COMPUTER-AIDED PROCESS DESIGN TOOLS FOR DEBOTTLENECKING A BATCH PHARMACEUTICAL PRODUCTION

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ABSTRACT

The main objective of this work is to model and to debottleneck a batch pharmaceutical production with computer-aided process design (CAPD) and simulation tools. An eye drop production case study is firstly modelled based on a pharmaceutical production plant. Throughput analysis is next utilised to identify process bottlenecks that limit the increase of production and to evaluate different debottlenecking schemes. Scheme 1 considers an effort to maximise process throughput for a single batch operation, while Schemes 2 and 3 explore the possibility of minimising combined utilisation value of the process bottleneck. With the increase of batch throughput, installation of a new labelling process and the addition of an intermediate tank, Scheme 3 is identified as the debottlenecking scheme that achieves the increased production demand of 25%.

Keywords: *Batch Processing, Debottlenecking, Modelling and Optimisation, Pharmaceutical Production, Throughput Analysis*

1.0 INTRODUCTION

Computer Aided Process Design (CAPD) and simulation tools have been widely used in the bulk and petrochemical industries since the early 1960's. It involves the use of computers to perform steady-state heat and mass balancing as well as sizing and costing calculations for a process [1]. However, the use of these CAPD and simulation tools has only emerged in the pharmaceutical manufacturing in the past decade [2-9]. Compared to the readily available process simulators in the bulk and petrochemical industries, there are only a limited number of simulators available for pharmaceutical process modelling. This includes Batches by Batch Process Technologies, Batch Plus by Aspen Technology, SuperPro Designer by Intelligen as well as Batch Design Kit by Hyprotech. This situation is mainly due to the uncommon unit operations and the batch operation nature of pharmaceutical processing. Due to its relatively new emergence, more work needs to be done in this sector.

This paper describes the use of a batch process simulation tool in modelling and debottlenecking of an eye-drop production at a pharmaceutical facility. Due to increasing customer demand of the eye-drop product, the pharmaceutical plant authority is looking for alternative expansion schemes to increase the production rate for an addition of 25% of the existing capacity. As the production capacity is limited by current operating condition and equipment setup, a debottlenecking study is needed for an increase in production.

2.0 BACKGROUND THEORY

In order to increase process throughput, *process bottleneck* that limit the current production need to be identified. Bottlenecks are process limitations that are related to either equipment or resources (*e.g.* demand for various utilities, labour and raw material). Hence, *process debottlenecking* can be defined as the identification and removal of obstacles in the attempt to increase the plant throughput [5]. In batch manufacturing, two types of process bottlenecks are encountered. These are the equipment capacity-related *size* bottleneck (an equipment that is limited in size) as well as the *scheduling* bottleneck (due to the long occupancy of an equipment during a process) [5]. The ability to identify and remove process bottlenecks that create obstacles in a manufacturing process will increase plant throughput and fulfil customer needs.

A good tool to identify batch process bottleneck is throughput analysis study. Throughput analysis measures the equipment utilisation in a batch process with two variables, *i.e.* the capacity utilisation and *equipment uptime* [5-6]. *Capacity utilisation* is defined as the percentage of the current operating load of an equipment (*e.g.* vessel volume for a reactor or filtering area of a filter) relative to its maximum load, *i.e.*:

$$\text{Equipment capacity utilisation} = \frac{\text{Actual capacity}}{\text{Maximum capacity}} \times 100\% \quad (1)$$

For instance, a vessel with 100% capacity utilisation means that its current content has reached to its maximum level. On the other hand, equipment uptime measures the effectiveness of a piece of equipment that is utilised in time. It is given as the percentage of the equipment utilisation time over the plant cycle time, *i.e.*:

$$\text{Equipment uptime} = \frac{\text{Total time equipment is utilised per batch}}{\text{Plant cycle time}} \quad (2)$$

For example, a reactor that operates for 5 hours within a batch process with a cycle time of 10 hours has an uptime of 50%. The product of equipment capacity utilisation and its uptime defines the combined utilisation of the respective equipment [5-6].

In an ideal situation, a plant should have all equipment running at 100% combined utilisation to achieve maximum production. However, this is often not the case. All process equipment will normally feature different utilisation. The ability to raise utilisation of the equipment will help in raising process throughput. Processing step with the highest combined utilisation is normally identified as the first candidate for process debottlenecking [5, 9]. CAPD and simulation tools that are capable of tracking *capacity utilisation* and *equipment uptime* can facilitate the identification of process bottlenecks and the development of various debottlenecking scenarios. A pharmaceutical production of liquid eye drop is used to illustrate the concept.

