Analyzing Mechanical Defect Variability in Tablet Manufacturing: A Comprehensive Investigation of Machine Performance Consistency

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Abstract

This study analyzes mechanical edge defects in the production of pharmaceutical tablets by analyzing performance variability across three rotary tablet compression machines. This investigation evaluates defect trends across ten production batches for each machine using statistical quality control methodologies, including control charts. The initial results indicate that Machine C exhibits the highest variability, mainly due to turret vibration, while both Machines A and C exhibit indications of undetected die wear. Following resolving these mechanical issues, all three machines exhibited enhancements in process stability and reduced defects. These findings accentuate the importance of integrating statistical monitoring with preventive maintenance to improve manufacturing consistency and ensure product quality within pharmaceutical operations.

Key Terms —Compression, Tablet Edge Defect, Maintenance..

Problem Statement

This research seeks to evaluate the mechanical defect patterns associated with three tablet compression machines by analyzing edge defects in the production of pharmaceutical tablets. Despite operating under similar conditions, the defect rates differ among the machines, potentially indicating underlying mechanical inconsistencies or process variations. Through an analysis of defect occurrences across multiple batches and statistical techniques such as control charts and Design of Experiments (DOE), this study aims to uncover trends, correlations, and potential root causes of the observed defects.

Methodology

- The study evaluates the variability of edge defects in tablets manufactured by three like-for-like compression machines, designated as A, B, and C.
- Data is collected across ten production batches per machine, each producing ~1,250,000 tablets.
- A random sample of 500 defects is analyzed for each drum, resulting in approximately 9,000 evaluated tablets per batch.
- Statistical methodologies were employed for data evaluation, including mean defect count, standard deviation, upper control limit (UCL), and lower control limit (LCL).
- C-charts served as tools for visualizing defect trends and identifying deviations or shifts in process behavior.
- The study analyzes the root causes of defects, including machine settings, component wear, and operator handling.
- Machines are ranked based on defect rates and stability metrics.

TABLE 1. MACHINE TABLETS EDGE DEFECTS PER BATCH

Activity	Description	Estimated Duration	Estimated Completion Date
Project Planning & Research Design	Define research objectives, scope, and methodology.	2 weeks	Week 2
Data Collection	Collect edge tablet defects data from 10 batches per machine.	4 weeks	Week 6
Data Organization	Structure the dataset for statistical analysis.	1 week	Week 7
Statistical Analysis	Calculate means, standard deviations, and control limits. Develop Control Charts (C-Charts).	2 weeks	Week 9
Interpretation	Generate graphics and interpret the edge tablet defect trends across machines.	1 week	Week 10
Identification of Variations	Identify patterns and out of control points. Investigate potential causes of defect trends.	2 weeks	Week 12
Comparative Analysis	Compare machine performances based on statistical findings.	2 weeks	Week 14
Results Discussion	Analysis and discussion of findings.	2 weeks	Week 16
Report Documentation	Generate the final report.	2 weeks	Week 18
Revision	Proofread, refine, and feedback incorporation.	1 week	Week 19
Submission of Final Report	Submit the research study.	-	Week 19

Results and Discussion

The average number of edge defects per 500 sampled tablets per batch drums indicated significant differences among the three machines. Machine A exhibited a mean of tablet edge defect count of 42.7, Machine B recorded the lowest count at 36.9, and Machine C had the highest average at 51.2. Standard deviation analysis further highlighted the degree of variability, with Machine B showing the least variation ($\sigma \approx 3.7$), Machine A exhibiting moderate variation ($\sigma \approx 4.3$), and Machine C presenting the greatest variability ($\sigma \approx 5.8$). These metrics were subsequently used to construct control charts that visually represent the stability of each machine's output across batches.

TABLE 2. MACHINE TABLETS EDGE DEFECTS PER BATCH

Batch	Machine A	Machine B	Machine C
Batch 1	45	36	50
Batch 2	43	37	52
Batch 3	40	35	54
Batch 4	41	34	53
Batch 5	39	38	48
Batch 6	44	37	51
Batch 7	47	36	55
Batch 8	46	35	57
Batch 9	42	37	49
Batch 10	38	39	60

