Replacement of manufacturing plastic containers with 600l stainless steel bins

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Abstract *— In order to improve Compression, Coating and Packaging areas at the pharmaceutical company Sandoz in Wilson, NC, it was evaluated the possibility of replacing the current plastic containers used to hold and transport approximately 13.0 kg of solid tablets with a 600 liters 316L Stainless Steel Bins that can hold up to 400 kg of solid tablets. The main purpose of this project was to reduce human errors, contain and reduce dust in manufacturing rooms, improve ergonomics and reduce costs. In order to improve these aspects of the process, the company decided to execute an Engineering Study to generate justifiable data to support further implementation activities for the replacement. After the execution of the Engineering Study, it was concluded that the replacement was an effective solution to the manufacturing areas current situations.*

Key Terms *— Acceptable quality limit/level, Engineering Study, Coating, Compression and Packaging.*

INTRODUCTION

Actually, at Sandoz Pharmaceutical new methods to improve the manufacturing process has been evaluated. One of the possible methods to improve the manufacturing area is the replacement of the current manufacturing plastic containers with a 600L Stainless Steel Bin.

The current manufacturing operation uses plastic containers to transport tablets from Compression to Coating to Packaging as presented in Figure 1. As an example, the drug Metformin 1000mg has a batch size of 2,160.3 kg with theoretical yield of 1,837,000 tablets. This batch is sub-divided in 9 equal parts of 240 kg for the Coating process. Each sub-batch consists of at least 18 plastic containers, but can be as many as 20 plastic containers. This means that a complete batch of Metformin 1000mg consists of 162 plastic containers. After being loaded with the product, each plastic container weighs approximately 13 Kg. These plastic containers are labeled and accounted for throughout this process.

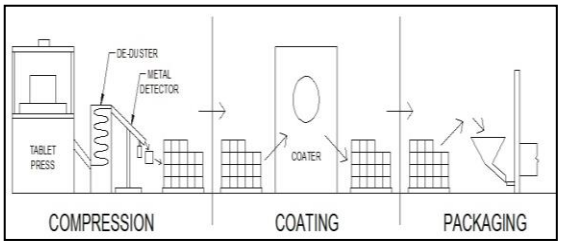

Figure 1
Actual Plastic Containers Manufacturing Process

Currently, open product transfer happens in Compression, Coating and Packaging. Dust is observed in these activities when this product is processed. The product and room are exposed to the fugitive dust from these operations. Also, the operator has to label, load and unload each plastic container during Coating and unload each to the filler hoppers during the Packaging process. In 2012, twelve investigations were generated due to the handling of these plastic containers. This process is open to human errors since the operator needs to label and document each plastic container in the Batch Record used to track the product. Besides, in 2012, there was one OSHA recordable case with one operator due to weight of actual plastic containers.

After evaluating the manufacturing process, Sandoz decided to execute an Engineering Study using a 600L Stainless Steel Bin instead of the plastic containers to verify how the tablets and dust behaves from Compression to Coating to Packaging as described in Figure 2. With the use of the Stainless Steel Bins the product will be transported

and lifted using a motorized pallet truck and Stainless Steel Platforms at Coating and Packaging to minimize any possible injuries to the operators that can be cause for lifting product in the different areas of the process.

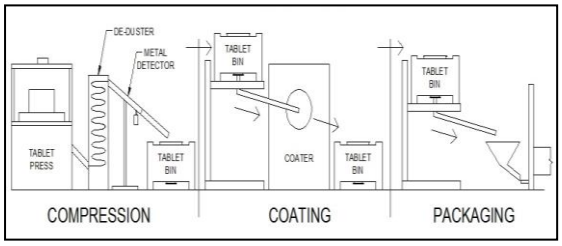

Figure 2
600L Stainless Steel Manufacturing Process

OBJECTIVE

The objective of this project was to generate and execute an Engineering Study in order to obtain sustainable data to support or reject further implementations of the new 600L Stainless Steel Bins at the manufacturing areas in Sandoz at Wilson, NC.

METHODOLOGY

The purpose of this Engineering Study was to evaluate how the tablets behave with the new Stainless Steel Bin. Tablet inspections were performed to verify the defect of severely broken tablets since, with the transition from the plastic containers to the 600L Stainless Steel Bins, the tablets may break by falling or handling/staging inside these Stainless Steel Bins. Also, as part of the Engineering Study, an evaluation was performed to verify that the facility has the capacity to clean this new Bin with their current equipment.

In order to perform the inspection of the tablets, Sandoz uses its own procedure based on the Acceptable quality limit/level (AQL) methodology. AQL is as the maximum fraction defective or defects per unit that can be considered satisfactory as a process average [1].

Sandoz has different types of categories in which it organizes product defects. Sandoz organizes these defects in the following scales: Minor, Major B, Major A or Critical. As per Sandoz procedures, severely broken tablets defect was inside the Major A defect which means that this defect should be no more than 0.15% of the whole population.