Table 1: Major equipment specification

Quantity	Procedure/ Equipment	Specification
Pre-Blending section		
1	P-1/V-101	Volume = 90 L
1	P-2/V-102	Volume = 10 L
1	P-3/V-103	Volume = 80 L
1	P-4/V-104	Volume = 5 L
Main Blending Section		
1	P-5/V-105	Volume = 90 L
Packaging section		
1	P-6/HL-101	Maintain as in design mode
1	P-7/FL-101	Rated throughput = 40 entities/minute
1	P-8/LB-101	Rated throughput = 30 entities/minute
1	P-9/BX-101	Rated throughput = 5 entities/min

3.0 MODEL DEVELOPMENT – LIQUID EYE DROP PRODUCTION

Figure 1 shows the base case simulation flowsheet for the production of eye drop modelled in SuperPro Designer v6.0 [10]. The base case simulation model was developed to reflect the actual operating condition in the pharmaceutical manufacturing facility that is operated in batch processing mode. In the modelling environment of SuperPro Designer, this involves the modelling of a few *operations* that take place sequentially in a single *unit procedure* [10]. In the base case model, the production capacity for a single batch is estimated as 60 L of liquid eye drop. As shown in Figure 1, there are ten major processing steps in three different sub-sections. This includes deionised water (DI) storing tank (P-1/V-101), pheny blending (P-2/V-102), SDP, DHP, SM and NEO blending (P-3/V-103) and active ingredient blending (P-4/V-104) in the Pre-Blending Section; raw materials blending in the Main Blending Section (P-5/V-105); as well as pressurisation (P-6/HP-101), filling (P-7/FL-101), labelling (P-8/LB-101), and carton packaging (P-9/BX-101) in the Packaging sections. All raw materials charging are carried out at room temperature. Table 1 shows the main specification of the equipment that is modelled as rating mode in the simulation software.

At the beginning of the manufacturing process, (DI) is stored in the storage tank V-101 before being transferred into the other Pre-Blending Tanks (V-102, V-103, V-104) and the