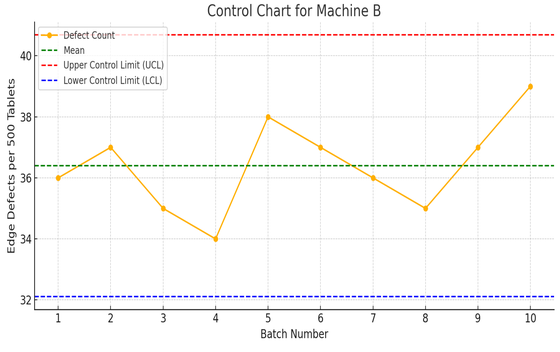

FIGURE 1. MACHINE B TABLETS EDGE DEFECTS PER BATCH

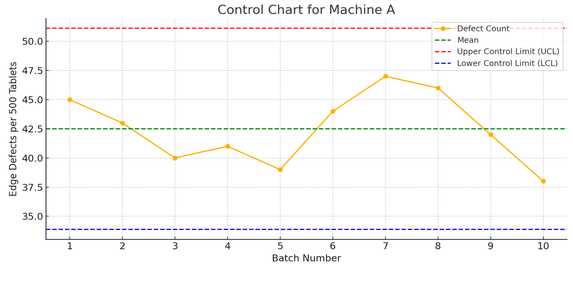

FIGURE 2. MACHINE A TABLETS EDGE DEFECTS PER BATCH

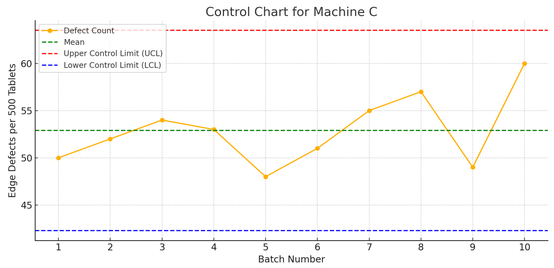

FIGURE 3. MACHINE C TABLETS EDGE DEFECTS PER BATCH

A mechanical investigation identified that Machine C was subjected to excessive vibration in its turret assembly, resulting in misalignment. Additionally, manufacturing operators did not initially recognize die wear, leading to minor inconsistencies in tablet shape and compression dynamics.

TABLE 3. MACHINE TABLETS EDGE DEFECTS PER BATCH AFTER MECHANICAL ISSUES RESOLUTION

Batch	Machine A	Machine B	Machine C
Batch 1	40	36	45
Batch 2	39	35	44
Batch 3	38	34	43
Batch 4	37	33	42
Batch 5	36	34	41
Batch 6	38	35	43
Batch 7	39	36	44
Batch 8	37	34	42
Batch 9	36	33	41
Batch 10	35	32	40

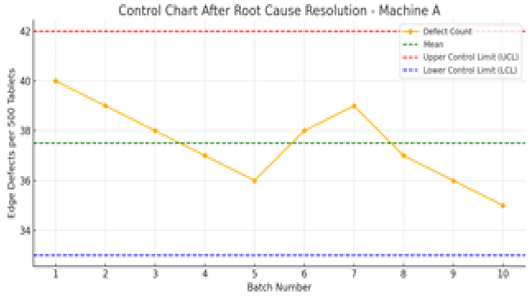

FIGURE 4. MACHINE B TABLETS EDGE DEFECTS PER BATCH

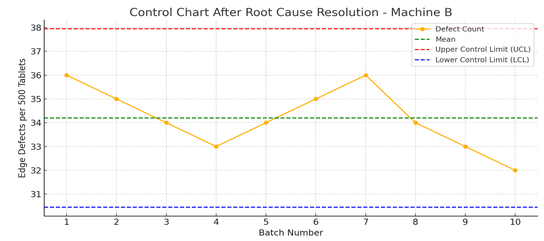

FIGURE 5. MACHINE B TABLETS EDGE DEFECTS PER BATCH

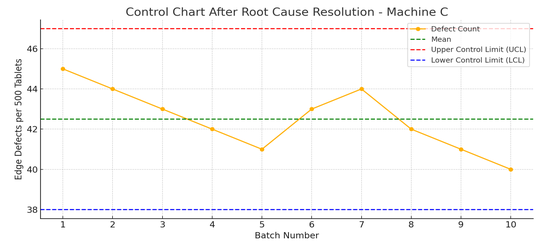

FIGURE 6. MACHINE C TABLETS EDGE DEFECTS PER BATCH

Conclusions

The following points can be concluded:

1. Analysis revealed mechanical issues (turret vibration in Machine C, undetected die wear in Machines A and C) caused high and inconsistent defect rates.
2. Control charts effectively identified variability and supported root cause investigation.
3. Corrective actions led to improved stability and reduced defect counts across all compression machines.
4. Machine C showed the most significant improvement after interventions.
5. The study emphasizes the value of combining data-driven monitoring, proactive maintenance, and operator attention to detail to ensure consistent tablet quality.

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