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Optimization the cost of poor quality in pharmaceutical manufacturing by Taguchi method

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ABSTRACT

In today's world of manufacturing competitiveness, quality is a prerequisite and it is no longer a differentiator. Although people in developing countries have started understanding the importance of quality in any sector, but this fact is still not clear to decision makers that a substantial amount is lost in terms of cost of poor quality (COPQ). Classically, it was considered poor quality, every product with at least one quality characteristic exceeding the tolerance limits. Consequently, the estimate of COPQ considers only products outside acceptance zone defined according to the requirements specification. In one side, the conformity with specifications aims only customer satisfaction; in other side, according to TAGUCHI, the COPQ should be calculated not only from compared limits of tolerance but also with respect to the target values of each quality characteristics. Thus, the purpose of optimization is to respect the customer's needs, control of manufacturing processes and reducing the cost of production. The TAGUCHI approach has demonstrated high efficiency in the uni-criterion optimization process, when it is based on a single quality characteristic, but few studies have been conducted for multi criteria optimization. In this work, we propose an approach for the COPQ calculation in Moroccan pharmaceutical company by applying the TAGUCHI approach considering three quality characteristics of a coated tablet namely: Weight, Thickness and Hardness. We can arrive at an optimal quality product with a rate of poor quality reduction of 0.1€/article. Furthermore, the paper discusses the results and some advantages of this method in pharmaceutical sector.

Keywords: Cost of poor quality, Optimization, TAGUCHI approach, Manufacturing, Pharmaceutical company.

INTRODUCTION

The Moroccan pharmaceuticals industry is a strategic sector for the national economy and for the regular, safe supply of drugs. The activities of this sector generate an annual turnover of around 1 billion euro. The quality of the drugs produced in Morocco is internationally recognized, and Morocco exports nearly 60% of its drug production, much of which goes to Europe and Africa [12]. Today's pharmaceutical companies are internally facing an increasing pressure to manufacture complex products with high quality, reduced lead times, low cost and at the same time increase shareholders profitability.

The key factors, affecting the product quality are from of enterprise interior, including the enterprise lead's cognition, quality organization level, worker's actual ability, high quality raw materials, advanced technique and equipments, reliable inspection [16].

Generally speaking, quality characteristics can be divided into three types: nominal the best, larger the better and smaller the better. In the traditional concept of the quality evaluation system, a product is determined to be nonconforming if the quality characteristic of a product fails to meet the engineering specification limits and then a certain amount of quality loss is incurred. On the other hand, believed that a poorly designed product causes society to incur losses from the initial design stage to the product usage [9].

Therefore, Taguchi defined the loss function as the deviation from the target/nominal quality characteristic. In other words, the Taguchi's quality loss is incurred when quality characteristics of a product deviates from its target value regardless how small the deviation is. Since then, the quality loss concept has been shifted from "defined by specification limits" to "define by user" and Taguchi's loss function has been extensively used for determining the engineering tolerance [5].

In this paper, we start with an overview of the Taguchi Quality Loss Function (QLF); Followed by applying the Taguchi approach in Moroccan pharmaceutical company. The purpose is to calculate the COPQ considering three quality characteristics of a coated tablet (weight, thickness and hardness). Finally the paper discusses the results and some advantages of this method.

THE TAGUCHI QUALITY LOSS FUNCTION

Taguchi Methods was developed by Dr. Genichi Taguchi. It combined engineering and statistical methods that achieve rapid improvements in cost and quality by optimizing product design and manufacturing processes. There are three statements that apply for the methods [2]:

- We cannot reduce cost without affecting quality;
- We can improve quality without increasing cost;
- We can reduce cost by reducing variation or by improving quality. Therefore, when we do so, performance and quality will automatically improve.

Taguchi defined quality as "the loss imparted to society from the time the product is shipped" [10].Fundamental to this approach to quality engineering is this concept of loss. He associated loss with every product that meets the customer's hand. This loss include, among other things , consumer dissatisfaction, added warranty costs to the producer, and loss due to a company's bad reputation , which leads to eventual loss of market share.

