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USE OF THE INDICATOR OF OVERALL EFFECTIVENESS OF EQUIPMENT AS A TOOL FOR CONTINUOUS IMPROVEMENT: CASE STUDY APPLIED TO THE PHARMACEUTICAL PRODUCTION

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Abstract

The pharmaceutical industry is inserted into a scene of fierce competition, facing rising costs of research and development and is subject to greater regulatory requirements. It is important that pharmaceutical companies seek to design, measure and improve the performance of its operations and of its equipment. The performance indicator named overall effectiveness of equipment (*Overall Equipment Effectiveness* -OEE) is often adopted to evaluate the performance of machines and production lines. The aim of this study is to evaluate the use of OEE as tool for performance evaluation, identification of losses and as a basis for the development of continuous improvement actions in a public national pharmaceutical laboratory. The results indicated that, although the OEE has been employed to measure the performance of an individual equipment, he made possible the identification of waste that impacted the production process as a whole. The OEE has allowed managers to prioritize actions directed to the Elimination of the main waste identified, being used as a tool to support the production management.

Keywords: Pharmaceutical industry; performance indicators; overall effectiveness of equipment; continuous improvement.

1. INTRODUCTION

During the last two decades, the pharmaceutical industry showed significant growth, originating, inter alia, industrial concentration, high profits and combination of growth in consumption of medicinal products with price increase (Vargas *et al.*, 2009). The world pharmaceutical market is highly concentrated. Although composed of a large number of companies, is controlled by some multinationals. Due to the complexity of processes and related knowledges, pharmaceutical companies do not manufacture all varieties of medicines, specializing in certain therapeutic classes, what characterizes the pharmaceutical industry as a differentiated oligopoly (Santos *et* pine, 2012). This sector has faced several challenges, as Herlant exposed (2010), among which:

- The expiration of patents for products sales leaders in the industry and the consequent competition with generic market;
- The adoption, by the regulatory agencies, stricter criteria for proof of safety and efficacy of medicinal products;
- The criticism from patients, of the press and the Government in the light of the high prices of medicines;
- A research and development process long, costly and with high uncertainty.

A critical issue that contributes to the increase of the General costs of the sector, in addition to the P & D, is the rising cost of manufacture: for brand-name medications, that cost fluctuates between 27 and 30% of the value of sales (Basu *et al.*, 2008). In this context, the pharmaceutical companies have sought to reevaluate their operations in search of greater operational efficiency. Practices used in automotive

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and electronics to reduce process times, eliminate waste and reduce costs have been adopted in pharmaceutical branch. Since 2004, an international *benchmarking* study called "*Operational Excellence in the Pharmaceutical Industry*" is conducted by the *Institute of Technology Management* (ITEM) of the University of St. Gallen, in Switzerland, which assesses the technical deployment of operational management in the pharmaceutical industry from the adoption of different established concepts of production management, as the *Just in Time* (JIT), Total Quality Management (TQM) and Total Productive Maintenance (TPM). Based on the experience of the most efficient, one of the main results of the survey pointed out that the first step to achieving operational excellence is the standardized and stable operation of the equipment (Friedli *et* Goetzfried, 2010).

One of the ways to standardize and stabilize the operation of the equipment is to plan and manage its use, in the context of a production system. The overall effectiveness of indicator equipment (*Overall Equipment Effectiveness* -OEE), originally employed in the automotive industry, is currently used in various industries to support the planning and management of the use of equipment, measuring, evenly and consistently, the factors that directly affect its performance (Ahuja *et* Khamba, 2008).

In a public pharmaceutical laboratory located in Rio de Janeiro, there was the need to quantify the productivity losses of equipment and develop actions to eliminate them, with a view to increasing the efficiency of the production system.

This work seeks to show the importance of using the OEE as an instrument of management support, showing the results of your application in the lab in question, in particular, its use in the identification and quantification of waste, serving as a basis for the design of continuous improvement actions.

In the next section of this article, will be presented the concepts and calculations of the OEE. In the third section, will be described in the method adopted; and, in the following section, the assessment of the production flows for critical equipment. In the fifth section, will be discussed the implementation of the indicator; and on Friday, the results of the analysis of the OEE, including waste and the improvement actions identified. In the last section, will be presented for the completion of the work.

2. OVERALL EQUIPMENT EFFECTIVENESS INDICATOR

The OEE was proposed by Seiki Nakajima to track the progress of the TPM. The goal of the TPM is to achieve the maximum effectiveness of the equipment, resulting in the Elimination of faults, in the reduction of downtimes, switch, in the increase of productivity and improvement of quality (Ahuja *et* Khamba, 2008).

The OEE is the product of three indexes (*see* equation 1):

$$\text{OEE} = \text{"Availability X Performance x Efficiency Quality Rate"} \quad (1)$$

These indexes quantify the six big losses that impact the operation of the equipment and which were identified by Nakajima. Loss or waste are defined as activities that absorb resources, but do not create value. In table 1, can be viewed the indexes and the losses which affect the rates in question.