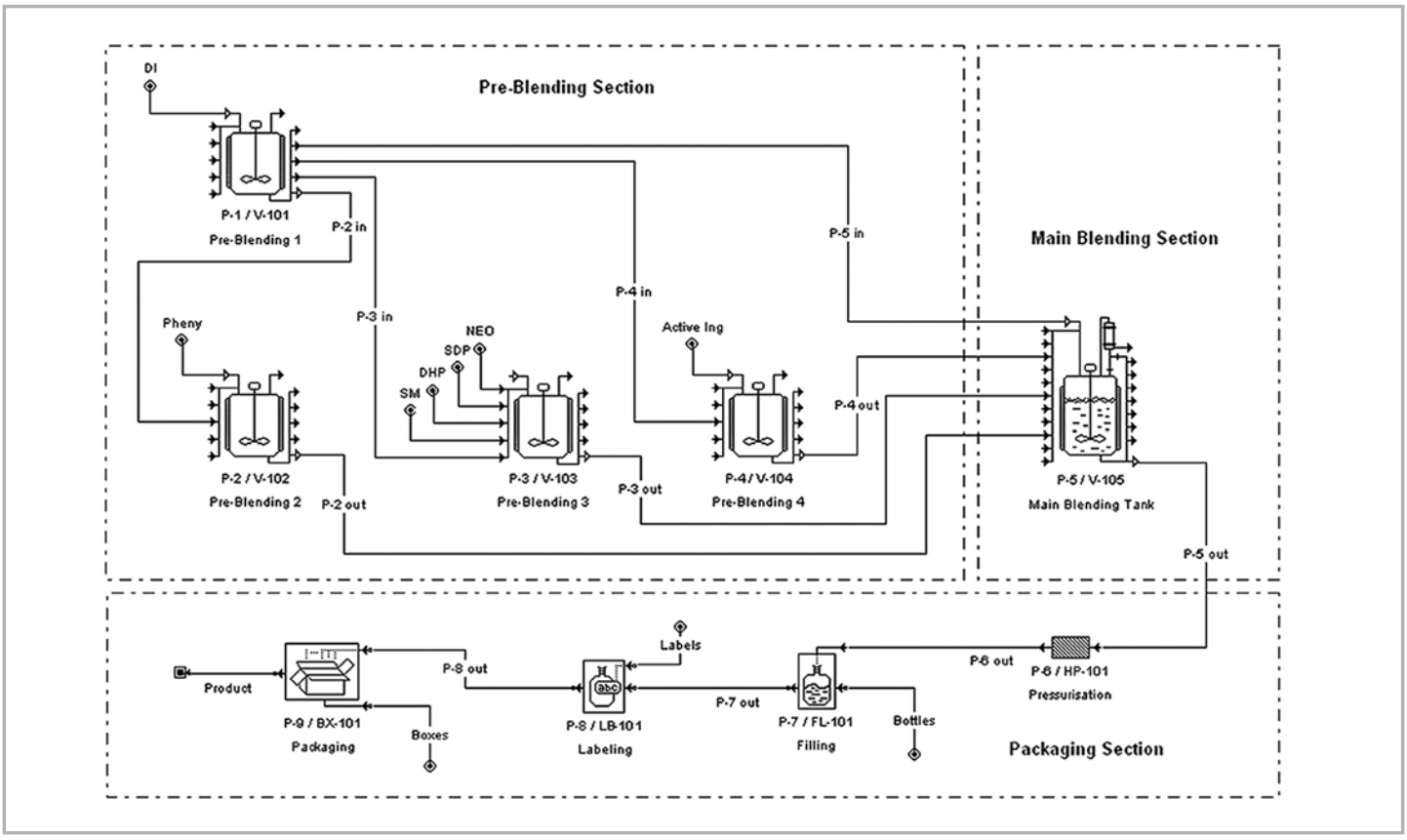

Figure 1: Base case simulation flowsheet

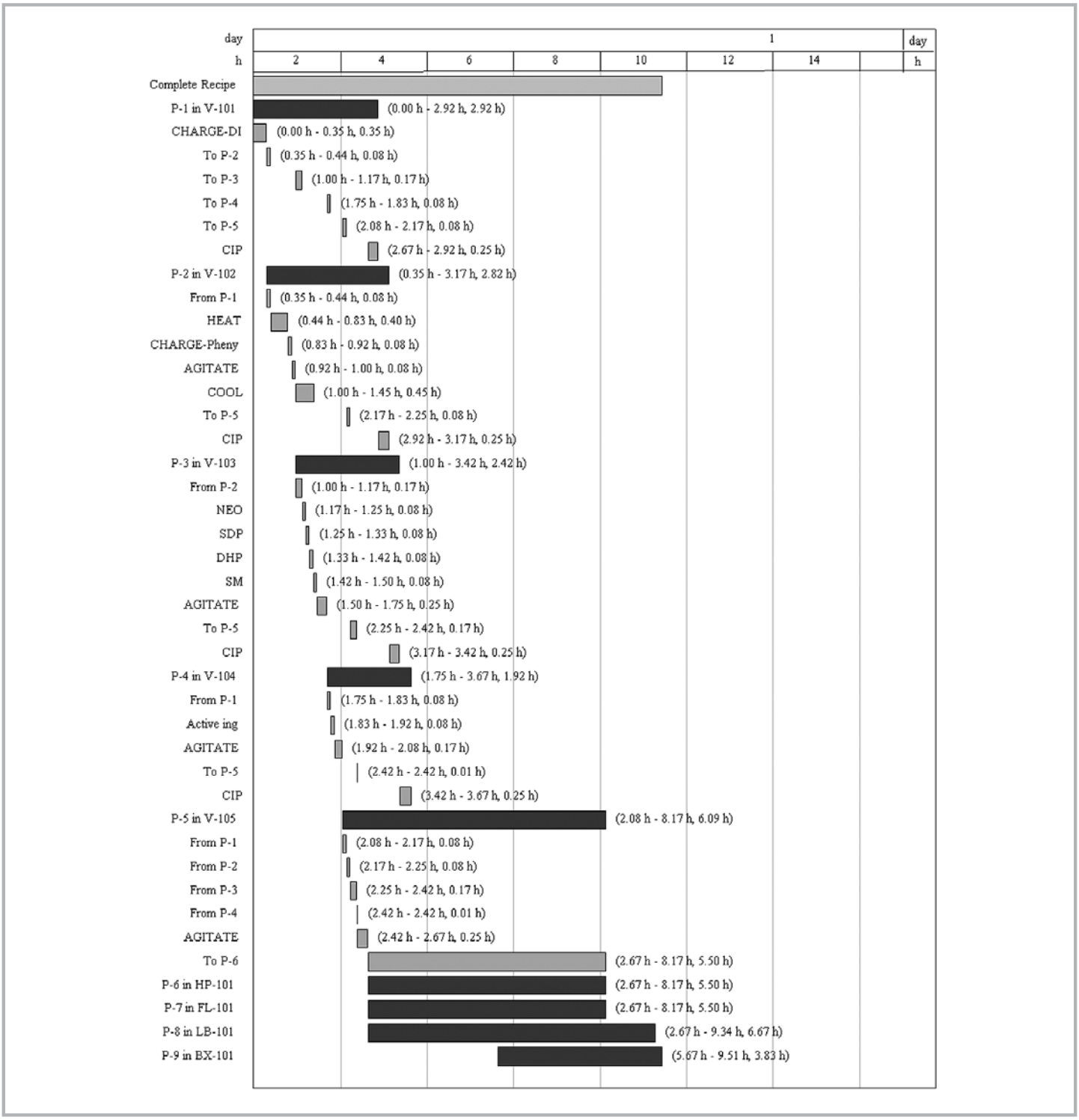

Figure 2: Operation Gantt Chart for the complete recipe of a single batch operation of eye drop production (number in parenthesis indicate start time and end time, as well as the duration for each procedure/operation)

