

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.

Problem

Presently, at Sandoz Pharmaceutical new methods to improve the manufacturing process have 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. This procedure have the following disadvantages:

- ❑ Dust is observed in these activities when the product is processed. The product and room are exposed to the fugitive dust from these operations.
- ❑ Investigations since this process is open to human errors because the operator needs to label and document each plastic container in the Batch Record used to track the product.
- ❑ Ergonomics, in 2012, there was one OSHA recordable case with one operator due to weight of actual plastic containers.

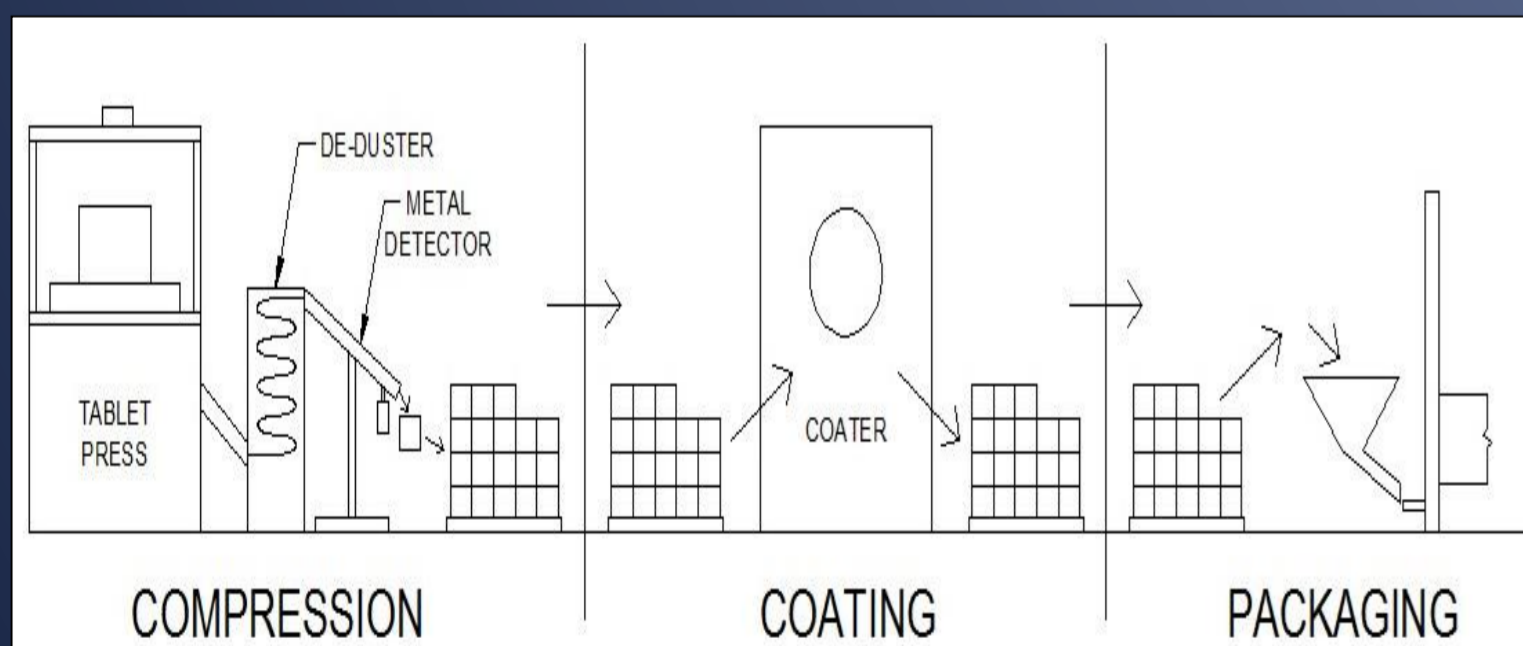


Figure 1: Actual Plastic Containers Manufacturing Process

Procedure

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

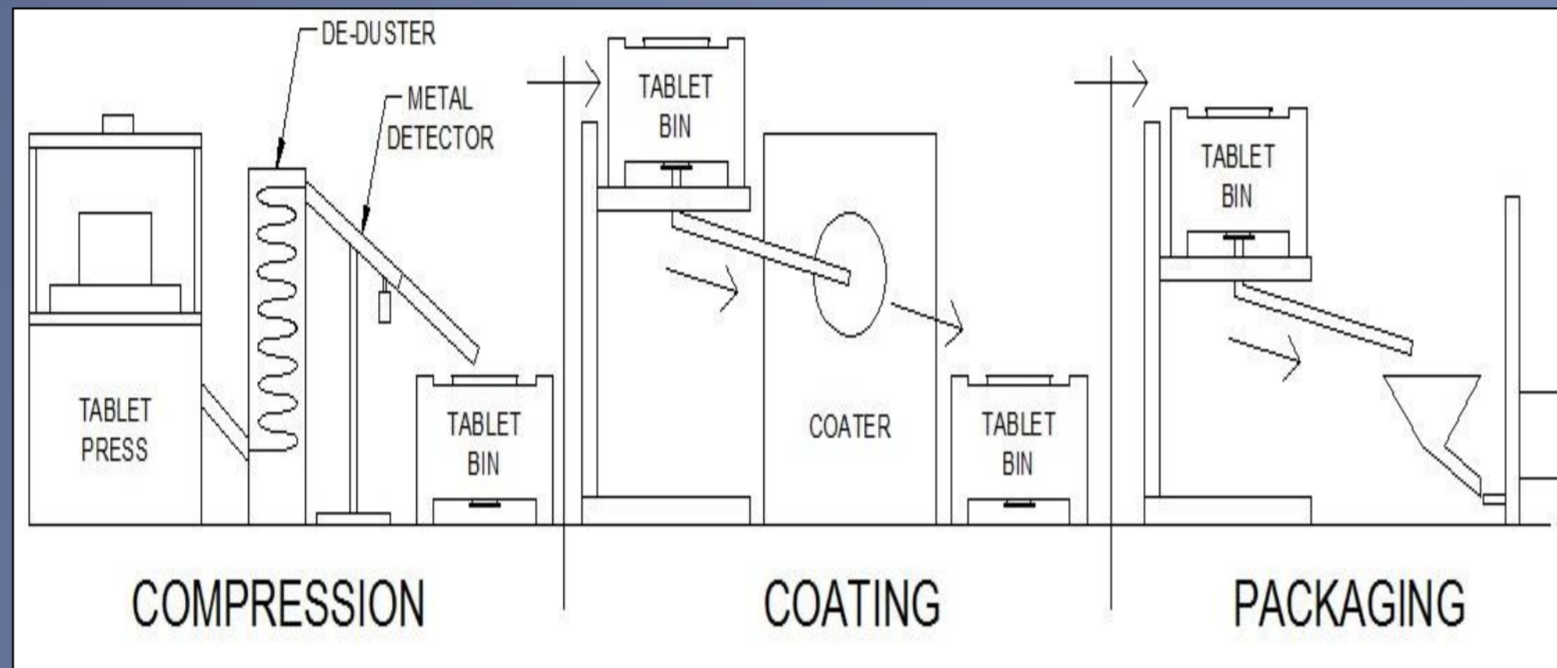


Figure 2: 600L Stainless Steel Manufacturing Process

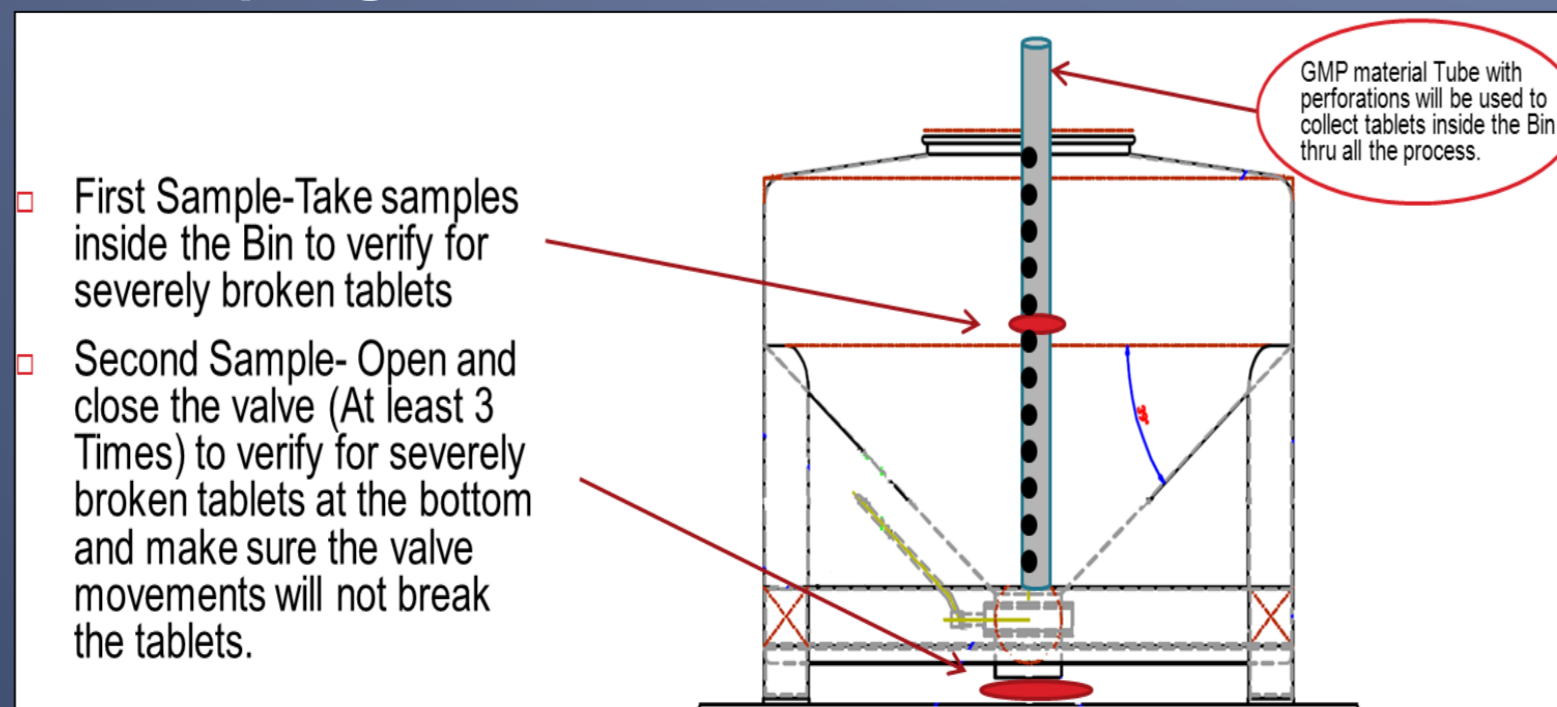
Sampling Plan

Based on Sandoz AQL Inspection Procedures [1], for a population of more than 500,000 tablets, an inspection of 2,000 tablets needs to be performed. Also, for Sandoz, the severely broken tablet defect is considered a Major A defect. This means that the acceptance and reject criteria for a Major A defect of 2,000 samples is 5 or less for acceptance and 6 or more for reject, refer to Table 1

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			
500 Units	Accept 0	Accept 1	Accept 3	Accept 8
	Reject 1	Reject 2	Reject 4	Reject 9
800 Units	Accept 0	Accept 2	Accept 5	Accept 12
	Reject 1	Reject 3	Reject 6	Reject 13
1,250 Units	Accept 0	Accept 3	Accept 8	Accept 18
	Reject 1	Reject 4	Reject 9	Reject 19
2,000 Units	Accept 0	Accept 5	Accept 12	Accept 18
	Reject 1	Reject 6	Reject 13	Reject 19