Table 1 - Relationship between losses and OEE indexes

Indexes	Losses	Definition of losses
Availability	Breaks and crashes	Defect or abnormal condition that prevents the proper functioning of the equipment
	Set ups and tweaks	Time for the exchange of machine and settings
Performance efficiency	Idleness and small stops	Short outages. Characterized by intermittent shutdowns.
	Reduced speed	Actual speed lower than the theoretical speed
Quality rate	Defects in the process	Non-conforming units (defective) and rework
	Losses relating to initial startup (startup) of the equipment	Reduction of the quantity of products in line according to the necessary adjustments to the machine reaches the condition of regime after a long stop period

Source: Elaborated from Hansen (2006)

Figure 1, below, illustrates how the losses measured by the indicator affect the total equipment uptime.

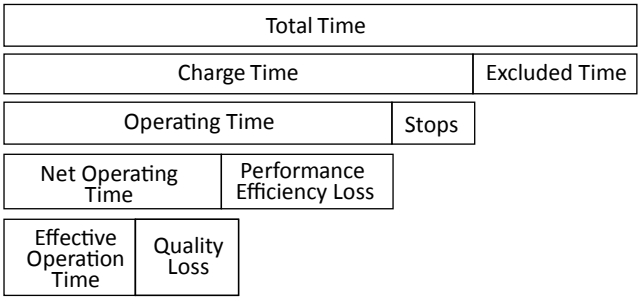

Figure 1 - OEE – times and losses
Source: Elaborated from Sujkowski (2006)

Electronic Journal of Management & System
Volume 11, Number 1, 2016, pp. 49-60
DOI: 10.20985/1980-5160.2016.v11n1.788

The present times in Figure 1 are defined in string (Hansen, 2006):

- Total time-total time available in a given period. For a week, this time is 168 hours (24 hours'/day x 7 days/week);
- Deleted time-time for which there is production scheduled, such as: weekends, holidays, breaks for meals, preventive maintenance and testing. The remaining time (Total time discounted the Time Excluded) is called Load time;
- Charging time-time during which the regular production activities and gaps that were not programmed;
- Charts-time concerning unplanned stalls (gaps, breaks, etc.);
- Operating time-part of the time in which the equipment is actually producing. Is the difference between the charge time and the stops;
- NET operating time-difference between the operating time and the time for performance efficiency losses, as, for example, the production time with speed lower than the theoretical;
- Effective operating time-difference between net operating time and time losses relating to quality, such as the time spent producing non-conforming units.

Decomposing the indicator in its contents, it is possible to check the impact of each of them on the performance of the equipment. The availability indicates the fraction of the time planned for the production (load time), in which the equipment is actually producing. The formula of this index is described in equation (2) (Hansen, 2006):

$$\text{Disponibilidade} = \frac{\text{(Tempo Operacional)}}{\text{(Tempo de Carga)}} \times 100 \quad (2)$$

For the calculation of the terms used in equation (2), *see* Figure 1 and equations (3) and (4).

$$\text{Operating Time} = \text{Charging Time} - \text{Charts} \quad (3)$$

$$\text{Charging Time} = \text{Total Time} - \text{Deleted Time} \quad (4)$$

Performance efficiency is the ratio of the operating time and the theoretical time of operation. For the calculation of performance efficiency, Hansen (2006) presents the formula (5).

$$\text{Performance Efficiency} = \frac{\text{Theoretical or Ideal Cycle Time}}{\text{Actual Cycle Time}} \times 100 \quad (5)$$

Where the Theoretical or Ideal cycle time is the time required for the equipment to produce a product unit at the rate projected by the manufacturer of the equipment or the best speed determined for each product (highest speed reached during a significant period of time with the stable process) (Hansen, 2006).

In the case of batch processes, the need to set the cycle time as a batch processing time is referenced in Alvarez *et* Antunes (2001). Junker (2009) describes a modified version of the OEE, in which performance efficiency is calculated according to equation (6).

$$\text{Performance Efficiency} = \frac{\text{Theoretical or Ideal Processing Time}}{\text{Actual Processing Time}} \times 100 \quad (6)$$

Where the actual processing time of a batch is equal to the operating time (time when the equipment is effectively producing) (Hansen, 2006).

The quality rate indicates the ratio of the quantity of products and the total quantity of products. The formula of calculation of this index is presented in equation (7) (et Pintelon Muchiri, 2008).

$$\text{Quality Rate} = \frac{\text{Number of Complying Products}}{\text{Total Amount of Products}} \times 100 \quad (7)$$

The original calculation of the OEE is restricted to measure only the losses directly related to the operation of the equipment. Losses arising in production systems and that represent potential opportunities for improvement are not considered by the indicator. In the light of that limitation, emerged in the literature modified versions of the OEE, in whose structures were included losses of factory management system, such as charts for lack of raw material, by the use of non-compliant materials, lack of demand, among others. In addition to these versions, formulations were developed whose basic structure is very similar to that of the OEE, showing changes in the formulas for calculating the indexes (Badiger *et* Gandhinathan, 2008). As an example, the productivity is cited as Indicator of the *Total Effective Equipment Productivity* (TEEP), whose index of availability is calculated by replacing the charging time by the total time (24 hours/day) (Prates *et* Bandeira, 2011).