Main Blending Tank (V-105). The agitation processes in each Pre-Blending Tank is carried out manually. Upon the completion of the transfer-in operation from all Pre-Blending tanks to the Main Blending Tank, the products are once again blended to obtain uniform composition before the product mixture is sent to the Packaging Section. In the Packaging Section, the blended product from the Main Blending Tank is first undergo pressurisation (P-6/HP-101) before it is filled into the 5 mL bottle in the filling procedure (P-7/FL-101). The bottles are then sent to the labelling procedure (P-8/LB-101) and followed by carton packaging procedure (P-9/BX-101) where the eye drop bottles are packed manually into the carton boxes with 12 bottles per box.

As the manufacturing process is carried out in a batch operation mode, efforts have been made to document the scheduling details of each processing steps. This includes the *setup time*, *process time*, *and start time* of each individual operation in each unit procedure. Setup time (SUT) is the preparation time needed before an operation takes place. Often, this involves the loading of raw material (*e.g.* from loading area), equipment preparation

Table 2: Scheduling summary for operations and procedures in the base case model

Procedure/ Equipment	Operation	SUT (mins)	PT	ST
P-1/V-101	Charge DI Water	20	47L/min	Beginning of batch
	Transfer out to P-2	–	5 min	After DI Water charge
	Transfer out to P-3	–	10 mins	After agitation in P-2
	Transfer out to P-4	–	5 mins	After agitation in P-3
	Transfer out to P-5	–	5 mins	After agitation in P-4
	CIP	–	15 mins	Starts with transfer out in P-5 (to P-6)
P-2/V-102	Transfer in from P-1	–	Master-Slave with P-2 transfer out in P-1	Starts with P-2 transfer out in P-1
	Heating (to 100°C)	5	4°C/min	After transfer in from P-1
	Charge pheny	–	5 mins	After heating
	Agitation	–	5 mins	After pheny charge
	Cooling (to 27°C)	–	2°C/min	After agitation
	Transfer out to P-5	–	5 min	After transfer out in P-1 (to P-5)
	CIP	–	15 mins	After CIP in P-1
P-3/V-103	Transfer in from P-1	–	Master-Slave with P-3 transfer out in P-1	Starts with P-3 transfer out in P-1
	Charge NEO	–	5 min	After transfer in from P-1
	Charge SDP	–	5 mins	After NEO charge
	Charge DHP	–	5 mins	After SDP charge
	Charge SM	–	5 min	After DHP charge
	Agitation	–	15 min	After SM charge
	Transfer out to P-5	–	10 min	After transfer out in P-2 (to P-5)
	CIP	–	15 mins	After CIP in P-2
P-4/V-104	Transfer in from P-1	–	Master-Slave with P-4 transfer out in P-1	Starts with P-4 transfer out in P-1
	Charge Active Ing	–	5 min	After transfer in from P-1
	Agitation	–	10 min	After Active Ing charge
	Transfer out to P-5	–	10 kg/min	After transfer out in P-3 (to P-5)
	CIP	–	15 mins	After CIP in P-3
P-5/V-105	Transfer in from P-1	–	Master-Slave with transfer out in P-1	Starts with transfer out in P-1 (to P-5)
	Transfer in from P-2	–	Master-Slave with transfer out in P-2	Starts with transfer in from P-2 (to P-5)
	Transfer in from P-3	–	Master-Slave with transfer out in P-3	Starts with transfer in from P-3 (to P-5)
	Transfer in from P-4	–	Master-Slave with transfer out in P-4	Starts with transfer in from P-4 (to P-5)
	Agitation	–	15 min	After transfer in from P-4
	Transfer out to P-6	–	Master-Slave with Filling in P-7	After agitation
P-6/HP-101	Pressurisation	–	Master-Slave with Filling in P-7	Starts with transfer out in P-5 (to P-6)
P-7/FL-101	Filling (Fill level: 5 mL/ bottle)	30	Calculate based on operating throughput of 40 entities/min	Starts with transfer out in P-5 (to P-6)
P-8/LB-101	Labelling	–	Calculate based on operating throughput of 30 entities/min	Starts with filling in P-7
P-9/BX-101	Packing (Boxing capacity: 12 items/box)	30	Calculate based on operating throughput of 5 sealed box/min	3 hours after the labelling in P-8 starts

or setup that often occur in batch processing. Process time (PT), on the other hand, represents the actual processing duration needed for each operation. Finally, start time (ST) documents the beginning of an operation. It should also be noted that the process time for some operations are dependant upon operations of other procedure. For instant, duration for transfer out operation in P-5 and high pressure operation of P-6 (both regard as "slave" operation) are set to follow the filling operation of P-7 (regard as "master" operation), using the Master-Slave Relationship function of SuperPro Designer v6.0 [10]. Process scheduling summary for all procedures in the base case model is shown in Table 2. The Operation Gantt Chart in Figure 2 shows the complete recipe of a single batch process.