In order to start the Engineering Study, the company decided to use the product Lisinopril 20mg since this product has the highest customers complains related to broken tablets. This means that Lisinopril 20mg was the worst case scenario to test the new Bins. Lisinopril 20mg Batch has a theoretical yield of 1,000,000 tablets.

Based on Sandoz AQL methodology and following Table 1, the sample size of a population of 1,000,000 tablets of Lisinopril 20mg is 2,000 tablets based on a Major A defect. Also, the acceptance a reject criteria for this sample size is 5 or less for acceptance and 6 for reject. This means, that 5 or less severely broken tablets are accepted in the 2,000 tablets inspection inside the 600L Stainless Steel Bin

Samples were taken inside the Bin using a perforated tube and opening and closing the valve as described in Figure 3. The sample of 2,000 tablets was separated in the following manner; 1,000 tablets were collected from inside the Bin using the perforated tube, to verify the tablets behavior in the loading process, and 1,000 tablets were collected from the valve at the bottom to verify the tablets that received the first impact inside the Bin.

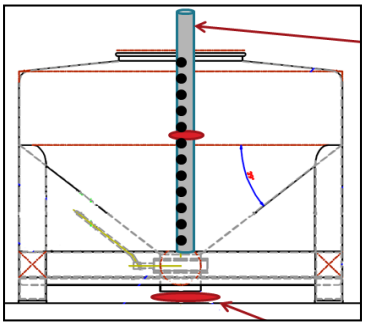

Figure 3
Sampling process Description

Table 1
Sandoz AQL Methodology

NUMBER OF UNITS IN QUESTION	SAMPLE SIZE (General Level III for Tightened Inspections)			
	Critical 0.01%	Major A 0.15%	Major B 0.40%	Minor 1.0%
10,001 - 35,000	500 Units	500 Units	500 Units	500 Units
35,001 - 150,000	800 Units	800 Units	800 Units	800 Units
150,001 - 500,000	1250 Units	1250 Units	1250 Units	1250 Units
500,001 +	2000 Units	2000 Units	2000 Units	2000 Units
Sample Size	**Tightened Inspection Accept / Reject Criteria**			
	Critical 0.01%	Major A 0.15%	Major B 0.40%	Minor 1.0%
500 Units	Accept 0 Reject 1	Accept 1 Reject 2	Accept 3 Reject 4	Accept 8 Reject 9
800 Units	Accept 0 Reject 1	Accept 2 Reject 3	Accept 5 Reject 6	Accept 12 Reject 13
1,250 Units	Accept 0 Reject 1	Accept 3 Reject 4	Accept 8 Reject 9	Accept 18 Reject 19
2,000 Units	Accept 0 Reject 1	Accept 5 Reject 6	Accept 12 Reject 13	Accept 18 Reject 19

The tablets were inspected using the inspection tool, similar to the one of Figure 4, which holds 200 tablets and documented in the Engineering Study in order to verify the tablets carefully.

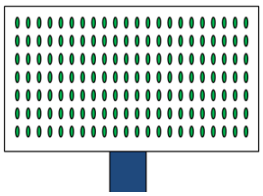

Figure 4
Inspection Tool

After knowing the sample size and the acceptance and reject criteria of the severely broken tablets defect, samples were taken in the different parts of the process of the Engineering Study, (refer to the Table 2).

Table 2
Sampling Process

Process Stage	Test Function	Sample/Size
Compression	Severely broken tablets Inspection	Sample: 2,000 tablets collected from the Bin
		Population Size: 500,001+ tablets
Coating	Severely broken tablets Inspection	Sample: 2,000 tablets collected from the Bin
		Population Size: 500,001+ tablets
Packaging	Severely broken tablets Inspection	Sample: 2,000 tablets collected from the Bin
		Population Size: 500,001+ tablets
Handling and Staging	Severely broken tablets Inspection	Sample: 2,000 tablets collected from the Bin
		Population Size: 500,001+ tablets
Bin Washer Machine	Visual Inspection	N/A

- **Compression:** In the Compression area, the 600 liter 316L Stainless Steel Bin was evaluated to verify the integrity of the tablets. This step was performed by loading the product into the Stainless Steel Bin through the Tablet Deduster/Metal Detector combo unit as described in Figure 5. Tablet samples were collected after this procedure to verify the integrity of the tablets related to the Major A defect, severely broken tablets.