The OEE can be applied to any machine, and, in General, are prioritized equipment whose performances are admittedly unsatisfactory, which are installed in areas with high capital investment and bottleneck features (equipment which limit the production capacity of the whole system). Another

Electronic Journal of Management & System
Volume 11, Number 1, 2016, pp. 49-60
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factor considered in the selection of the machines is the processing of products, whose volume, cost and strategic role are critical to the Organization (Hansen, 2006).

The OEE, however, is not only a tool for evaluating the performance of an equipment. In fact, the individual assessment of the equipment system evaluation represents little of production, you need to consider the treatment of information. However, by enabling the identification and quantification of losses that affect the equipment, the OEE also recognize that impact waste production system as a whole. To detect the root cause of the waste analysis techniques are used (as, for example, the diagram of "Ishikawa", 5W2H etc.) from the recorded data for the calculation of the OEE. The use of OEE goes beyond simple performance measurement, serving as the basis for the identification of the root causes of the losses and to develop continuous improvement actions.

3. RESEARCH METHOD

This research falls primarily on the traditional approach of a case study, since its aim is not restricted to only analyze quantitatively determined phenomenon, but rather conduct a holistic assessment of the use of the OEE, production system that goes beyond pure and simple behavior of the equipment itself. This research is a case study of instrumental, and, in that respect, the work consisted of three basic steps.

3.1 Description of research method

3.1.1. Understanding and evaluation of the process of production for critical equipment

To apply the OEE, the production system was analyzed, and thus was chosen an equipment whose priority was effectiveness improvement to the system. It was decided to apply the OEE in equipment used in the production of antiretroviral drugs, hereinafter here A, B and C, which are strategic for the institution because they constitute the largest revenue in the lab.

3.1.2. The deployment of OEE

The deployment step of the OEE is composed by the following activities: first, the definition of losses to be pointed, then by the systematization of data collection and estimates of the OEE, and, as a result, the training of operators and for the evaluation of the first records of data and results of the OEE.

At the end of this step, an analysis of the difficulties and critical factors observed in the process of implementation of the indicator.

3.1.3. Use and evaluation of the OEE

The third stage understood the use of the indicator as a tool for identifying losses and development of continuous improvement actions in line with anti-retroviral drugs. After the consolidation of the use of the indicator were recorded losses of greater impact on the equipment and its root causes. Then, were proposed and evaluated actions to reduce these inefficiencies in conjunction with the Manager and supervisors. During this step, the data and the results of OEE were provided in the equipment room for employees' access. Meetings were held with the operators for the analysis of the results and the proposal of improvements. The immediate deployment of the improvement actions identified was subject to the technical and economic feasibility. The improvements that were not adopted immediately were recorded for future deployment.

The following subsections present the development of these activities.

3.2. Application of the research method

3.2.1. Understanding and evaluation of the process of PRODUCTION for Critical Equipment

Flowcharts of production of antiretroviral drugs A, B and C are presented in Figure 2.

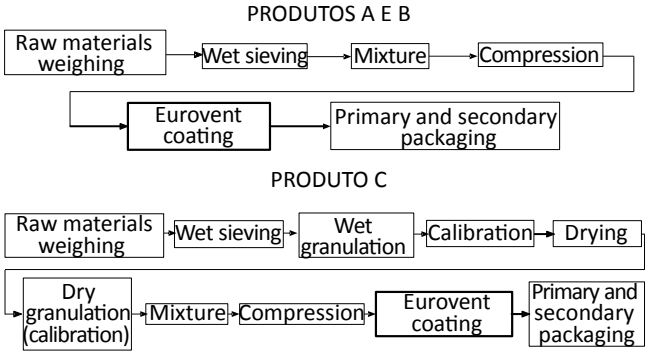

Figure 2 - Production flowcharts of medicinal products A, B and C
Source: the authors themselves

In the case of products, A and B, the raw materials are heavy, sifted (Thistles) and mixed. As a result, the mixture of raw materials is compressed, and the pills that are generated are coated. The packaging is performed in line

Electronic Journal of Management & System
Volume 11, Number 1, 2016, pp. 49-60
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filling jars. The production process of the medicine (C) includes a number of additional steps: after weighing and sieving, the raw materials are grainy, calibrated, dry and calibrated again. These phases are required so that the mixture acquires the necessary features for compression. The subsequent steps are common to the production flow chart and b. During the stages of production, the sector of in-process Control performs analysis in intermediate product (product in the process) in order to prevent non-conformities are detected only in the final product. After coating, the in-process Control inspects the aspect of the tablets. This inspection is verified the presence of tablets broken, chipped, with rough imperfections and other irregularities. For each type of deviation (non-conformity) of aspect, there is an acceptance criterion established. If the amount of pills with deviation exceeds the specified threshold, the batch is selected. In the selection, production officials inspect the appearance of all the pills in the batch and non-compliant units are discarded for later destruction.

For the case study, was selected the Eurovent DC 200 equipment, used in the finishing process of the antiretroviral drugs A, B and C.