Quality costs or poor quality costs are usually quantified in terms of scrap and rework, warranty, or other tangible costs. What about the hidden costs or long-term losses related to engineering, management time, inventory, customer dissatisfaction, and lost market share? Can we quantify these? [7] Perhaps, but not accurately. Indeed we must find a way to approximate these hidden and long-term losses, because they are the largest contributors to total quality loss. Taguchi Methods uses the quality loss function for this purpose.

QLF depends on the type of quality characteristic involved like [4]:
- Nominal-the-best (achieving a desired target value with minima variation: dimension and output voltage);
- Smaller-the-better (minimizing a response: shrinkage and wear);
- Larger-the-better (maximizing a response: pull-off force and tensile strength);
- Attribute (classifying and/or counting data: appearance);
- Dynamic (response varies depending on input: speed of a fan drive should vary depending on the engine temperature).

Loss can occur not only when a product is outside the specifications, but also when a product falls with specifications. Further, it is reasonable to believe that loss continually increases as a product deviates further from the target value, as the parabola (QLF) as shown in Figure 3. The loss isn't linear. Taguchi theorized that the loss is proportional to the square of the distance from the target value [3].

$$L = k\,(y - T)^2 \tag{1}$$

With:
L : Financial loss in €
K : Cost coefficient
y : value of quality characteristic
T : Target value

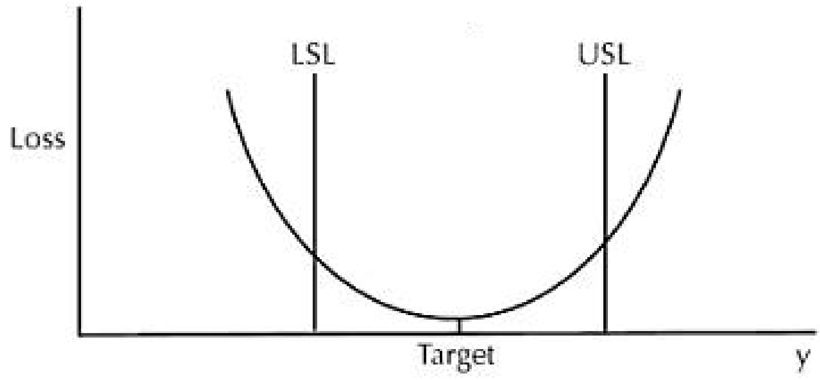


Figure 1. The Taguchi Quality Loss Function

From the quality cost perspective, the closer a company can get to its quality targets, the more it reduces quality related costs. Theoretically, if a company can consistently attain its quality targets, quality-related costs will be minimized and will consist only of those costs incurred to sustain the target quality level [1] .

EXPERIMENTAL APPROACH

In this study, a sample of 378 articles of the coated tablet was studied. For every article we measured at the same time the values of three quality characteristics: weight, thickness and hardness. For each of these three characteristics, we defined the limits of specifications to be respected and the target values to be reached:

Table 1. Specification Limits and the target Values of quality characteristics of the coated tablet

	Lower specification limits	Target value	Upper specification limits
Weight (grams)	0.729	0.759	0.789
Thickness(millimeters)	6.7	6.9	7.1
Hardness (Newton)	280	310	355

Seen the importance of three characteristics in the process of manufacturing, we attributed them the same coefficient of importance during the calculation of the COPQ.

We shall distinguish products according to their conformity compared with these requirements. Depending on the case, we shall have a product:

Nomenclature	
W	Conform to the weight
W'	Not conform to the weight
T	Conform to the thickness
T'	Not conform to the thickness
H	Conform to the hardness
H'	Not conform to the hardness

1st category	2nd category	3rd category	4th category
The three characteristics studied are conform to the specifications	The one of the three characteristics studied is conform to the specifications	Two of the three characteristics studied are conform to the specifications	The three characteristics studied are not conform to the specifications: W', T' and H'
W, T and H	W', T' and H	W', T and H	W', T' and H'
	W', T and H'	W, T' and H	
	W, T' and H'	W, T and H'	

Figure 2. Categories of product according to the conformity or not compared with the specification

3.1 Categories of products studied according to degree of conformity
We can define 4 categories of product according to the conformity or not compared with the specifications as shown in Figure 2.

