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Application of six sigma technique on vials washing process

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Abstract

In the proposed research work firstly Six Sigma technique was applied for decreasing the vials breaking during washing process by high speed rotator vials washing machine (Ambica ARVW-120) with washing rate of 60 vials per minute. The problems defined by the supervisor of the process that the breaking of vials during washing process. After the long observation of the process various parameters as mentioned below were analyzed (vials breaking). when vials enters from the turn table to the in feed worm then at this stage the point comes where the vials have to turn in inverted position at the hard surface, if the intensity of dropping or turning of the vials at surface is high then it causes breaking of vials, and those vials having bubble on their neck, have more chances to break. Second reason, when vials enters in the washing area through in-feed worm, then supporting plate (which is attached with rubber) is responsible for proper placement of vials from in feed worm to the gripper.

Due to this the plate, vials easily fixed. through neck on the star wheel. During this process the elasticity of the rubber belt reduces with time and due to this the supporting plate may not able to place the vials to the gripper properly and if vials do not placed to the gripper then it falls down to the stainless steel plate in the washing area and broke.

Key-words: Six Sigma, Washing, Techniques

Introduction

The routine distribution curve was first proposed by Carl Frederick Gauss (1777–1855), who is credited with giving rise to Six Sigma as a measurement standard. Walter Shewhart demonstrated in the 1920s that a process needs to be corrected when it deviates three standard deviations from the mean, which is when six sigma as a measurement benchmark for product variation was first established. Although many metrics (such as Cpk, Zero Defects, etc.) later emerged, Bill Smith, an engineer at Motorola, is credited with creating the term "Six Sigma" (by the way, "Six Sigma" is an officially registered trademark of Motorola). [1,2]

Dr. Mikel Harry and engineer Bill Smith developed a six-step process that focuses on using stats to enhance yield and reduce defects. Six Sigma is said to have its roots in Bill Smith. It has been noted that the conventional quality standards, such as counting flaws in thousands of chances, didn't offer sufficient system granularity. The manufacturing sector has begun measuring faults per million opportunities, and the corporation has taken the lead in developing an atmosphere and culture that support the six sigma approach. [3]

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Six Sigma And the Pharmaceutical Industry

Some pharmaceutical businesses have been using Six Sigma in recent years, mostly with the goal of cutting costs and cycle times. One company's packaging division's supplier and material clearance process is a success story. Due to the complexity of the process, locating and certifying a supplier of packaging materials typically takes a full year. The Six Sigma team was established, followed the critical routes of four prototype products, examined and pinpointed process issues. They were able to significantly cut the cycle time from twelve to five months and streamline the process by applying the Six Sigma technique. [4,5]

Material and Methods

This work was carried out at the vials washing machine facility of Schon Pharmaceutical Limited, Indore. The assigned problem was to prevent breaking of vials during vials washing process. Before elaborating the defects it is likely to make a glance on a vials washing machine.

Rotary Vials Washing Machine

The purpose of the High Speed Automatic Rotary Vial Washing Machine is to wash vials with the least amount of machine-to-container contact possible. Positive container washing is ensured by the machine's specifically built Gripper system, which holds the container from the neck and inverts it until the washing process is finished. The vessel is then released on the outfeed worm mechanism to reach its upright state. With the use of replacement parts, the machine is capable of washing containers of different sizes. For consumers who need efficiency and GMP, the Pharmaceutical, Veterinary, and Biotech industries employ Automatic Rotary Vial Washing Machines extensively.

Salient feature

- AISI SS 316L stainless steel is used for all contact parts that come into touch with the wash medium and the inside surface of vials.
- AISI SS 304 stainless steel and engineering plastic are used to make other parts. cGMP requirements are followed in the processing, treatment, and equipment selection of all finishes and welding joints.
- Six internal washing zones with 18 jets each. 15 gripper cassettes, each containing two grippers.
- Fits vials ranging from 2 ml to 100 ml.
- The washing order can be customized to meet the needs of the client. Three 25 liter tanks and three pumps.
- Every washing area has its own circuit to prevent contamination.
- Vials automatically enter and exit.
- Maximum output of 240 vials per minute

Vials

A vial, sometimes referred to as a phial or flacon, is a tiny glass or plastic container or bottle that is frequently used to hold liquid, powder, or capsule forms of medication. They can also be employed as scientific sample vessels in analytical chromatography auto sampler systems, for example. Glass vials have been around since classical antiquity; in modern times, vials are typically composed of polypropylene or another plastic.