Analyzing the process of production of these medicines, it was concluded that the coating is the bottleneck, as the phase with the greater processing time. This motivated the choice of Eurovent. Possible improvements to this equipment would increase its production capacity, allowing its use not only for anti-retroviral drugs, but also shared in the production of other medicines.

Another justification for choice of Eurovent was the difficulty encountered in the initial (*startup*) of the equipment. Between receipt of the equipment in the lab and the beginning of the operation, several complications occurred. The manufacturer of the equipment ceased publication before the installation of the machine. During the initial testing phase, were detected deviations in automation and equipment failures. In the light of these problems, we decided to apply the OEE to Eurovent to know the factors that impacted their performance, especially those of relevance to preventative maintenance and reliability, as, for example, the causes of failures.

The Tablet coating process consists of its covering with a film of polymer base. About the pills in motion, a suspension, which is dried by a hot air flow.

The equipment consists of a drum which rotates about a horizontal axis, as can be seen in Figure 3.

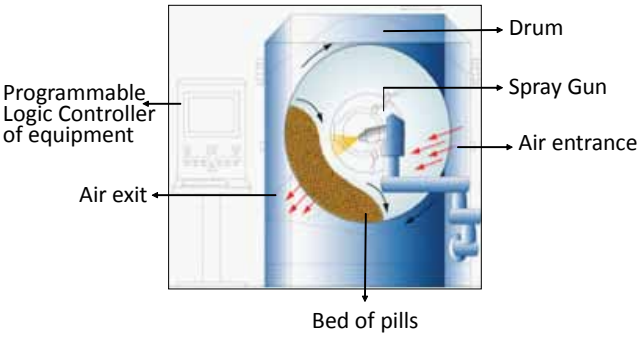

Figure 3. The inner coating equipment, emphasizing the sprinkler gun.

Source: Elaborated from Glatt Pharmaceutical Services (2012)

Such equipment features a hood attached to your exhaust pipe and the side of the drum. With the rotation of the drum, the tablets inside are moved around a cascading scroll flow (bed). The equipment presents units of inflating and air exhaust. The control of inbound and outbound flows of air generates negative pressure (depression) inside the drum and ensures that the hot air is blown through the bed of pills. Equipment, are engaged a pump and spray guns. This process is automated so that the coating process parameters (temperatures of inflating and air exhaust, depression, speed of the drum, among others) can be monitored and/or controlled via Programmable Logic Controller (PLC).

3.2.2. Deployment of OEE

The first step of the deployment itself was assigned, together with operators, the most common causes of the machine stops (loss of availability). The structure adopted by the loss was based on the structure used by the ITEM on international benchmarking studies in the pharmaceutical industry (Friedli *et* Goetzfried, 2010), namely:

- • Loss of availability: REF-meals, 01-02-machine exchanges adjustments during the process, 03-04, vestment – waiting for corrective maintenance, 05-06-corrective maintenance, repair performed by the operator, 07-lack of raw material, intermediate product/08-raw material/intermediary product does not comply, 09 – environmental conditions do not comply, 10 – lack or maintenance of utilities, 11-lack of operator, 12 – waiting for approval of intermediate product , 13-meetings/training, 14-other stops;

- • Performance efficiency losses: the idleness and small, low speed;

- • Quality Loss: defects in the process, losses relating to initial startup (*startup)* of equipment.

Electronic Journal of Management & System
Volume 11, Number 1, 2016, pp. 49-60
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As a result, the collection of data and the calculation of the OEE were systemized. The availability was calculated by equation (2), using the data recorded by operators in form prepared for this purpose. This data consisted in the intervals of production time and machine stops. Such form was also used to record observations pertaining to, for example, the description of the reasons of maintenance.

For the calculation of performance Efficiency, was adopted the equation (6). Due to the coating of tablets is a batch process, cycle time was regarded as the time of processing of the batch (or lot), since it is not possible to determine the finish time of a unit of product.

As there was a theoretical processing time established for products, was adopted as the criterion determining the shortest time between finishing the first 20 lots produced consecutively.

The Quality rate was calculated using equation (7). The total amount of products (the denominator formula) corresponded to the initial amount of tablets in the finishing process, i.e. the quantity of tablets obtained in previous phase – the compression. The amount of products complying (numerator of the formula) corresponded to the amount of tablets obtained in coating, with the exception of selected batches. In these cases, the amount of products complying corresponded to the amount obtained after the selection (*see* item 4.1).

It was established that both the indexes as the OEE would be calculated for each lot and per month, in Excel spreadsheets.

3.2.3. Data and Evaluation results of OEE and deployment process analysis

The training of operators, and the first records of data and results of OEE were accompanied by the researcher. By working in the production, the researcher could have the general perception of the consistency between the notes and the occurrences of production, and can verify, for example, if the equipment failures had been registered with the correct time interval and properly. The greatest difficulty encountered by operators was the classification of some charts and production event codes availability losses due to errors of interpretation. It was also noticed that sometimes two events occurred at the same time, and the operator was in doubt about which point. Maintenance notes, there was a lack of detail in the description of the events, which would make the analysis of the types of failures, as well as its incidence and effectiveness of maintenance.

