

Integration of Labelling and Assembly Section of Blood Bags and Despatch Automation at HLL

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Abstract— As long as the revolution in industry exists, the requirements and the demands of man exists to compete with the same production industry. So updation and validation of any system is necessary. The aim of the proposed system is to integrate the labelling, assembly, filling and coiling area, avoiding batch mixing and also to make an automated final end thereby reducing the labour and manual interface with machines; even though manual intervention is not totally unavoidable. The proposed system can be divided into two stages. Stage 1 is the integration of labelling, assembly, filling and coiling followed by Sterilization. Stage 2 is the packing end where the system is automated with a QR code reader to avoid batch mixing after visual inspection. This paper gives an insight towards the requirement and efficiency improvement in adopting an automated system.

Keywords— Bloodbag, QR code reader

I. INTRODUCTION

A Mini Ratna Central Public Sector Enterprise under the Ministry of Health and Family Welfare, HLL is a global provider of a wide range of contraceptives, hospital products and pharma products and healthcare solutions in the country. HLL, a contraceptives major, has been in the blood bag business for over the last two decades.

HLL mainly produces blood bags of Haemopack and Donato starting from single bags to penta bags. Production of blood bags at the Akkulam factory commenced during 1994-95, initially with a semi automatic high frequency welding machine with an installed capacity of 2.5 million bags per annum. With the addition of one more similar machine in 2001, the installed capacity was increased. With this expansion, HLL increased its market share of blood bags both in the domestic and global markets.

HL Haemopack LD bag is a closed system for collection and pre-process leukocyte depletion of whole blood at blood bank. This incorporates latest generation leukocyte filter which depletes over 99.99% leukocytes and achieves log 4 reduction using surface adhesion technology. These blood bags also incorporate the inline blood sampling system.

The new 20,000 sq ft unit started producing HLL's new range of blood collection bags under the brand name Donato, which was introduced in the market in October 2010. The Donato Block features the 4-UP fully automatic high frequency welding machines along with other auxiliary machines and equipment. Donato blood bags are specially designed to meet the exacting physical chemical and biological requirements for safe handling and storage of blood and blood components safely. They are manufactured in Class 10000 clean room in the new facility with minimal human handling. With this expansion, the total installed capacity of blood bags increased to 16.5 million packs from the present 11.5million packs. Total project cost of the unit was

approximately Rs. 20 crore. The 4-UP high frequency welding machine at the new unit has the latest features for quick die change over, die and mandrel setting and die/mandrel alignment. These features reduced the skill dependence on operators during die changing, and ensured improved positioning and alignment of die and mandrels, which is most critical to ensure blood bag quality..

II. BLOOD COLLECTION PROCESS

The Separation of blood components

At the collection site, the donor's blood is collected into a plastic bag (the main bag), a part of a set consisting of three plastic bags connected with plastic tubes. The whole set is sterile and has never been used before. The tubes enable the transfer of parts of the blood from one bag to another without breaking the chain of sterility. The main bag contains matter preventing the blood from coagulating.

After the collection, the blood is centrifuged so that it is divided into three layers in the main bag, according to the density of each part. After the centrifugation, the plasma, which is on top, is pressed into an empty plastic bag (the plasma bag) through a plastic tube in the top of the bag. The red blood corpuscles, which are on the bottom, are lead into another plastic bag (the SAGM bag), containing liquid with nutrients for the red blood corpuscles, through a tube in the bottom of the bag. The layer in between, which remains in the main bag, is called the buffy coat. It contains large amounts of blood platelets and white blood corpuscles, and it is used for producing concentrates of blood platelets. Thus, the collected whole blood is split into three different components in each their plastic bag. In this way, it is possible to store the components separately under optimum conditions, depending on their respective requirements.

All blood components are labelled with a unique and clear collection number that makes it possible to trace where the blood has been collected, where it has been stored, and to which patient it has been administered. All this information is registered in the blood bank's computer system..

Storing the blood components

Distinct rules have been laid down regarding the storage of the individual blood components. The rules take the storage temperature into special account because the shelf life is particularly dependent on the temperature. The requirement for correct and constant temperature when storing blood is due to the fact that the blood has to stay as fresh as possible. When storing blood, the temperature must be measured all the time and registered continuously so that the storage temperature can be documented.

Types of Blood bags

The blood bags produced in HLL AFT are of different types, categorised as single, double, triple, quadruple and penta bags; in different volumes like, 250ml, 350ml and 450 ml.

Single Blood Bag

A single blood bag is designed for collection, storage and transfusion of whole blood. It Contains 63 ml CPDA-1 anticoagulant solution. Also available with CPD anticoagulant solution. Its capacity ranges are 250, 350, 450 ml. It also contains 16G tamper-proof needle and standard donor tubing.