Problems and project selection basis – (Define Phase)

During washing process of glass vials through Ambica (AVRW-120) it was observed that many glass vials were broken down in the machine. This adds the extra money in the process and extra time also to complete the required target of washing of required number of vials. From every 100 vials at least 10 vials breaks and the cost of one vial is 80 paise. So what will be the cost of 10000 vials. This broken vials is high in figure and so adds the loss in high figure. So we should remove or reduce this type of defects from the process to increase revenues of company. This defect can reduce by the help of six sigma technology.If the above problem will solved then it makes the process more efficient, decrease the number of defects and prevent the loss, ultimately profit figure will increases.

Measure phase-

The information review and data collection was undertaken at thisstage to measure the present performance of the organization. The current process is also quantified then. The following metrics are established to make this stage more systematic:

ISSN: 0976-7126
Pal *et al.*, 15(6):22-28, 2024

Production output is the amount made.
Casting that is rejected as defective (r) because it has a fault (s)
A defect is any nonconformance.
After rejections, yield (y) is the output.
Opportunity (m) – likelihood of being flawed (count of flaws)
Chance of defects (p(x))The likelihood that a single casting will have one or more defects The ratio of faulty to output is known as the defective percentage. The ratio of defective to prevalent defect opportunities is known as defects per opportunity (DPO).
DPO multiplied by one million equals defects per million opportunities (DPMO).
Analysis was done on 4 batches each batch contains 10000 vials and has some rejections due to breakage of vials.

Table no.1.1 mean rejection of vials during washing

S. no.	Batch (10000 vials)	Rejection	Rejection %	Mean rejection
1	V1	22	0.22	22.25
2	V2	24	0.24	
3	V3	22	0.22	
4	V4	21	0.21	

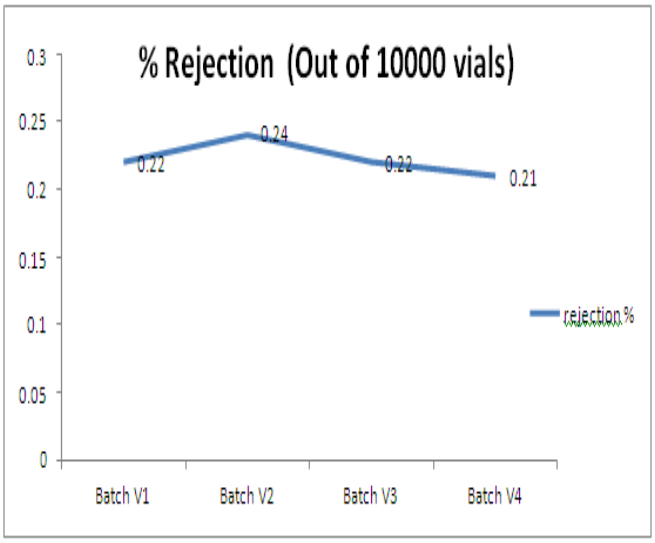

Fig.1.1 % rejection of vials due to breakage

Calculation of sigma level before implementation of solution

TO =Total number of Product Units x Opportunities

50643 x 1 = 50643

Defects Per Opportunity - DPO

$$DPO = \frac{\text{Total Number of Defects}}{\text{Total Opportunity}} = \frac{110}{50000} = 0.0022$$

Defects Per Million Opportunities - DPMO

DPMO = DPO x 1,000,000 = 0.0022x 1000000 = 2200

According to the conversion table:

4.5Sigma=2200 DPMO

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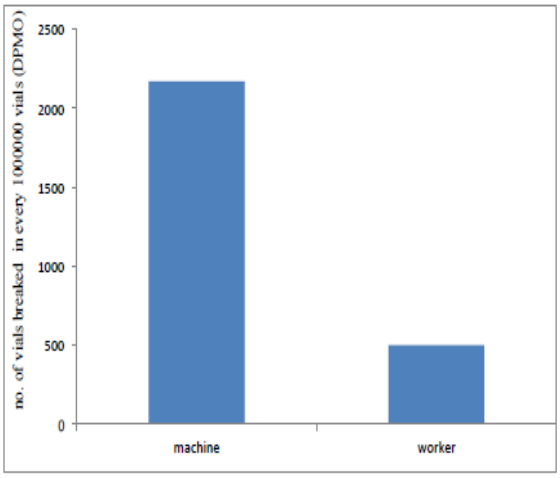