After a month of records, a new training with operators to remedy the difficulties encountered. For the implementation of the indicator were fundamental: the training of operators, the clear definition of the losses to be recorded and the description of the level of detail required in the notes. In addition, it was observed that the monitoring of initial records it is important to identify difficulties and resolve doubts.

4. RESULTS

4.1. Analysis of the root causes of the OEE, waste and actions for improvement

The OEE Eurovent coating equipment was calculated for 11 months. As can be seen in Figure 4a, the OEE Eurovent equipment ranged between 18 and 44%, being the indicator was not calculated during 5 and 6. During this period, due to flaws in the machine and deviations in appearance a product, equipment processing was stopped for checking the overall functioning of the machine. The index of availability was the most impacted the results of the indicator, which can be seen in the unfolding of the OEE on its component indices (figures 4b, 4c and 4d). The results of months 2 and 4 have also been influenced by quality, which performed in these months, lower than the rest of the analysis period.

4.1.1. Individual examination of quality index

Between 1 and 9, the values of the indices of quality of this equipment 24%, and ranged the average for the period was 91% (Figure 4b). In the last four months analyzed, the amplitude (dispersion) of results reduced to 6%, and the average of the index increased to 97%.

The lowest quality indexes observed (in 2, 4 and 9) were due to income (ratio between the actual amount of product obtained in a proceeding and the amount that should theoretically be achieved) downs of some batches of the product c. These lots showed deviations of aspect, which were classified into two main types: broken or chipped edges and spots.

In meetings with the sectors of pharmaceutical technical assistance and quality assurance, discussed actions to reduce the deviations. Among the actions taken include:

- Fine-tuning and progressive in product coating parameters (input air temperature and rate of application of suspension). This optimization of the parameters was performed without exceeding the specified control in the development of the product and validated. In this action, the involvement of operators and their contributions to the improvement of the process were very important;

Electronic Journal of Management & System
Volume 11, Number 1, 2016, pp. 49-60
DOI: 10.20985/1980-5160.2016.v11n1.788

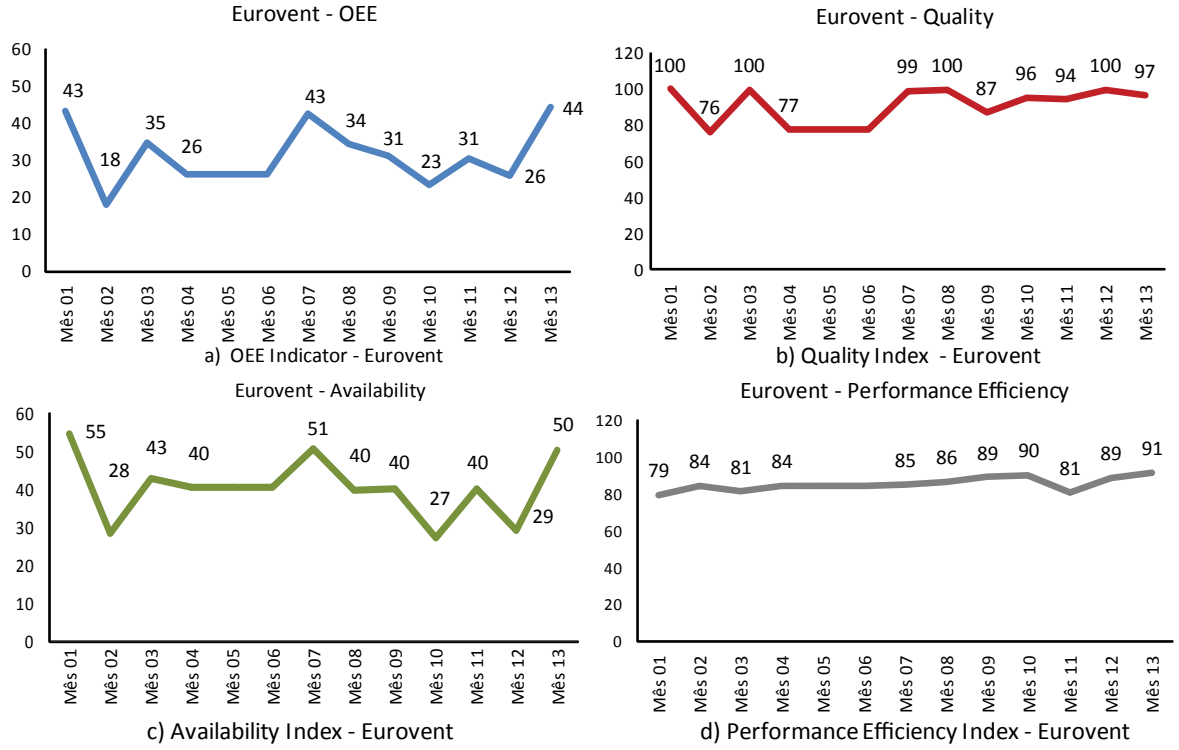


Figure 4 - OEE and indexes relating to equipment Eurovent DC 200
Source: The authors themselves

• In view of the likely correlation between the faults on the machine and the presence of stains on pills, equipment processing was stopped for checking the overall functioning of the machine. This resulted in the realization of the following corrective maintenance on equipment: correction of the depression of the drum, see control valve of the inflating air, adjust the opening of the exhaust hood and repositioning of compressed air hoses.