3.2 Determination of conformity and non-conformity rates
We have determined the number of articles among which the values of three quality characteristics: weight, Thickness and Hardness, are conform to the specifications.

The ratio between the numbers of conform articles and the total number of controlled articles constitutes the rate of conformity R_C.

$$R_c = \frac{\sum_{i=1}^{n}(W, H, T)}{n} \tag{2}$$

Where R_C : Rate of conformity
R_{nc} : Rate of non conformity
n : Total number of controlled articles

By deduction, the total rate of non-conformity representing the number of articles which have at least one of the three characteristics is not conform to the specifications is defined as follows:

$$R_{nc} = 1 - R_c \tag{3}$$

For each of three types of non-conformity listed, we proceeded to determine the elementary rate of each [14]:
- Non conformity rate of articles (W', T' and H)

$$R_{(W',T',H)} = \frac{\sum_{i=1}^{n}(W', T', H)}{n} \tag{4}$$

- Non conformity rate of articles (W', T and H')

$$R_{(W',T,H')} = \frac{\sum_{i=1}^{n}(W', T, H')}{n} \tag{5}$$

- Non conformity rate of articles (W, T' and H')

$$R_{(W,T',H')} = \frac{\sum_{i=1}^{n}(W, T', H')}{n} \tag{6}$$

- Non conformity rate of articles (W', T and H)

$$R_{(W',T,H)} = \frac{\sum_{i=1}^{n}(W', T, H)}{n} \tag{7}$$

- Non conformity rate of articles (W, T' and H)

$$R_{(W,T',H)} = \frac{\sum_{i=1}^{n}(W, T', H)}{n} \tag{8}$$

- Non conformity rate of articles (W, T and H')

$$R_{(W,T,H')} = \frac{\sum_{i=1}^{n}(W, T, H')}{n} \tag{9}$$

- Non conformity rate of articles (W', T' and H')

$$R_{(W',T',H')} = \frac{\sum_{i=1}^{n}(W', T', H')}{n} \tag{10}$$

3.3 Average values of the weight, thickness and hardness
For every category of the studied article, we determined the average value of three characteristics: weight, thickness and hardness:

Table 2: Formula for calculating the average value of the weight, thickness and hardness

Weight	Thickness	Hardness
$W_{(W,T,H)} = \sum_{i=1}^{n}(W,T,H)i/n$	$T_{(W,T,H)} = \sum_{i=1}^{n}(W,T,H)i/n$	$H_{(W,T,H)} = \sum_{i=1}^{n}(W,T,H)i/n$
$W_{(W',T',H)} = \sum_{i=1}^{n}(W',T',H)i/n$	$T_{(W',T',H)} = \sum_{i=1}^{n}(W',T',H)i/n$	$H_{(W',T',H)} = \sum_{i=1}^{n}(W',T',H)i/n$
$W_{(w',T,H')} = \sum_{i=1}^{n}(W',T,H')i/n$	$T_{(W',T,H')} = \sum_{i=1}^{n}(W',T,H')i/n$	$H_{(W',T,H')} = \sum_{i=1}^{n}(W',T,H')\, i/n$
$W_{(W,T',H')} = \sum_{i=1}^{n}(W,T',H')i/n$	$T_{(W,T',H')} = \sum_{i=1}^{n}(W,T',H')i/n$	$H_{(W,T',H')} = \sum_{i=1}^{n}(W,T',H')i/n$
$W_{(W',T,H)} = \sum_{i=1}^{n}(W',T,H)i/n$	$T_{(W',T,H)} = \sum_{i=1}^{n}(W',T,H)i/n$	$H_{(W',T,H)} = \sum_{i=1}^{n}(W',T,H)i/n$
$W_{(W,T',H)} = \sum_{i=1}^{n}(W,T',H)i/n$	$T_{(W,T',H)} = \sum_{i=1}^{n}(W,T',H)i/n$	$H_{(W,T',H)} = \sum_{i=1}^{n}(W,T',H)i/n$
$W_{(W,T,H')} = \sum_{i=1}^{n}(W,T,H')i/n$	$T_{(W,T,H')} = \sum_{i=1}^{n}(W,T,H')i/n$	$H_{(W,T,H')} = \sum_{i=1}^{n}(W,T,H')i/n$
$W_{(W',T',H')} = \sum_{i=1}^{n}(W',T',H')i/n$	$T_{(W',T',H')} = \sum_{i=1}^{n}(W',T',H')i/n$	$H_{(W',T',H')} = \sum_{i=1}^{n}(W',T',H')i/n$