4.0 BOTTLENECK IDENTIFICATION VIA THROUGHPUT ANALYSIS

In the current operation, the annual operating time for the eye drop manufacturing is taken as 2080 hours, which is based on 52 operation weeks, 5 days a week and 8 hours operation per day. Increasing daily operating duration is determined to be

uneconomical due to the high operating cost in hiring additional staff. From the base case simulation, a complete batch of liquid eye drop is found to have a process batch time of 9.51 hrs and a *minimum cycle time* of 6.67 hrs (P-8/LB101; Figure 2). The minimum cycle time of the process is defined as the minimum time possible between the start of two consecutive batches, and is determined by the procedure that occupies the longest duration within a batch process [10]. In the case of eye drop manufacturing, the minimum cycle time corresponds to the prolonged labelling procedure P-8. With an interval of 2 hrs for tank cleaning between batches, this sets the plant annual production at 239 batches of liquid eye drop product.

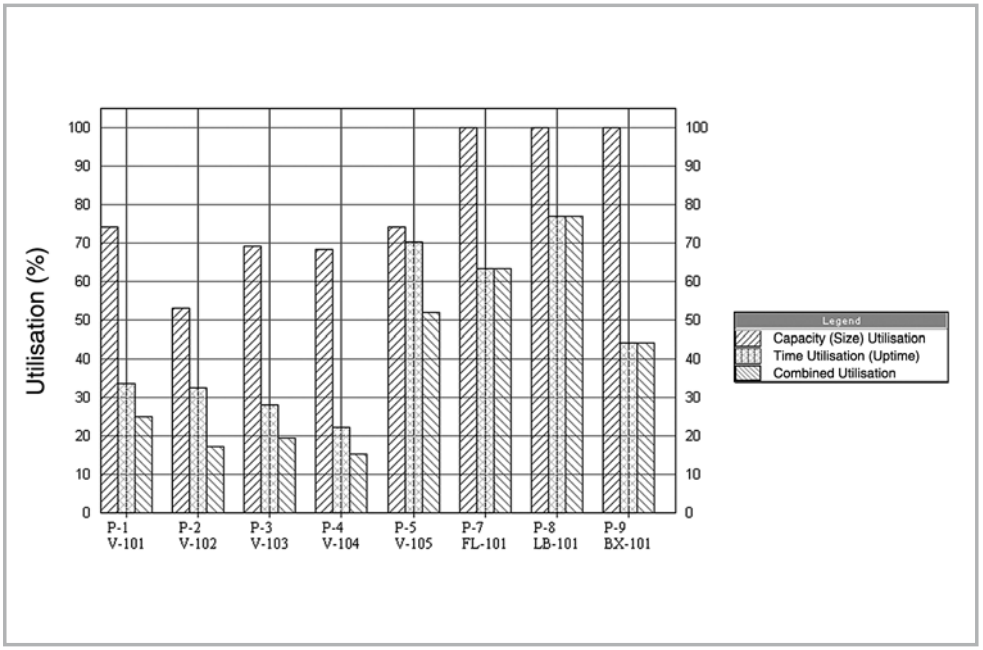

Figure 3: Capacity, time and combined utilisation of base case simulation

Throughput analysis is utilised to identify process bottleneck systematically. Figure 3 displays the capacity, time and combined utilisation of all the procedure/equipment pairs in the base case simulation mode generated by SuperPro Designer. A few observations can be made here. First, all vessels in the Pre-Blending and Main Blending Sections (V101-V105) are underutilised, with capacity utilisation of approximately 70%. Hence, debottlenecking strategy should firstly aim to fully utilise these vessels to increase the batch throughput before any new equipment is installed [5].