Such corrective actions have been effective. This fact was confirmed by monitoring the number of deviations in appearance that originate in the finishing process. After the calculation of the OEE (13 month), this monitoring was carried out for 5 months, employing the *software* of management of non-conformities, used at the institution. These 5 months, 80 lots of product C were coated in the equipment and not show non-conformities. The Elimination of this diversion increased the average income of lots of medicine C at 9%, as well as eliminated the wasteful costs (related to labor used in the selection of pills and the destruction of discarded medicines).

4.1.2. Individual analysis of availability index

The OEE variation over the months was similar to the variation of availability (Figure 4 c) depending on the high impact of this factor on the scorecard, compared to other indexes.

Figure 5 Shows a Pareto chart of production stops, and, as you can see, the biggest loss of availability was caused by the time of return of products or batches.

The *set ups* accounted for 52% of the total. This result was consistent with other studies, which showed that the *set ups* are significant pharmaceutical industry wastes, arising from the high level of sanitization and high frequency of cleaning required and of the regulatory requirements to which this industry is subjected (Sugai *et al.*, 2007; Gilmore *et* Smith, 1996).

A work of improvement of the *setup* of the equipment was started in month 11, after cleaning validation studies. These studies determined changes in agents and in cleaning the equipment and procedures of the respective room.

Two months after the end of the calculation of the OEE, the implementation of the principles of early exchange of tools (EET) was held. Initially, the exchanges were accompanied to the identification of the activities carried out and the registration of its duration. It was determined the precedence of the tasks according to

Electronic Journal of Management & System
Volume 11, Number 1, 2016, pp. 49-60
DOI: 10.20985/1980-5160.2016.v11n1.788

the dependency between them, i.e. There were actions that necessarily should be preceded by others. The activities were classified in *set up* operations intern, which should be carried out with the equipment stopped, and *set up* external, that could be performed with the machine in operation. Trading activities were reorganized, and, when possible, *set up* operations were converted into internal *set up* outside. For example, the transport of materials (parts, cleaning agents, etc.) required for the Exchange and the next batch has spent running while the equipment was still in operation. The tasks of the internal *set up* were divided between two operators. Thus, the activities that were performed sequentially began to be performed in parallel. In addition, were made reference marks and scales in some pieces of equipment to facilitate and expedite the adjustment required in exchange of product formats.

In table 1, can be viewed by the average durations of *set ups*, times of return obtained with the use of EET and the respective percentages of reduction. Fit note that pharmaceutical companies classify the exchanges between lots of the same product as partial or superficial, while exchanges between lots of different products are called total or profound.

As the coating step was the bottleneck of production lines for medicines, (B) and (C), reducing the time of preparation of the equipment has increased not only the capacity of the machine, but also the global flow capacity of the production lines of A, B and c. prior to implantation of the EET, every campaign of seven lots of product were spent, on average, 33.36 hours of *set up*. After the use of the tool, this time reduced to 9.27 hours, on average, every batch, 24.09 7 campaign hours for processing.

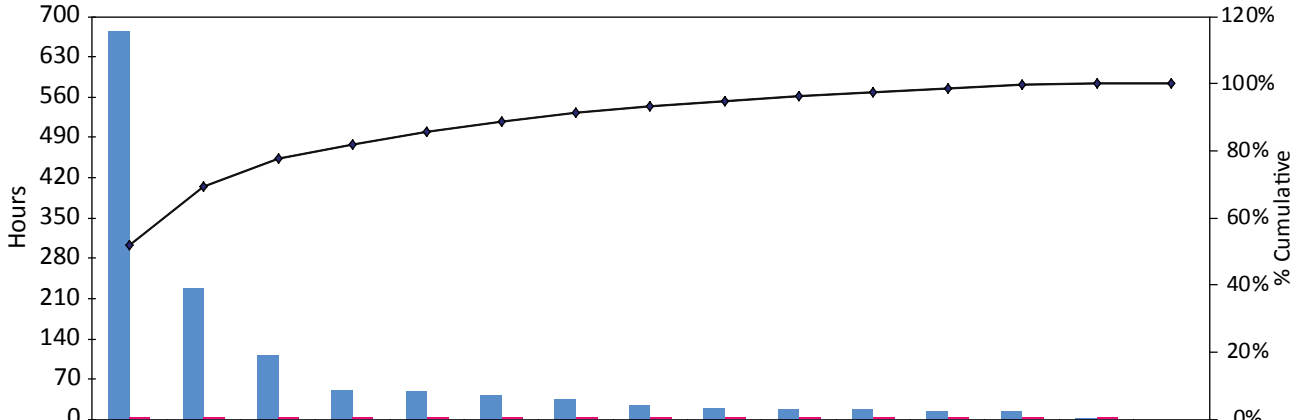
Table 1 - Eurovent-comparison of average times to *set up* with the times of return obtained with the adoption of the EET

Type of set up	The average time of set up (h)	Time of return obtained with the use of the EET (h)	Reduction (%)
Partial	3.45	0.92	73.33
Total	12.66	3.75	70.38

Source: The authors themselves

In total, the other most significant outage causes were: corrective maintenance and other stops. Outages resulting from corrective maintenance were its smaller than those caused by trade. However, the flaws become unstable equipment operation, and can increase processing time of lots and compromising the quality of the products. Reduced reliability of the machines contributes to the formation of in-process inventory and for the lack of adherence to the production scheduling (Friedli *et* Goetzfried, 2010).