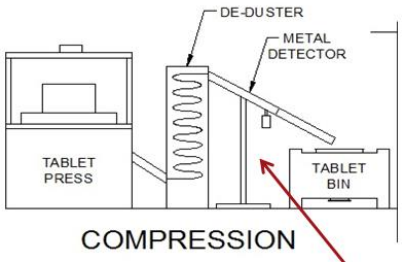

Figure 5
Compression Sampling Plan

- **Coating:** In the Coating area, the 600 liter 316L Stainless Steel Bin and Coating Stainless Steel movable platform was evaluated to verify the integrity of the tablets. This step was performed by loading the product into the Coater machine through the Stainless Steel movable platform using the Motorized pallet truck, as described in Figure 6. Then, the product was unloaded from the Coater machine to the Stainless Steel Bin. Tablet samples were collected after this procedure to verify the integrity of the tablets related to the Major A defect, severely broken tablets.

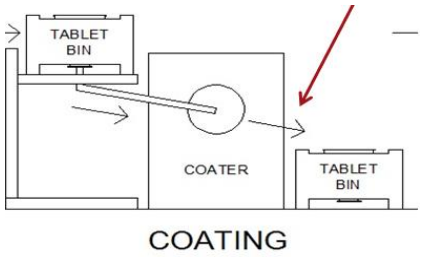

Figure 6
Coating Sampling Plan

- **Packaging:** In the Packaging area, the 600 liter 316L Stainless Steel Bin and Packaging Stainless Steel movable platform was evaluated to verify the integrity of the tablets. This step was performed by loading the product into the Tablet Elevator Hopper through the packaging Stainless Steel movable platform using the Motorized pallet truck, as described in Figure 7. Tablet samples were collected after this procedure to verify the integrity of the tablets.

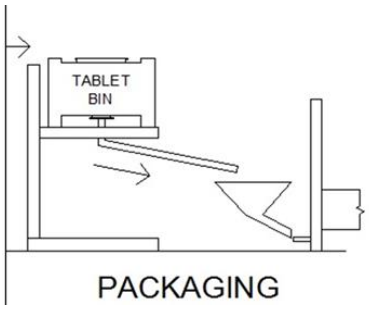

Figure 7
Packaging Sampling Plan

- **Handling and Staging:** The 600 liter 316L Stainless Steel Bin was evaluated to verify the integrity of the tablets after the simulation of the manufacturing transfer process. This step was performed by loading the product into the Stainless Steel Bin and then, transferring the Bins thru the different areas: Compression, Coating and Packaging; simulating conditions close to the existing material transfer process. Tablet samples were collected after this procedure to verify the integrity of the tablets.

After each sample was taken, at the different stages of the process, the product that remains in the 600L Stainless Steel Bins was unloaded. Then, the Bin was loaded again following the process described in the Compression process to complete the next step of the procedure.

In addition, after all samples were taken, the Bin was placed in the Bin Washer machine in order to perform a Visual Inspection of the Bin after the cleaning process. This will ensure that the Bin Washer has the ability to clean the new Stainless Steel Bin.

RESULTS

After the Engineering Study was executed, the results obtained are described in Table 3. In the Compression area the total of severely broken tablets found was 1. In Coating area the total of severely broken tablets found was 3. In Packaging area the total of severely broken tablets found was 2. Finally, in the handling and staging process the total of severely broken tablets found was 0. Table 3 shows that the quantity of broken tablets found in the samples collected at the different process steps was less than 5 which means that the results obtained were inside the acceptance criteria range. Also, after cleaning the 600L SS Bin inside the Bin Washer machine, it was noticed that the Bin was visually clean of any product residue or foreign matter. After evaluating the results it is concluded that the replacement of the plastic containers with the new 600L Stainless Steel Bins does not affect the behavior of the tablets.

Table 3
Engineering Study Results

Process Stage	Defect Description	Sample/Size	Quantity of Defects in sample or results	Accept / Reject Criteria	Acceptance criteria met? (Yes/No)
Compression	Severely broken tablets Inspection	Sample: 2,000 tablets collected from the Bin Population Size: 500,001+ tablets	1	5 / 6	Yes
Coating	Severely broken tablets Inspection	Sample: 2,000 tablets collected from the Bin Population Size: 500,001+ tablets	3	5 / 6	Yes
Packaging	Severely broken tablets Inspection	Sample: 2,000 tablets collected from the Bin Population Size: 500,001+ tablets	2	5 / 6	Yes
Handling and Staging	Severely broken tablets Inspection	Sample: 2,000 tablets collected from the Bin Population Size: 500,001+ tablets	0	5 / 6	Yes
Bin Washer Machine	Cleaning Visual Inspection	N/A	Visually Clean	Visually Clean / Visually Not Clean	Yes

COST AND BENEFITS

Analyzing and comparing the Cost and Benefits of implementing the replacement of the plastic containers with the 600L Stainless Steel Bin, the company decided to start the implementation with just one product in order to see the process flow and then verify the viability to expand these Stainless Steel Bins to other products. The product that the company suggestes was Metformin 1000mg since this is the company high volume product. In 2012, 125 Batches of Metformin were manufactured in Sandoz at Wilson, NC.