Fig.2 DPMO involved in(breaking of vials) during washing process before implementation of solution

Defects stratification using the Pareto principle –

A Pareto graph shows how frequently specific occurrences happen. It's a bar graph with each frequency (or frequency range) displayed from left to right in a decreasing sequence of data relevance.

This is founded on the Pareto Principle, sometimes known as the crucial few law or the 80-20 rule. This concept, which was developed by Dr. Juran, the father of quality, and titled for renowned Italian economist Vilfredo Pareto, assists in identifying the "useful many" from the "vital few" in any given business situation. The "vital few" are identified and given our undivided attention in order to optimize financial expenditures.

Table no.2 Summary of defects data under Pareto principle

Total no. of vials	No. of Vials Broken	Cumulative Quantity of Vials Broken	% Cumulative
Fifty thousand	110	110	2.564103
One lakh	220	330	7.692308
Three lakh	660	990	23.07692
Five lakh	1100	2090	48.71795
Ten lakh	2200	4290	100

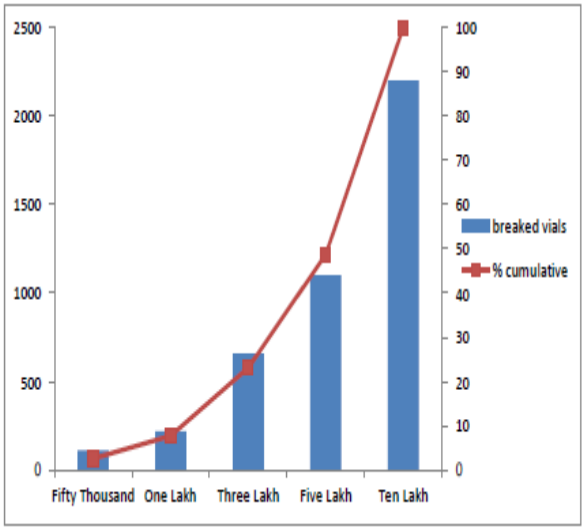

Fig.3 Graph shows defect summary of vials

Analyze stage-

The main indicators of success for the good and method are analyzed and benchmarked at this phase. Subsequently, a gap analysis is frequently conducted to ascertain the shared elements of effective performance, that is, the criteria that account for the highest performing students in the class. Redefining the performance target may be required in certain situations. Several statistical and fundamental QC technologies are utilized to analyze the performance of the product or process.

Root cause examination

As in the above section, we understand the kind of problems encountered in the process. Now in this section we are trying to recognize the root reason of troubles in the procedure.

Defect probability:

By machine

- Washing parameters
- In-feed worm
- Supporting plate
- Out-feed worm

By workers

- Improper training
- Carelessness behavior
- Fatigued Workers
- Hurried Workers

Flow chart for vials washing using Ambica (AVRW-120) and the steps which are responsible for breakage

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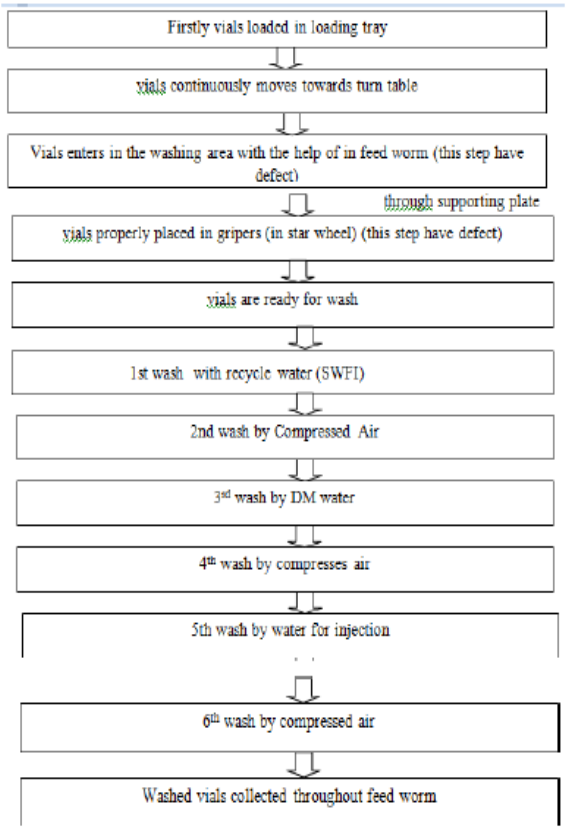