Due to the likely correlation between equipment failures and the aspect of the product C, the coating on the equipment was stopped for checking the overall functioning of the machine. In this way, the necessary corrective maintenance was performed. It was observed that the failure caused by insufficient depression of the drum was due to the saturation of the exhaust filters, and weekly



	01 EXCHAGE	05 MAINT	14 OTHER STOP	12 APPROV INTERM	11 LACK OPERATOR	06 REPAIR OPER	09 NON-COMP ENVIRON COND	04 WAITING MAINT	07 LACK RAW MAT / INT PROD	13 REUN / TRAINING	10 LACK / MAINT UTILIT	15 ENVIR COND	03 PARAMEN	02 ADJUST	08 LACK RAW MAT / INT PROD NOT INTERM
Hours	675	227	113	51	49	42	36	25	19	17	17	16	15	3	0
%	52%	17%	9%	4%	4%	3%	3%	2%	1%	1%	1%	1%	1%	0%	0%
% Cumulative	52%	69%	78%	82%	86%	89%	92%	93%	95%	96%	97%	99%	100%	100%	100%

Figure 5 - Pareto chart of production stops-Eurovent 1 Month to 13

Source: The authors themselves

Electronic Journal of Management & System
Volume 11, Number 1, 2016, pp. 49-60
DOI: 10.20985/1980-5160.2016.v11n1.788

cleaning of these filters has been included in the preventive maintenance routines. As a result of this measure, there was no more records depression insufficient on the drum. During periods without production scheduling, preventive maintenance activities were carried out, however, there have been various types of defects in the equipment during the total period analyzed. This was due to the fact that part of the failures followed random patterns, were not failures whose occurrences were proportionate to the time of use of the equipment.

Preventive maintenance activities are based on an estimated probability that the machine will break down or fail within a specified interval of time. However, for some components, the likelihood of failure increases with the time of operation. In these cases, the maintenance based exclusively on operating time has no effect on the rate of failure. An action for the reduction of the number of random crashes is the implementation of more efficient methods of maintenance, such as predictive and proactive. This deployment would benefit the entire production system, since random faults are observed in equipment of all work centers. In the code of other stops, were pointed disruptions relating to cleaning validation routines (sampling, time to wait for results of analysis), the temporary operator offsets to other activities, waiting for documentation and follow-up carried out by the process service industry. The largest percentages of code 14 (other stops) in relation to the load time were observed between 9 and 12 and were due to the activities of cleaning validation.

Resuming the Pareto analysis, it appears that the other outages accounted for losses of little significant availability, since each percentage less than presented 5% of the total. For some of these outages, were recorded observations relevant to the establishment of future continuous improvement actions.

It was observed, for example, sometimes the activities of approval of intermediate product (physical-chemical analyses and records in batch documentation) delayed the start, due to the short time interval between the compression and coating and the non-existence of an iron Lung in product process.

All repairs carried out by the operator were due to correction of faults in spraying of pistols. By virtue of these notes, Maintenance checked the pistols and requested the purchase of new units.

The charts for lack of intermediary were not significant. However, during the time period analyzed, if reprogramming of the work centers, which reduced the incidence of this type of outage. The lack of adherence to the schedule and the consequent reprogramming were due to deviations of quality of raw materials, the equipment capacity constraints of the Department of quality control and procurement processes which are submitted the public laboratories pharmaceuticals. Law No. 8666, of 1993 (Brazil, 1993), which regulates the purchases of official laboratories provides that these must be carried out by means of bids, based on the criterion of the lowest price. The delay and the lack of flexibility of the bidding process (Hasenclever *et al.*, 2008) aggravate in emergency cases, as, for example, when delays in supplies, Deprecations of raw materials and packaging materials and the need for purchases of parts for the repair of equipment outages. In these cases, production is interrupted for longer periods, and it is necessary to reprogram the work centers.

4.1.3. Individual examination of performance efficiency index

Observing the behavior of the performance efficiency index of equipment in Figure 4 d, there is a growing trend, with the exception of the month 11. This month, there were flaws in the inflation and deviations in the operation of the spray gun. It was noted the occurrence of lower temperatures of the air blown and lower rates of spraying. Consequently, coating times increased, reducing the efficiency ratio.

During the time period examined, there were no records of equipment operation interruptions for stops less than 5 minutes (small charts).

Were observed lots whose processing time went beyond the theoretical. Finishing times vary according to characteristics inherent in the process itself. At the finish, it is not always possible to use parameterization, which provides the lowest process time. Sometimes, the parameters need to be adjusted, impacting the operation time.