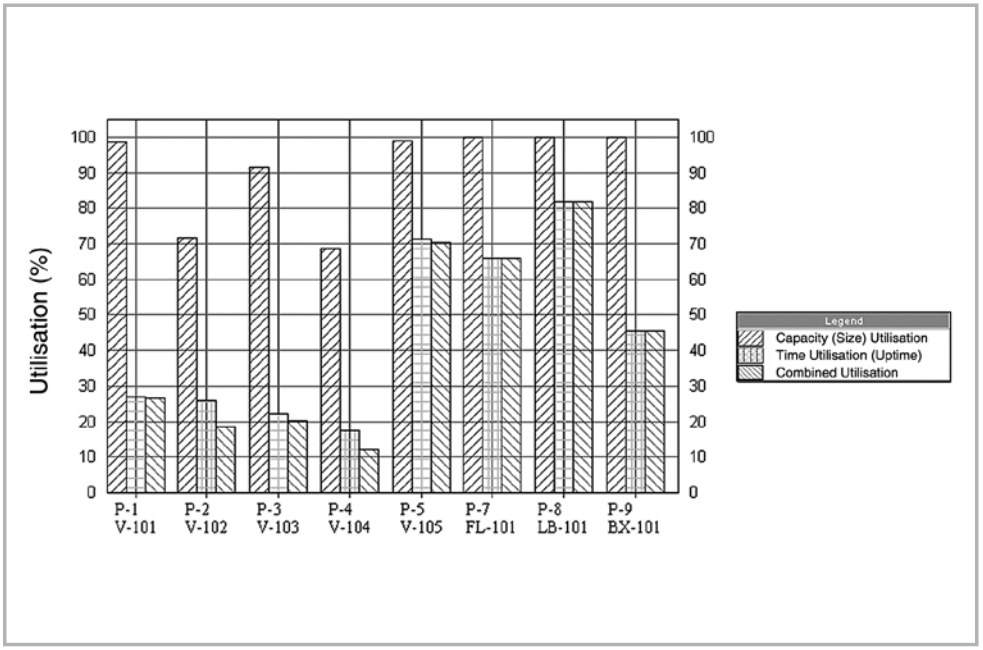

Figure 4: Throughput analysis chart for Scheme 1

Second, as shown in Figure 3, the labelling procedure P-8 (LB-101) has the highest combined utilisation among all procedures, *i.e.* 76.9%, due to its equipment capacity utilisation of 100% and the equipment uptime of 76.9%. The high equipment uptime of this procedure is mainly due to its slow operating speed (30 labels/min). This also makes it the scheduling bottleneck of the process, *i.e.* process with longest operating duration (see Operation Gantt Chart in Figure 2). Hence, bebottlecking strategies should be developed to reduce either size or time utilisation of this process bottleneck. The debottlenecking objective has been set by the plant authority to increase the eye drop production by 25%.

5.0 PROCESS DEBOTTLENECKING SCHEMES

Three debottlenecking schemes were developed and analysed using SuperPro Designer v6.0 [10]. In Scheme 1, all equipment and machineries in the existing production were maintained. The main strategy in this scheme was to increase raw material feed to the process up to the maximum capacity of the equipment. This corresponded to a capacity of 80 L eye drop liquid per batch. Due to the increase of process throughput, simulation result showed that the annual production for this scheme was decreased to 190 batches due to the prolonged minimum cycle time from 6.67 hrs (in the base case simulation) to 8.89 hrs. However, this negative effect of the prolonged minimum cycle time (which will lead to reduced number of annual batches) is offset by the increase of batch throughput of 16001 bottles. This eventually leads to higher production of 3.04 million of eye drop products per annum, corresponds to an increase of 6.0% as compared to the base case simulation. From the simulation and throughput analysis results (shown in Figure 4), the labelling procedure P-8 was determined to remain as the scheduling bottleneck with a combined utilisation of 81.6%. Besides, two vessels V-101 and V-105 have reached their maximum capacity utilisation to the increase of raw material feed.