For the calculation of the weight, thickness and hardness averages of a production constituted by 378 samples. We need to calculate two elements [8], namely:

- The average values of the quality characteristic: weight, thickness and hardness of every category of coated tablet;
- The rate of conformity and non-conformity of every category.

Consequently, the average weight (μ_W), average thickness (μ_T) and average hardness (μ_H) of the studied population are calculated According to following both formulae:

$$(\mu_W) = [W_{(W,T,H)} x\, R_c] + [W_{(W',T',H)} x\, R_{(W',T',H)}] + [W_{(W',T,H')} x\, R_{(W',T,H')}] + [W_{(W,T',H')}\, x\, R_{(W,T',H')}] + [W_{(W',T,H)}\, x\, R_{(W',T,H)}] + [W_{(W,T',H)} x\, R_{(W,T',H)}] + [W_{(W,T,H')} x\, R_{(W,T,H')}] + [W_{(W',T',H')} x\, R_{(W',T',H')}] \quad (16)$$

$$(\mu_T), = [T_{(W,T,H)} x\, R_c] + [T_{(W,T',H)} x\, R_{(W',T',H)}] + [T_{(W',T,H')} x\, R_{(W',T,H')}] + [T_{(W,T',H')}\, x\, R_{(W,T',H')}] + [T_{(W',T,H)}\, x\, R_{(W',T,H)}] + [T_{(W,T',H)} x\, R_{(W,T',H)}] + [W_{(W,T,H')} x\, R_{(W,T,H')}] + [T_{(W',T',H')} x\, R_{(W',T',H')}] \quad (12)$$

$$(\mu_H) = [H_{(W,T,H)} x\, R_c] + [H_{(W',T',H)} x\, R_{(W',T',H)}] + [H_{(W',T,H')} x\, R_{(W',T,H')}] + [H_{(W,T',H')}\, x\, R_{(W,T',H')}] + [H_{(W',T,H)}\, x\, R_{(W',T,H)}] + [H_{(W,T',H)} x\, R_{(W,T',H)}] + [H_{(W,T,H')} x\, R_{(W,T,H')}] + [H_{(W',T',H')} x\, R_{(W',T',H')}] \quad (13)$$

3.4 Estimation of Taguchi loss function

For the calculation of the financial losses according to the Taguchi approach in the case of only one characteristic Quality, we need to apply the following formulas [7,13]:

$$L = k(\sigma^2 + (\mu - T)^2) \quad (14)$$

Where L : Financial loss
K : Loss coefficient
σ^2 : Variance
μ : Average
T : Target value

$$K = \text{Cost of each unit} / [(USL - LSL)/2]^2 \quad (15)$$

LSL and USL are respectively the lower and the upper specification limit

Therefore, the cost lost in weight is estimated according to the formula below:

$$L_W = K_W(\sigma^2{}_W + (\mu_W - T_W)^2) \quad (16)$$
$$= K_W\Big(\sigma^2{}_W + (W_{(W,T,H)} x\, R_c + W_{(W',T',H)} x\, R_{(W',T',H)} + W_{(W',T,H')} x\, R_{(W',T,H')} + W_{(W,T',H')}\, x\, R_{(W,T',H')} + W_{(W',T,H)}\, x\, R_{(W',T,H)} + W_{(W,T',H)} x\, R_{(W,T',H)} + W_{(W,T,H')} x\, R_{(W,T,H')} + W_{(W',T',H')} x\, R_{(W',T',H')} - T_W)^2\Big)$$