In the process, the operator monitors the aspect of the tablets and shall carry out the changes, if necessary. For example, if at the beginning of the coating the tablets are crumbly (that is, with low wear resistance by friction), the speed of rotation of the drum must be reduced in order to lower the risk of imperfections on the surface of the pills, since the parameters are interdependent. With the reduction of drum rotation, the flow of application of suspension should be decreased and/or the input air temperature must be increased, otherwise, the pills may be overly humid and, thus, some clinging to the other.

Air humidity fluctuations of entry can also change the coating and drying conditions, making it necessary to adjust the process variables (Pinto *et* Fernandes, 2001).

Electronic Journal of Management & System
Volume 11, Number 1, 2016, pp. 49-60
DOI: 10.20985/1980-5160.2016.v11n1.788

As a result of these facts, is provided to the operator to change the parameters, since within the tracks specified in product development and validated. During the process, at regular intervals, the operator checks the average weight of the nuclei, and the application is terminated when the specified range to the coated tablets is reached. Even though the operators say that, in General, use the total amount of suspension, the end of the spraying is determined by the weight gain pills, allowing variations, albeit small, of the total volume of suspension applied and, consequently, the finish time.

Another factor that contributes to the oscillation of the process is the need for reheating of the nuclei, if any extended stops during the spraying of the suspension. After meals and shift change periods, or after the correction of deviations in the functioning of the equipment, the pills are heated again before continuing with the application of the coating film.

In the light of the foregoing, the action identified for improvement of this index has been the reduction of process variability sources that interfere in the finish time: equipment failures, the parameterization process, physical attributes of the intermediate product (such as the hardness and friability, that determine the mechanical strength of the pills during the coating) and total volume of sprayed suspension. To minimize the variability of the process, the institution can adopt statistical process control (SPC) and the design of experiments, methods that can be used for all processes, benefiting the production system as a whole.

In table 2, it can be shown a summary of the main waste and improvement actions identified based on use of the OEE.

5. CONCLUSION

Through this case study, confirmed that the OEE can be used as an instrument of support to the management of pharmaceutical production. In addition to measuring equipment performance bottleneck of three lines, the scorecard allowed identify and quantify the losses directly associated with the operation of the resource, as well as waste which have an impact on the production system. It was shown that the OEE is a tool for the promotion of continuous improvement, in that it enabled the prioritization and the development of actions aimed at reducing the main waste identified. It was found that even minor losses influence on an equipment should be assessed, as they may represent opportunities for improvement of simple and rapid deployment or with impact in several work centers.

In the implementation phase of the bookmark, the critical factors identified were training, the clear definition of the losses to be pointed and the monitoring of initial records with the officials responsible for data collection. When using the indicator, it was observed that the participation of operators in discussions of results stimulated their involvement with the tool and with the proposition of improvements.

Manual data collection proved to be cumbersome, due to the need of entering a large number of records in Excel spreadsheets. A large part of these records was already entered in the computerized system. For this reason, it was proposed an evaluation of the system in order to check if this could be used to calculate the indexes and index finger.

For the study, equipment availability was the largest factor impacting the OEE and the times of exchange for lots/products the major causes of interruption of operation of the feature. Through the rapid exchange of tools, the time of *set up* of the equipment were reduced by approximately 70%. Depending on the equipment being the resource bottleneck of production lines of three medicines to the institution, the reduction of the time of preparation of the machine increased global flow capacity of these lines. With the improving of equipment performance, this will no longer be a resource bottleneck, and the application of OEE may be extended to other critical machines and lines for the institution.

High impact machine Exchange times various production processes, as well as the occurrence of random crashes and the processing time higher than the theoretical, among other identified through the OEE. The indicator promotes the continuous improvement of the performance of equipment and, ultimately, of the manufacturing operations. Using the OEE has generated a number of other improvements, some of which were adopted immediately and others will have their assessed in future deployments.

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Electronic Journal of Management & System
Volume 11, Number 1, 2016, pp. 49-60
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Table 2 - Summary of the main or detected improvement actions using the OEE

OEE Index analyzed	Major waste Identified	Improvement actions	Status of Improvement Actions
Quality	Aspect of deviations detected in the product C	Adjustments in product coating parameters	Fulfilled
		Check the general operation of the equipment because of possible correlation between failures and adjustments on the machine and the presence of appearance of deviations in pills	Fulfilled
Availability	Set up times	Use of EET	Fulfilled
	Equipment failure	" Activity included in the preventive maintenance routines (weekly cleaning of exhaust filters of equipment)"	Fulfilled
		Implementation of predictive and / or proactive maintenance to minimize random failures	Implementation to be evaluated
	Other stops - mostly due to cleaning validation activities	No applicable improvement actions because the validation activities are not routine. The waste was eliminated with the completion of validation	Not applicable
Performance Efficiency	Higher processing time than theoretical processing	Implementation of SPC and design of experiments to reduce process variability that affects the operating time	Implementation to be evaluated

Source: The authors themselves

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