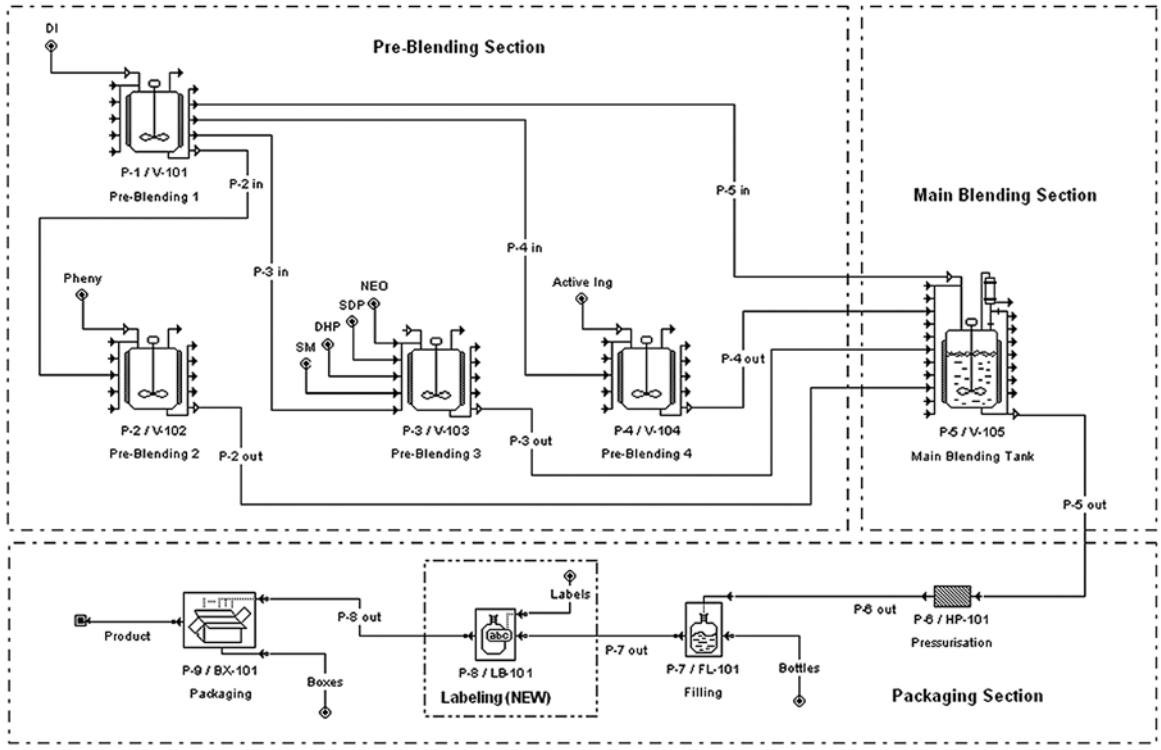

Figure 5: Simulation flowsheet for debottlenecking Scheme 2

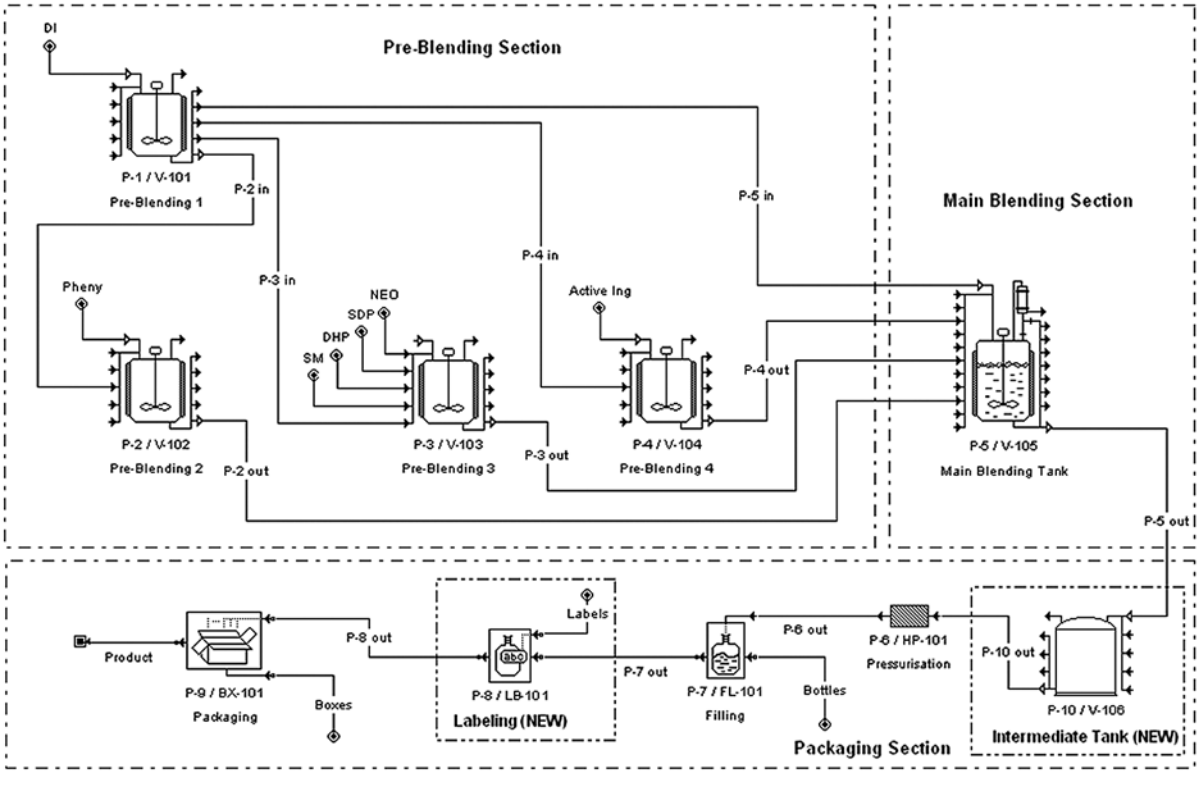

Figure 6: Simulation flowsheet for debottlenecking Scheme 3

Table 3: Process throughput of all schemes

Throughput parameters	Base case	Scheme 1	Scheme 2	Scheme 3
Batch production (bottles/batch)	12,000	16,001	16,001	16,001
Plant batch time (hour)	9.51	11.57	10.62	10.71
Minimum cycle time (hour)	6.67	8.89	7.76	7.25
Number of batches/year	239	190	213	224
Annual production (bottles/yr)	2,868,000	3,040,190	3,408,213	3,584,224
Increment of production (%)	–	6.0	18.8	25.0