Double Bag

A double bag is designed to separate whole blood into plasma and red cells. It eliminates the possibility of contamination. The Primary bag contains 63 ml CPDA-1 anticoagulant solution. Also available with CPD anticoagulant solution The 300 ml transfer bag contains no solution. For a 450ml double bag, the capacity is 1 x 450 ml and a 1 x 300 ml transfer bag.

Solution	Purpose	Storage Period	Additive Concentrations (per 100 ml)
CPD	Anticoagulant and storage of Blood	21 days	Sodium Citrate (dihydrate)....2.63g
			Citric Acid (monohydrate)...0.299g
			Dextrose (monohydrate).....2.55g
			Monobasic Sodium
			Biphosphate (monohydrate)0.222g
CPDA 1	Anticoagulant and storage of Blood	35 days	Sodium Citrate (dihydrate)....2.63g
			Citric Acid (monohydrate)...0.299g
			Dextrose (monohydrate).....2.9g
			Monobasic Sodium
			Biphosphate (monohydrate)0.222g
			Adenine.....0.0275g
SAGM	Red cell Preservation	42 days	Dextrose (monohydrate).....0.900g
			Sodium Chloride.....0.877g
			Adenine.....0.0169g
			D-Mannitol.....0.525g

III. EXISTING SYSTEM

HL Haemopack LD bag is a closed system for collection and pre-process leukocyte depletion of whole blood at blood bank. This incorporates latest generation leukocyte filter which depletes over 99.99% leukocytes and achieves log 4 reduction using surface adhesion technology. These blood bags also incorporate the inline blood sampling system.

The main components of bloodbag are sheet, tube, transfusion port, Needle holder, Needle cover and Needle. Packing materials include PP cover, aluminium foil cover and corrugated box. Out of the above components, HLL produces sheet, tube, transfusion port, Needle holder and Needle cover. Depending upon production requirements, components are purchased from the qualified vendor. All the production process are conducted in class 10000 clean rooms. Quality Assurance Department does the raw material, component and final product inspection. The anticoagulant solutions such as CPD, CPDA and SAGM are manufactured here. The QA Department performs inprocess and final inspection of the anticoagulant solution. The production facility has been designed as per the stipulated guidelines and Clean room is as per the requirement of ISO14644 Standards.

The operational procedures of blood bag manufacturing are categorised under 24 major heads. They are:

1. Cleaning of components
2. Tube extrusion
3. Sheet extrusion
4. HF welding
5. BOV assembly
6. Slitting, Punching and Trimming of bags
7. YC & Multiple bag Assembly
8. Needle assembly

9. Automatic Needle Assembly
10. Labelling
11. Anticoagulant preparation
12. Anticoagulant filling
13. Coiling
14. Air expulsion and sealing
15. Visual inspection
16. Autoclaving
17. Bags drying
18. Final visual inspection
19. Foil stamping and packing
20. Master cartooning
21. Manufacturing procedure for transfer bag and connector
22. Leak checking of bags
23. Sampling arm/ Sampling device assembly
24. Wiping of PP cover with sodium Hypochlorite after FVI

The plastic processing section starts with reception of PVC Pellets from stores in bags of 25 Kg. They are transferred to buckets and shifted and stored inside the clean room near the needle assembly area for using the same at sheet extrusion/ Tube extrusion machine. The extruded tubes are bundled and stored inside the tube storage racks or in buckets. Extruded sheets are packed using PE cover immediately after completing one set of extruded sheet rolls. The same will be stored on sheet storage racks.

The stored sheets are transferred to the blood bag manufacturing section. There are mainly two sections here namely Semiautomatic which is a half automated and half manual section and a fully automatic 4 up machine that produces four bags at a time. The semiautomatic section manufactures bags automatically with aid of machines, sheets are loaded manually. Once the bag manufacturing is done, the

BOV assembly followed by Slitting, Punching and trimming of bags are done manually. The four up machine on the other hand handles all these steps automatically with the aid of a PAC controller, pneumatic cylinders and robotic arms. The BOV assembly and Slitting, Punching and trimming of bags are all done automatically and produces four bags at a time. HLL mainly produces blood bags of Haemopack and Donato starting from single bags to penta bags. The bags are then transferred to labelling section.