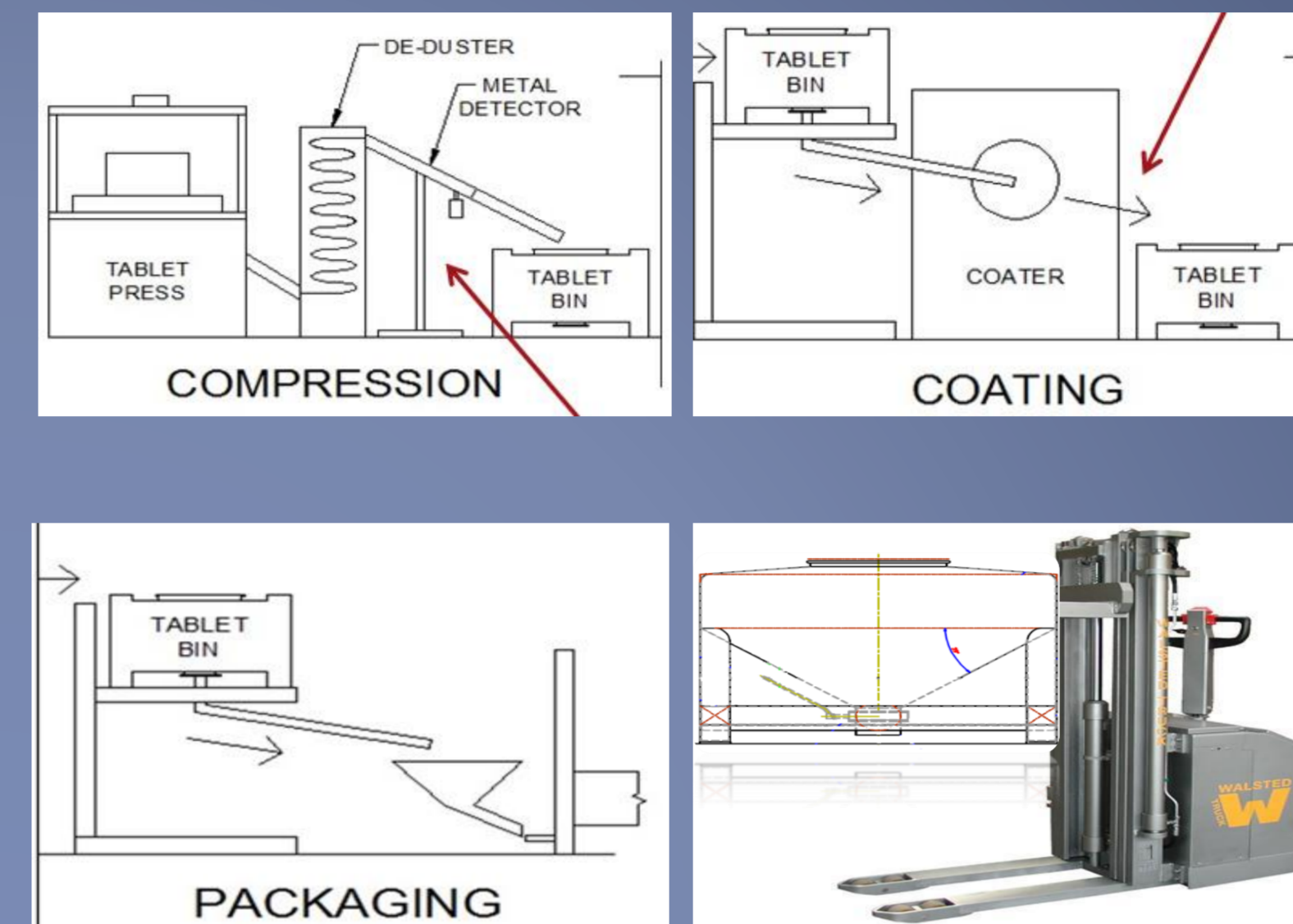
Sampling Procedure



- ❑ First Sample-Take samples inside the Bin to verify for severely broken tablets
- ❑ Second Sample- Open and close the valve (At least 3 Times) to verify for severely broken tablets at the bottom and make sure the valve movements will not break the tablets.

Methodology

Inspections Performed



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	1	5 / 6	Yes
		Population Size: 500,001+ tablets			
Coating	Severely broken tablets Inspection	Sample: 2,000 tablets collected from the Bin	3	5 / 6	Yes
		Population Size: 500,001+ tablets			
Packaging	Severely broken tablets Inspection	Sample: 2,000 tablets collected from the Bin	2	5 / 6	Yes
		Population Size: 500,001+ tablets			
Handling and Staging	Severely broken tablets Inspection	Sample: 2,000 tablets collected from the Bin	0	5 / 6	Yes
		Population Size: 500,001+ tablets			
Bin Washer Machine	Cleaning Visual Inspection	N/A	Visually Clean	Visually Clean / Visually Not Clean	Yes

Cost and Benefits

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

Benefits

Head Count Cost			
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

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

Gran Total per Year \$ 211,310.00

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

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:

- ❑ 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 need to document 162 plastic containers per Batch, in some cases.
- ❑ 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.

References

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