Table 4: Combined utilisation values for all unit procedures in different schemes

Equipment Tag	Procedure Name	Base case	Scheme 1	Scheme 2	Scheme 3
P-1 V-101	Pre-Blending 1	25.0	26.6	29.7	31.3
P-2 V-102	Pre-Blending 2	17.3	18.5	20.7	21.8
P-3 V-103	Pre-Blending 3	19.3	20.3	22.7	23.9
P-4 V-104	Pre-Blending 4	15.1	12.1	13.5	14.3
P-5 V-105	Main Blending Tank	52.0	70.3	**78.5**	7.2
P-7 FL-101	Filler	63.5	65.8	73.5	**77.5**
P-8 LB-101	Labeller	76.9	**81.6**	68.3	72.1
P-9 BX-101	Packaging	44.2	45.4	50.7	53.5

Debottlecking Scheme 2 (Figure 5) is built upon Scheme 1 (with higher batch throughput), where a new labelling machine (P-8/LB-101) with a rated throughput of 40 label/min was installed. As a result of the higher labelling speed, the equipment update uptime is reduced, which leads to lower combined utilisation of 68.3%. Besides, the combined utilisation for other procedures have significantly increased. In other words, these procedures are better utilised in the overall context of the process. Simulation results reported that an increase of 18.8% was achieved for the annual production (3.41 million bottles/year) as compared to the base case simulation. With the installation of a new and faster labelling machine, the Main Blending Tank (P-5/V-105) appeared as the new process bottleneck with a combined utilisation value of 78.5%. To further increase the plant annual production, debottlenecking should focus on reducing the long duration of the transfer out operation in P-5/V-105 (see Figure 2). This will be carried out in Scheme 3.

Scheme 3 for process debottlenecking is shown in Figure 6, which is built upon Scheme 2, *i.e.* with the newly installed labelling machine. As shown in Figure 6, where an additional intermediate tank (P-610/V-106) is installed between the Main Blending Tank (P-5/V-105) and high pressure operation (P-7/HP-101). The blended eye drop product will be transferred to this tank upon the completion of the blending operation in the Main Blending Tank (P5/V-101), while feeding the blended product to the filling machine. This enables the operations in the Pre-Blending and Main Blending Tanks to be carried out without having to wait for the completion of the filling operation. Simulation results showed that combined utilisation values of P-5/V-105 was reduced significantly to 7.2%. Similar to the case of Scheme 2, all other procedures demonstrate better utilisation in the overall context, represented by the increase of the combined utilisation values. The net result is the reduction of minimum cycle time to 7.25 hrs and an increased annual production rate of 3.58 million bottles, i.e. 25% as compared to the base case. Debottlenecking efforts were stopped at this scheme as the debottlenecking objective had been reached. Note that for both Schemes 2 and 3, it is assumed that the fixed cost of installing new equipment is within the capital expenditure limit of the plant authority. If the scheme is justified to be implemented, detailed economic analysis is to be carried out to evaluate its cost/benefit ratio, such as that carried out by previous study [9].

All the proposed debottlenecking schemes have demonstrated significant improvement on the annual production. Tables 3 and 4 summarised the process throughput and combined utilisation values for the base case simulation as well as all debottlenecking schemes. As shown in Table 4, the combined utilisation values for all unit procedures are increasing gradually with the proposed schemes, with the exceptional case for the process bottleneck (value in bold). In other words, by reducing the combined utilisation of the debottleneck equipment, the combined utilisation of other equipment will be raised, which also means that they are better utilised in the overall context of the process. Finally, note that all scheme presented here are bound with the limitation that the process is analysed during its steady-state operation. Similar exercises will have to be carried out to identify a suitable operating scheme.

6.0 CONCLUSION

In this work, (CAPD) and simulation tools were used in the systematic identification of the process bottleneck and debottlenecking study. An industrial pharmaceutical of liquid eye drop is used to demonstrate the effectiveness of the tools. The annual process throughput is increased for 25% with the increase of batch throughput, installation of a high speed labelling machine and the use of an intermediate tank. ■

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PROFILES

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