single bottle with syrup powder.

$$T\ total = T\ feed + T\ fill + T\ cap + T\ label + T\ packing \quad \ldots\ldots\ldots\ldots (2)$$

Where:

T feed = time of feeding the bottle (seconds). T fill = time of filling the bottle (seconds).

T cap = time of capping the bottle (seconds). T label = time of labeling the bottle (seconds).

T packing = time of packing the bottle (seconds).

By implementing the system design, it is found that the resultant time (T total) per one bottle is :

T total = 7 seconds + 3 seconds + 2 seconds + 3 seconds + 7 seconds = 22 second

For increasing the productivity , we need to speed up the five intervals in equation (2).It is found that speeding up the operation results in malfunction of the system .The optimum timing recorded is equal (22 seconds) for a bottle to be filled and packed. Figure (5) shows the characteristics curve of timing versus productivity for the system speed operation.

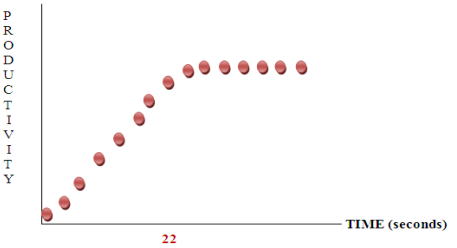


Figure (5) shows the characteristics curve of timing versus productivity for the system speed operation.

15.2: The packing system manipulator

15.2.1: Motor Position Control

This graph is showing the PID tuning results from the motor position control. The tuning has been done by trial and error for different values of the three terms of the PID controller. By using the proportional gain only (P), this results in a stable output with relatively slower time response. When a combination of proportional and integral controller (PI) is used, this gives faster time response compared to the proportional control (P). Figure (6) shows that by increasing the integral gain gradually an overshoot of 3% appears. By introducing the derivative controller (PID) in the system the output became unstable.

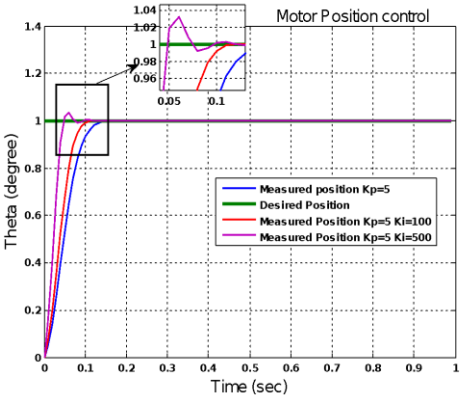


Figure (6) shows the effect of increasing the integral gain gradually gives low overshoot value.

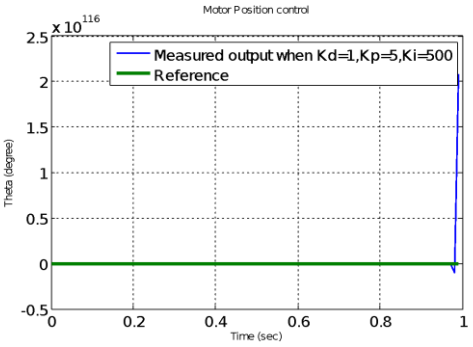


Figure (7) is showing the first iteration for three parameters of PID system

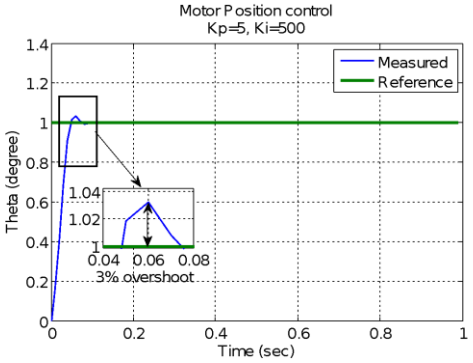
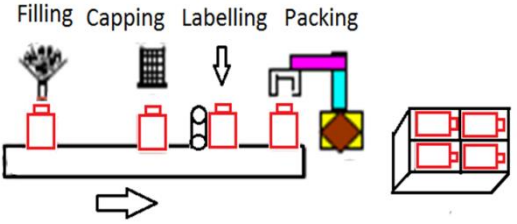


Figure (8) is showing the iteration for three parameters of PI system

16. THE PACKING TASK SIMULATION

To simulate the packing task we have assumed that a container is divided into four parts that needed to be filled by four bottles that's contained the required product. To achieve this described task the manipulator programmed to follow a certain trajectory in the space from the production pipeline last stage to the packing line. At the beginning the manipulator should pick the first bottle (bottle #1) and put it in its desired location in the container on the opposite direction. Then, it should proceed to fill the rest of the three remain places with bottles. In this work the drug pipeline assumed to be aligned with the packing line.