There are two labelling machines from videojet printers in use now. These printers have special options for adjusting the print area, size, quality etc and allows configuration setting of user field. Provisions are made for counting the number of labels printed by each machine. The labelling duration for one bag is approximately 1-2seconds. The machines are targeted to print 6500 labels in 8 hours. Mainly two types of labels are printed, Haemopack and Donato. They are readily available in rolls; around 2400 in each roll, with field space for entering manufacturer details related to the product. This ensures traceability of the product at the final end. HLL has a unique way of nomenclature labelling blood bags. For example, H07151293A reveals the following details about the product, H notates the manufacturing company Haemopack, 07 is the product code.07 stands for 450 ml, CPDA Double bag. 15 is the year of manufacture. 1293 is the mixing load and A denotes whether mixing load is batch A or B. Similarly, DH1151299B reveals the following details about the product, D notates the manufacturing company Donato. H1 stands for Triple bag platelet CPD Sigm 350 ml. 15 is the year of manufacture. 1299 is the mixing load and B denotes whether mixing load is A or B.

Once the bags are labelled, they are moved manually to the assembly section in crates. The assembly section consists of an Automatic Needle assembly machine from Titan and a manual needle assembly section. The needles are siliconized for maximum user comfort. The Y connector assembly is also done manually in the assembly section. Here Tubes are fixed to the appropriate ports of the blood bag with extreme care. All the labourers employed are well trained to read the code on the label. The various chemicals used in the assembly section are

1. Cyclohexanone
2. Methylene dichloride
3. MFC for Silicon oil preparation
4. Locite or Dymax glue
5. Dowcorning MDX4-4159 (50% medical grade dispersion) and Dowcorning Q79180 silicon fluid 0.65T to prepare silicon oil for automatic needle assembly.

The chemicals are stored in containers as received from stores with labels indicating batch number or group number. The containers are transferred to the storage area manually. These chemicals are used by the same as per the recommended ratios and separate batch numbers are assigned to the mix. The 16/17 Ultrathin wall Needles used in blood bags are stored in containers or cardboard boxes as received from the stores and are kept in designated storage areas.

The assembled bags are then moved to filling section. The bags are filled with anticoagulant solutions like CPD, CPDA or SAGM solution on prescribed proportions. These are done to preserve the blood and blood components. The raw materials required for the anticoagulant solution are directly intended from stores. They are

1. Dextrose

2. Sodium acid phosphate
3. Citric acid
4. Sodium citrate
5. Adenine
6. Mannitol
7. Sodium Chloride

The filling process is followed by assembly of connector to the Sigm bag and Needle assembly. It is then sent for Visual inspection and PP cover wrapping. At this stage, it is the responsibility of each labourer on wrapping section to ensure that all the bags belong to the same batch and load, there is no leakage of solution and there is a needle protector also fo Donato bags. The bags are then sent for sterilization ventilator autoclave and further to drying sections. At times, the drying process will not be proper so that remnants of water vapour will be there inside the PP Cover. Therefore, these PP covers will need to get dried once again. This may result in piling up of loads before the final stage since each drying session takes about 11 to 12 hours.

The dried bags are now ready for the Final Visual Inspection stage. This section is very crucial where all relevant details regarding the bags are to be checked like batch and load mixing is totally avoided, there is no water vapour content inside the PP cover because this can damage the anticoagulant adulteration, whether the needles are not bent and there is a needle protector and finally there is no leakage of the anticoagulant solution. After ensuring the quality of bags, they are sent to the packing section.

The various packing materials required are aluminium foil, Leaflet, Foil Pack Labels, Flow control clamp, Cartons, Cello tape and Strapping. Before final despatch of cartons, final weight checking of each carton is done so as to ensure that no batch mixing has occurred. The packed cartons are then moved to the outlet.

IV. PROPOSED SYSTEM

The proposed system can be divided into two stages. Stage 1 is the integration of labelling, assembly, filling and coiling followed by Sterilization. Stage 2 is the packing end where the system is automated after visual inspection.

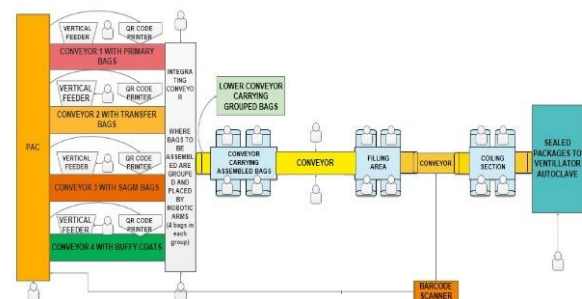


Fig 4.1 Stage 1 Integration of labelling, assembly, filling and coiling section.

Stage 1 Integration of labelling, assembly, filling and coiling section.