Similarly for the thickness, the lost cost is calculated according to the formula:

$$L_T = K_T(\sigma^2{}_T + (\mu_T - T_T)^2) \quad (17)$$
$$= T(\sigma^2{}_T + (T_{(W,T,H)} x\, R_c + T_{(W',T',H)} x\, R_{(W',T',H)} + T_{(W',T,H')} x\, R_{(W',T,H')} + T_{(W,T',H')}\, x\, R_{(W,T',H')} + T_{(W',T,H)}\, x\, R_{(W',T,H)} + T_{(W,T',H)} x\, R_{(W,T',H)} + T_{(W,T,H')} x\, R_{(W,T,H')} + T_{(W',T',H')} x\, R_{(W',T',H')} - T_T)^2)$$

Similarly for the hardness, the lost cost is calculated according to the formula:

$$L_H = K_H(\sigma^2{}_H + (\mu_H - T_H)^2) \quad (18)$$
$$= K_H(\sigma^2{}_H + (H_{(W,T,H)} x\, R_c + H_{(W',T',H)} x\, R_{(W',T',H)} + H_{(W',T,H')} x\, R_{(W',T,H')} + H_{(W,T',H')}\, x\, R_{(W,T',H')} + H_{(W',T,H)}\, x\, R_{(W',T,H)} + H_{(W,T',H)} x\, R_{(W,T',H)} + H_{(W,T,H')} x\, R_{(W,T,H')} + H_{(W',T',H')} x\, R_{(W',T',H')} - T_H)^2)$$

3.5 Taguchi loss function of multi-criteria average

Given that the quality of a product is the result of the satisfaction degree of all its characteristics to specifications. In another hand, the cost of its non quality is also the resultant of the sum of costs generated by derivation of each characteristic at even specifications. The overall average loss L $_{W,T,\ H}$ is by definition the sum of the relative elementary losses in Every quality characteristic of the coated tablet [6]. For the calculation of the overall average quality loss function of three characteristics: weight, thickness and hardness (L $_{W,\ T,\ H}$), we need of:

- Loss Function elementary of the three characteristics;
- Importance coefficient of the three characteristics: α_w, α_T and α_H

$$L_{W,T,H} = \alpha_W L_W + \alpha_T L_T + \alpha_H L_H \quad (19)$$
$$= \alpha_W K_W(\sigma^2{}_W + (\mu_W - T_W)^2) + \alpha_T K_T(\sigma^2{}_T + (\mu_T - T_T)^2) + \alpha_H K_H(\sigma^2{}_H + (\mu_H - T_H)^2)$$
$$= \alpha_W K_W\Big(\sigma^2{}_W + (W_{(W,T,H)} x\, R_c + W_{(W',T',H)} x\, R_{(W',T',H)} + W_{(W',T,H')} x\, R_{(W',T,H')} + W_{(W,T',H')}\, x\, R_{(W,T',H')} + W_{(W',T,H)}\, x\, R_{(W',T,H)} + W_{(W,T',H)} x\, R_{(W,T',H)} + W_{(W,T,H')} x\, R_{(W,T,H')} + W_{(W',T',H')} x\, R_{(W',T',H')} - T_W)^2\Big)$$
$$+\alpha_T K_T(\sigma^2{}_T + (T_{(W,T,H)} x\, R_c + T_{(W',T',H)} x\, R_{(W',T',H)} + T_{(W',T,H')} x\, R_{(W',T,H')} + T_{(WT',H')}\, x\, R_{(W,T',H')} + T_{(W',T,H)}\, x\, R_{(W',T,H)} + T_{(W,T',H)} x\, R_{(W,T',H)} + T_{(W,T,H')} x\, R_{(W,T,H')} + T_{(W',T',H')} x\, R_{(W',T',H')} - T_T)^2)$$
$$+ \alpha_H K_H(\sigma^2{}_H + (H_{(W,T,H)} x\, R_c + H_{(W',T',H)} x\, R_{(W',T',H)} + H_{(W',T,H')} x\, R_{(W',T,H')} + H_{(W,T',H')}\, x\, R_{(W,T',H')} + H_{(W',T,H)}\, x\, R_{(W',T,H)} + H_{(W,T',H)} x\, R_{(W,T',H)} + H_{(W,T,H')} x\, R_{(W,T,H')} + H_{(W',T',H')} x\, R_{(W',T',H')} - T_H)^2)$$