Figure (9) is showing the drug production pipeline



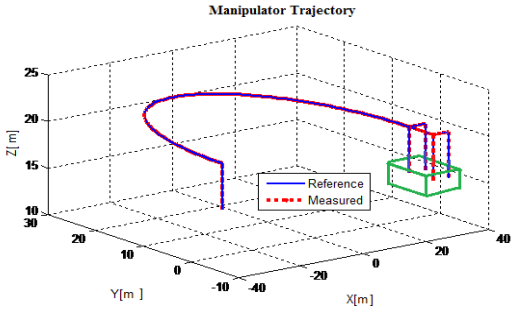


Figure (10) is showing the trajectory of the manipulator movement from the drug production pipeline to the packing system and vice versa.

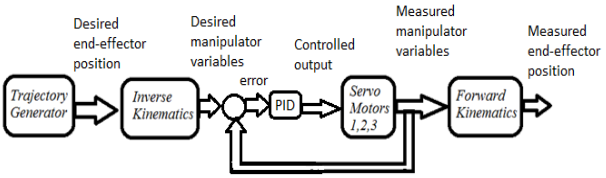


Figure (11) is showing the complete block diagram of control system

In this task the manipulator moves through two main recognized patterns either up or down along Z axis this type of movement occurs when the manipulator pick up or put down a bottle. The second type of movement is a rotation around Z axis with angle Θ varies from 180°→0° and 0°→180° to follow the trajectory shown in the figure () above, and it occurs when the manipulator moving from the drug production pipeline to the packing line and vice versa.

16.1. The manipulator trajectory planning

Heading from the drug production pipeline to packing line:

The initial position of the manipulator is [Xe,Ye,Ze]= [-30 ,0,20] that is where the manipulator starts it movement, then manipulator should pick up the desired bottle (bottle #1).

From [Xe,Ye,Ze] = [-30 ,0,15] and move through a certain trajectory to put it in the container at its final location [Xe,Ye,Ze]= [30 ,0,15], see the figure above. The trajectory been divided into the following segments:

- From end-effector initial position [-30 ,0,20] to the product (bottle#1) initial position [-30 ,0,15] (down)
- From the Product (bottle #1) initial position [-30 ,0,15] to end-effector initial position [-30 ,0,20] (up)
- From the end-effector initial position [-30 ,0,20] to the [30,0,20] (180° rotation)
- From [30,0,20] to product (bottle #1) final position[30,0,15](down)

Going back from packing line to the drug production pipeline:

After (bottle #1) is located at it desired position the manipulator will go back to the filling line through the same trajectory to pick the next product (bottle #2). The trajectory segments taken:

- From (bottle #1) final position[30,0,15] to [30,0,20] (up)
- From[30,0,20] to [-30 ,0,20] (180° rotation)
- From [-30 ,0,20] to product initial position (bottle #2)

After that the manipulator will complete to fill the container with the rest of the bottles (#2,#3,#4) at [35,0,15], [30,-5,15], and [35,-5,15] respectively, using the same segmentation strategy shown above (see figure (**5.7**))

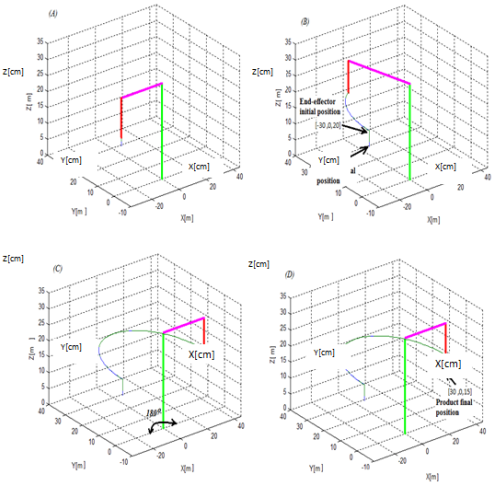


Figure (12) is showing the steps of trajectory of the manipulator simulation by mathlab