The cost of implementing the 600L Stainless Steel Bins for Metformin 1000mg is **$368,065.21**; refer to Table 4 for details.

Table 4
Project Costs

600L Stainless Steel Manufacturing Bins Project Cost			
Item	Price	Quantity	Total
600L Stainless Steel Bins Design	$ 19,125.00	1	$ 19,125.00
Stainless Steel Bins 600L	$ 5,993.00	16	$ 95,888.00
Soft Edge Valve 6 inches	$ 2,323.00	16	$ 37,168.00
Mobile Lifter	$ 84,000.00	2	$ 168,000.00
Manual Pallet Trucks	$ 5,120.00	2	$ 10,240.00
Coating Stainless Steel Platform	$ 4,750.00	1	$ 4,750.00
Packaging Stainless Steel Platform	$ 4,750.00	1	$ 4,750.00
Shipping Lifters	$ 15,000.00	1	$ 15,000.00
Shipping Bins and Valves	$ 4,750.00	2	$ 9,500.00
		Total	$ 364,421.00
		NC Tax (1%)	$ 3,644.21
		Total	$ 368,065.21

In other hand the benefits obtained with the implementation of this project can be categorized as: head count, material cost and cycle time.

- **Head Count:** Currently with the plastic containers two operators are necessary in Compression, Coating and Packaging areas when Metformin is manufactured. The reason is that one of the operators in these areas is responsible of loading and unloading the product from the plastic containers to the different equipment. With the implementation of the new 600L Stainless Steel Bins this second operator is not needed and this provides a Benefit of **$170,000.00** yearly in head count, refer to Table 5 for details.

Table 5
Head Count

Head Count			
Description	Amount / per year	Quantity	Total
Compression Operator	$ 60,000.00	1	$ 60,000.00
Coating Operator	$ 60,000.00	1	$ 60,000.00
Packaging Operator	$ 50,000.00	1	$ 50,000.00
		Total per Year	$ 170,000.00

- **Material Cost:** Each plastic container has a useful life of two years and needs to be prepared with two plastic bags and a label before can be loaded with product. Estimating that in the following three years the trending to produce 125 batches of Metformin 1000mg will continue, it can

be estimated that the total benefits in reduction of plastic containers, bags and labels yearly are **$41,310.00**, refer to Table 6.

Table 6
Materials Cost

Materials Cost				
Item	Cost	Units per Batch	Total Batches in 2012	Total
Plastic Containers (2 years life period)	$ 2.00	162	125	$ 40,500.00
Labels	$ 0.02	162	125	$ 405.00
Bags	$ 0.01	324	125	$ 405.00
			Total per Year	$ 41,310.00

- **Cycle Time:** With the implementations of the new Bins it was noticed an improvement in the Coating process. This improvement was obtained in the reduction of time needed to load the coater machine. With the current plastic containers the approximate time needed to load the coater machine with product was 15 minutes and, using the 600L Stainless Steel Bins and the Coating platform, the process only took 7 minutes. This gives an improvement in 53% in the Coating process. Although the loading and unloading process was improved in the other areas the cycle time does not improve since the speed of the machine remains the same in Compression and Packaging.

Comparing Cost and Benefits in Table 7, demonstrate that the project start to generates profits of **$14,054.79** in the second year of implementation and then in the third year the profits continue to grow to **$225,364.79** since the company need to purchase all plastic containers again. The useful life is one of the biggest differences between the plastic container and the Stainless Steel Bins since the useful life of the plastic containers is two years and the useful life of the 600L Stainless Steel Bins can be unlimited.

Table 7
Cost and Benefits

Benefits and Costs Per Year			
	Year 1	Year 2	Year 3
Benefits	$211,310.00	$170,810.00	$211,310.00
Costs	$ 368,065.21	0	0
Total	($156,755.21)	$14,054.79	$225,364.79

CONCLUSION AND RECOMMENDATIONS

After evaluating all data collected during the Engineering Study for the 600L Stainless Steel Bins it is concluded that the implementation of this project is favorable for the company.

Although the project starts to generate profits in the second year, the main reasons to implement this project are the dust reduction that was observed during the Engineering Study process, the expected reductions of investigations since with this new Stainless Steel Bins the operator does not needs to document 162 plastic containers in the Batch Records. Also, with the elimination of the plastic containers and the addition of these new Stainless Steel Bins, the ergonomic aspect of the process for the operators will improve. This improvement will eliminate any other OSHA recordable case due to the weight of lifting the plastic containers.

Further recommendations of this project will be the evaluation to expand the use of the 600L Stainless Steel Bins to the other products in the company.

REFERENCES

[1] J.M. Juran, A. Blanton Godfrey, "AQL definition", *Juran's Quality Hanbook*, 5th edition, September 1, 2000.