RESULTS AND DISCUSSION

4.1 Workforce of every category of conformity

The table 3 recapitulates the results of workforce determination of every coated tablet category the studied and based to the conformity or non conformity of three characteristics "weight", "thickness" and "hardness" in Specifications:

Table 3: Determination of the rate of conformity of different categories (W, T, H)

Product	Controlled effectives	Rate of conformity
W,T and H	395	0.829
W',T' and H	7	0.014
W', T and H'	9	0.018
W,T' and H'	12	0.018
W',T and H	4	0.008
W, T' and H	6	0.012
W,T and H'	41	0.086
W', T' and H'	2	0.004

4.2 Calculation of average values of quality characteristics

For each of the categories of conformity of population studied made up of n=378, we have calculated the average values of three quality characteristics: weight, thickness and hardness. These values are recapitulated in tables below:

Table 4: Determination of the average values for various categories of weight conformity

Product	Controlled effectives	Rate of conformity	Average weight values	Value of contribution
W,T and H	395	0.829	0.759	0.629
W',T' and H	7	0.014	0.756	0.010
W', T and H'	9	0.018	0.755	0.013
W,T' and H'	12	0.025	0.757	0.018
W',T and H	4	0.008	0.761	0.006
W, T' and H	6	0.012	0.758	0.009
W,T and H'	41	0.086	0.760	0.065
W', T' and H'	2	0.004	0.762	0.003

Table 5. Determination of the average values for various categories of thickness conformity

Product	Controlled effectives	Rate of conformity	Average thickness values	Value of contribution
W,T and H	395	0.829	6.9	5.720
W',T' and H	7	0.014	6.88	0.096
W', T and H'	9	0.018	6.7	0.120
W,T' and H'	12	0.025	6.92	0.173
W',T and H	4	0.008	6.86	0.054
W, T' and H	6	0.012	6.91	0.082
W,T and H'	41	0.086	6.93	0.595
W', T' and H'	2	0.004	6.87	0.027

Table 6. Determination of the average values for various categories of hardness conformity

Product	Controlled effectives	Rate of conformity	Average hardness values	Value of contribution
W,T and H	395	0.829	310	256.99
W',T' and H	7	0.014	299	4.186
W', T and H'	9	0.018	303	5.454
W,T' and H'	12	0.025	308	7.7
W',T and H	4	0.008	323	2.584
W, T' and H	6	0.012	312	3.744
W,T and H'	41	0.086	315	27.09
W', T' and H'	2	0.004	295	1.18

4.3 Total average values of quality characteristics

The average elementary values of every listed category and by application of the formulas (11, 12, and 13), we estimated the total average values of three characteristics: weight, thickness and hardness of the whole studied population.

Table 7. Total average values of quality characteristics

Total average weight	Total average Thickness	Total average Hardness
0.753	6.867	308.928

These three values constitute the average values probable at achieve while taking into account the probability of appearance of every category. These values are going to allow us to estimate the average loss owed at the deviation of every characteristic studied from the specifications and target values.

In this sense, by application of the formula (16, 17, 18,19), we can calculate the economic losses probable for three quality characteristics.

Table 8. Taguchi loss function of quality characteristics

	Weight	**Thickness**	**Hardness**
Total average values of the Taguchi loss function	0.05 €	0.16 €	0.06 €
Total value averages multi-criteria of the Taguchi loss function $\mathbf{L_{W,T,H}}$	**0.1 €**		

The figures 3, 4 and 5 show a three-dimensional presentation of the evolution of the Taguchi (QLF) multi criteria according to the evolution of:
- The hardness and the weight of the coated tablet.
- The hardness and the thickness of the coated tablet.
- The weight and the thickness of the coated tablet.