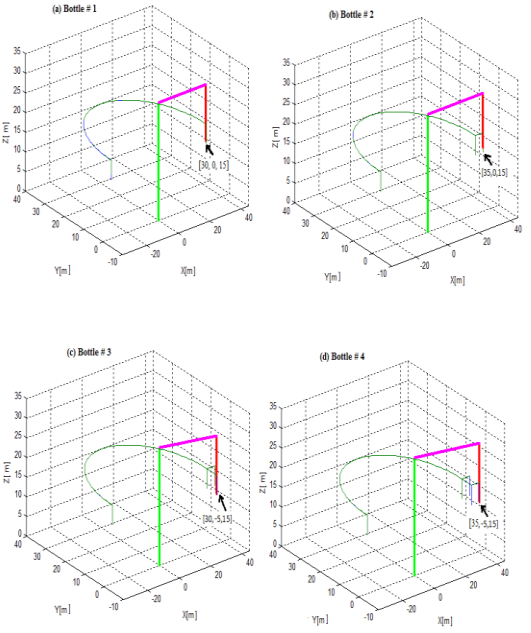


Figure (13) showing the picking and placing process

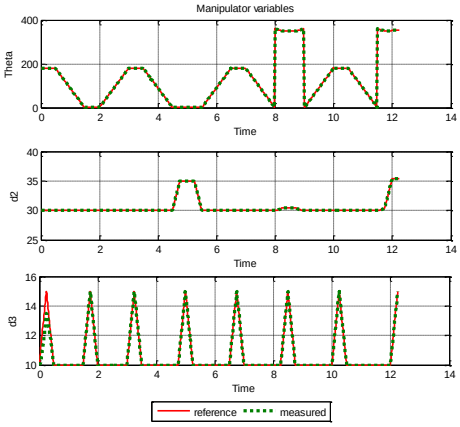


Figure (13) shows the manipulator variables with respect to time as the end-effector follows its desired trajectory in the space.

The above figure shows the manipulator variables with respect to time as the end-effector follows its desired trajectory in the space.

At the beginning, the angle Θ is 180° and through time as the manipulator rotate around z axis it will move from the second quarter to the first quarter (from 180° to 0°) and in the opposite direction (from 0° to180°) this movement will be repeated many time.

In the figure when the time (t) t= 8, 9 and 11.5 seconds a sharp change appears in the angle Θ which is due to the manipulator movement from the first quarter to the fourth, the angle causing this sudden change is equivalent to 0° and 360°. Also in the same figure the displacement s d_2 and d_3 are plotted against time apparently d_2 changes from 30 to 35 and d_3 changes from 10 to 15 cm.

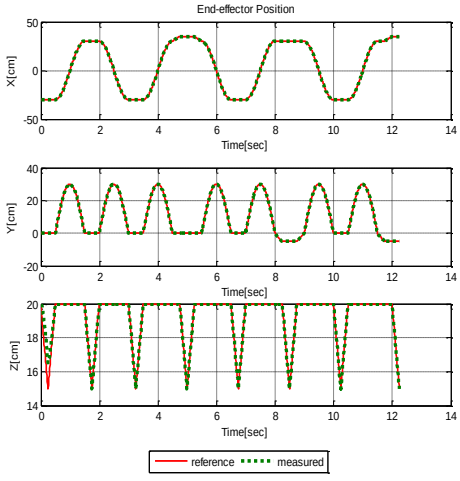


Figure (14) the end-effector changing position plotted against time in the three axes X,Y and Z.

In figure (14) above, the end-effector changing position plotted against time in the three axes X,Y and Z.

The position on X axis varies from -30 to 35 cm and it varies from -5 to 30 cm on Y axis and from 15 to 20 on Z axis. In both figures the measured output followed the desired reference input with a very negligible error.

17. CONCLUSION

Production automation is the application of certain regulations for the system depending on the complexity of the process being controlled .A variety of approaches being used according to the systems being used. In drug production, we need to go through a series of precise steps to accomplish the operation. This paper suggested a design based on using a microcontroller for processing. The microcontroller performs processing in the system. The processing is sequential and repetitive for feeding, bottling, filling, capping and labeling and packing operations.

- The automated drug system prototype hardware was implemented for automated drug production pipe line.
- The software for controlling this system was written using Mikroc program language and tested in the system hardware successfully.
- The system was developed to increase productivity and delivery of end product at uniform quality.
- This system can be employed at places where precision and accuracy are required.
- By using this human machine interface the whole system can be controlled supervision and interaction with human operators.
- The whole process can be monitored and controlled by only one operator.
- The operator working in this automated system can monitor and control the system from remote area.
- This can improve production reduce contamination and human error and cost.

By using this automated system in pharmaceutical industries advantages are faster cycle time, more speed, increased throughput, and maximized production.

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