The entire process is under the control of Programmable Automation Controller (PAC). There will be four conveyor belts running in parallel, which carries Primary, Transfer, Sigm and Buffy coat bags. If it is a single bag production command will be given to run the belts according to the requirements by the PAC. There will be a vertical feeder to

feed the bags to the conveyor belt. The design of the vertical feeder can be done in two different ways.

1. It will have a bottom plate that opens in regular intervals and let the bags fall to the conveyor or

2. A robotic arm could be used to fetch and place the bags in exact position so that the labelling falls exactly at the centre. But in this case the feasibility of robotic arms vacuum suction without the breakage or destruction of the bags is an important concern.

Each section will be followed by a line clearance session. The bags now arranged like a pack of cards moves through the conveyor belt to an integrated section. Meanwhile, a QR code printer is used to print and paste the label on each bags. QR Codes are the 2 dimensional barcodes that appear in marketing and advertising literature, and now they are being used as a way to order food and drinks from menus by a new generation of queue-busting phone apps. The QR code will be such that, it will embed all relevant details regarding the bag. It follows the same nomenclature as discussed earlier. DH1151299B reveals the following details about the product, D notates the manufacturing company Donato. H1 stands for Triple bag platelet CPD Sagm 350 ml. 15 is the year of manufacture. 1299 is the mixing load and B denotes whether mixing load is A or B. In addition to this, the codes will have details regarding the company of manufacture, date of production

Integrated section consists of robotic arms to group, pick and place each set of bags on the double conveyor system directed to the assembly area. The double conveyor system will have two conveyors running in parallel. The lower conveyor will be having grouped bags, those are manually assembled (YC assembly) in the assembly section and placed on the upper conveyor belt.

While discussing about the problems existing, it was noted out that at times primary bags and Sagm bag are mistaken and solution filling goes wrong. It is a major area of concern. So a coloured ring can be inserted on the primary bag to distinguish it from the other one during YC assembly. This ring can later be removed in the filling section after anticoagulant has been filled. The anticoagulants are filled on the corresponding bags and then placed on conveyor section to pass it on to the coiling section. The filling process is followed by assembly of connector to the Sagm bag and Needle assembly. It is then sent for Visual inspection and PP cover wrapping. At this stage, it is the responsibility of each labourer on wrapping section to ensure that all the bags belong to the same batch and load, there is no leakage of solution and there is a needle protector also for Donato bags. The bags are then sent for sterilization ventilator autoclave and further to drying sections.

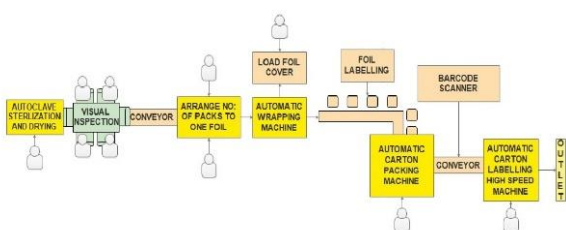


Fig 4.2 Stage 2 Despatch Automation

The dried bags are now ready for the Final Visual Inspection stage. This section is very crucial where all relevant details regarding the bags are to be checked like batch and load mixing is totally avoided, there is no water vapour content inside the PP cover because this can damage the anticoagulant adulteration, whether the needles are not bent and there is a needle protector and finally there is no leakage of the anticoagulant solution. After ensuring the quality of bags, they are sent to the packing section through conveyor system.

The number of bags to be kept in each aluminium foil pack are manually arranged and kept in conveyors with trays. Mean time the foils are also loaded manually to an automatic wrapping machine. The wrapped foils are moved through the conveyor belt where a foil labelling machine labels the packed foils. It should be ensured that the packs in a single foil belong to the same category ie; double, single etc and belong to a particular batch while loading to the autowrapping machine. The labelled foils are grouped and packed to cartons automatically by moving them through the conveyor system.

These cartons are then barcode scanned with a QR code reader to feed the details to a server system within the company and to ensure to ensure that no batch mixing has occurred. Before final despatch of cartons, final weight checking of each carton is done. The packed cartons are then moved to the outlet.

V. CONCLUSION

The aim of the proposed system is to integrate the labelling, assembly, filling and coiling area, avoiding batch mixing and also to make an automated final end thereby reducing the labour and manual interface with machines; even though manual intervention is not totally unavoidable. The proposed system can be divided into two stages. Stage 1 is the integration of labelling, assembly, filling and coiling followed by Sterilization. Stage 2 is the packing end where the system is automated after visual inspection. The System also proposes the usage of QR codes at labelling end and coloured ring on the primary bag to distinguish it from the other one during YC assembly. This ring can later be removed in the filling section after anticoagulant has been filled so that manual errors can be avoided. The system also proposes the usage of barcodes to avoid batch mixing.

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