The Taguchi loss function takes the minimal value in the interval [0-1 €] and this for optimal intersection values of:
- Weight values and hardness placing in the intervals: Weight = [0.74, 0.78], Hardness = [280,340].
- Hardness values and thickness placing in the intervals: Hardness = [280,340], Thickness = [6.8, 7.1].
- Weight values and thickness placing in the intervals: Weight = [0.74, 0.78], Thickness = [6.8,7.1].

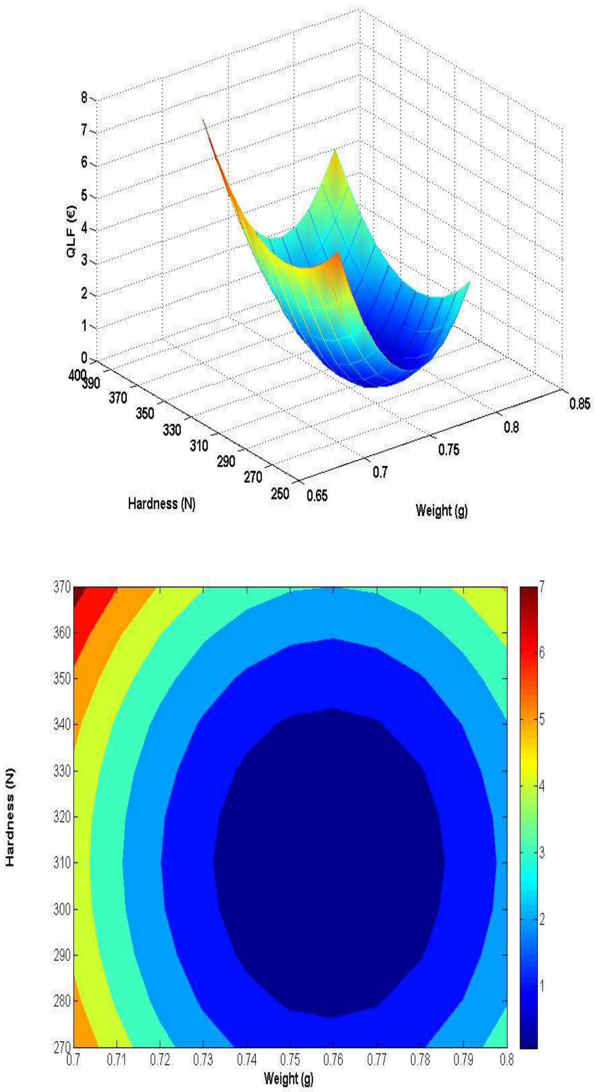


Figure 3. Evolution of QLF cost in function of the variation of hardness and weight