Fig.no.1.11 Flow chart shows the vials washing process and root causes

Firstly analysis was done on washing parameter that whether the washing parameter is responsible for breaking of vials or not.

S. No	Washing By	Operation At (Pressure)	Breakage
1	Recycled Water	2 kg/cm^2	No
2	Compressed Air	2 kg/cm^2	No
3	DM Water	2 kg/cm^2	No

Results

Vials are mainly washed by recycled water, compressed air, and DM water at the pressure of 2kg/cm2. So it was observed that at this particular parameter no breakage of vials occurred. So we can simply say that washing parameters were not responsible for the breaking of vials.

After the measure phase two root cause were observed which are:

1) During the washing process of vials, when vials enters from the turn table to the in feed worm then at this stage the point is come where the vials have to turn in inverted position at the hard surface. So if the intensity of dropping or turning of the vials at surface is high then it causes breaking of vials, those vials have bubble on their neck, have more chances to break.

For this an experiment was performed to determine the probability of vials broken during in feed worm process. Experiment was performed on 50 vials and result is shown in table no 1.6

Table No.1.6 shows the result of vials broken because of bubbles

S. No.	Total No. of Vials Having Bubbles	Broken	Unbroken
1	50	20	30
2	50	23	27
3	50	20	30

On the basis of result shown in table no. 40 % chances of vials breakage due to bubbles present on the neck of vials.

2) When vials enters in the washing area through in feed worm, then supporting plate (which is attached with rubber) is responsible for proper placement of vials from in feed worm to the gripper. Because of this the plate vials easily fixed through neck on the star wheel. During this process the elasticity of the rubber belt reduces and so by this the supporting plate may not able to place the vials to the gripper properly and if vials do not placed to the gripper then it falls down to the stainless steel plate in the washing area and broke.

Conclusion

In the proposed research work firstly Six Sigma technique was applied for decreasing the vials breaking during washing process by **high speed rotator vials washing machine (Ambica ARVW-120)** with washing rate of 60 vials per minute.

The problems defined by the supervisor of the process that the breaking of vials during washing process. After the long observation of the process various parameters as mentioned below were analyzed (vials breaking).

Defect probability: by machine and workers

The main problem found was breaking of number of vials during vials washing process because of two reasons - when vials enters from the turn table to the in feed worm then at this stage the point comes where the vials have to turn in inverted position at the hard surface, if the intensity of dropping or turning of the vials at surface is high then it causes breaking of vials, and those vials having bubble on their neck, have more chances to break. Second reason, when vials enters in the washing area through in-feed worm, then supporting plate (which is attached with rubber) is responsible for proper placement of vials from in feed worm to the gripper. Due to this the plate, vials easily fixed. through neck on the star wheel. During this process the elasticity of the rubber belt reduces with time and due to this the supporting plate may not able to place the vials to the gripper properly and if vials do not placed to the gripper then it falls down to the stainless steel plate in the washing area and broke.

It was challenging to achieve the necessary quality attributes before applying the sigma technique with the specifications that were in place. Following the suggested method's adoption, issues and their causes were determined, and recovery goals were explicitly specified.

The work done clearly indicate that process was improved by application of six sigma technique

Vials washing process

Before the implementation of six sigma technique the process worked on 4.5 sigma scale and thereafter process works on 4.9 sigma scale which proves the improvement in the process.

Six sigma matrices- Calculated for the breaking during vials washing process

Parameters	Previous	Present
Defect Rate	0.22%	0.12%
Defect Per Unit	0.0022	0.0012
DPMO	2200	1200
Sigma Scale	4.5	4.9

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