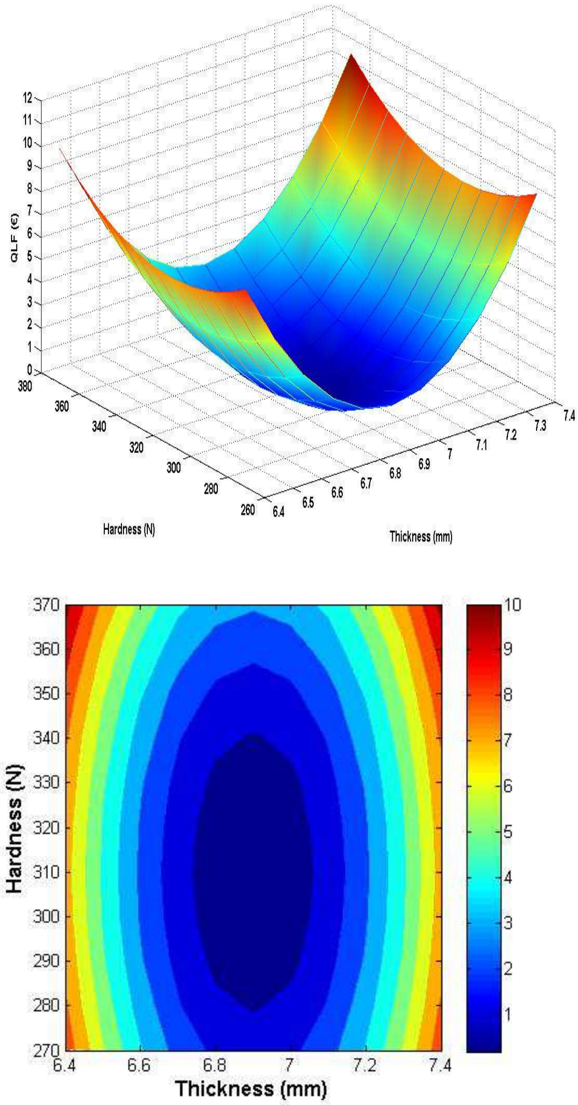
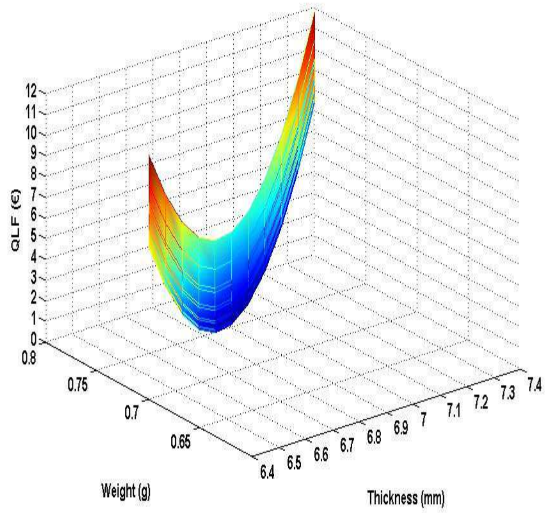


Figure 4. Evolution of QLF cost in function of the variation of hardness and thickness



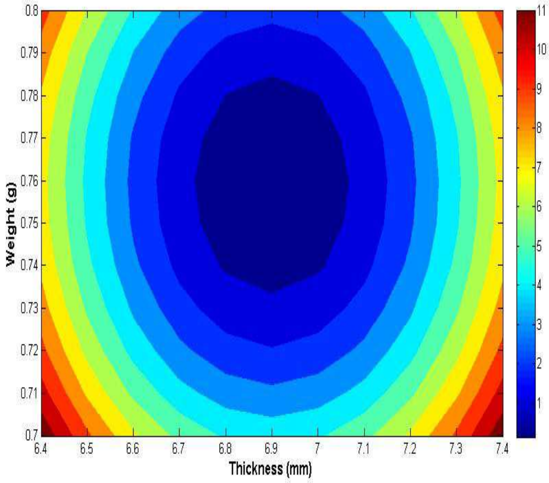


Figure 5. Evolution of QLF cost in function of the variation of weight and thickness

CONCLUSION

Financial analysts have estimated that COPQ typically amounts to 5 percent to 30 percent of gross sales for manufacturing and service companies [13]. Even non-profit organizations have similar numbers as a part of their bottom-line operations. Reducing COPQ may have the power to transform marginally successful companies into profitable ones.

In our case, we proceeded to calculate overall COPQ resulting from variations of three quality characteristics: weight, thickness and hardness compared with the target values, by exploiting the Taguchi quality loss function. This determination constitutes an essential stage before engage in an approach of manufacturing process optimization.

Based on the assumption that overall QLF of three quality characteristics studied is the sum of the three elementary QLF of each characteristic, we estimated the relational COPQ for these characteristics. This relation was presented well in the form of a three-dimensional graph, which allowed us to determine the rate of optimization of the quality of the finished product and the cost saved further to this approach. We can arrive at a product of optimal quality with a rate of poor quality reduction of the order of 0.1 € / article (0.5 % of selling price). Given these factors the application of Taguchi loss function can be an excellent tool when faced with determining the utility of competing scheduling policies or practices [15].

All levels of management, however, recognize that quality is an absolute necessity to survive and succeed in today's pharmaceutical companies. Therefore, understanding and determining COPQ are imperative to the success of an organization. In addition, COPQ provides quality management teams with the leverage necessary to support their process improvement efforts in the absence of hard euro and/or easily quantifiable financial calculations [11].

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