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RESEARCH ARTICLE

SIX SIGMA TECHNIQUE USED IN RISK ANALYSIS IN TABLET FORMULATION

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ABSTRACT:

FMEA is a systematic method for evaluating a process to identify where and how it might fail and access the relative impact of different failure, in order to identify the part of the process that are most in change needed. Failure Mode and Effect Analysis (FMEA) is a procedure which is performed after a failure mode effects analysis. Tablet is formulated in different steps, so the failure mode is studied for every step and also consider human failure and the technical risks, all these consider in the study. Each failure mode is ranked on estimated frequency of occurrence (O), probability that the failure would remain undetected later in process (D) and severity (S). Failure risk were calculated by Risk Priority Number (RPNs) i.e O*D*S. Failure mode with highest RPN scores is concider and subjected to the corrective action and FMEA was repeated. This technique is very useful in the evaluating the new process prior to the implementation when the process change the existing process. The aim of this paper is to demonstrate an application of this technique on the basis of FMEA.

Keywords: Failure Mode and Effects Analysis, Severity, Occurrence, Risk Priority Number.

INTRODUCTION

Six Sigma is a statistical term used to measure the performance of products and process against customer requirement. The six sigma approach aims to drive defects and things gone wrong to extraordinary low level, to increase first pass yield. First pass yield is a measure of the percentage of jobs that exit process right, on time at a single time. Number of technique used for six sigma analysis such as Capability Analysis, Cause and Effect Diagram, Chi Square-Test, Data Collection Plan, Design of Experiment, Discrete Data Analysis Method, Discrete Event Simulation, Failure Mode and Analysis(FMEA), Worst Case Analysis etc. Here FMEA technique is selected.

FMEA was developed outside of health care and now being used in health care to assess risk of failure and harm in process and identify the most important area for process improvement. The main objective is prevention of problems by reducing RPN (Risk Priority Number). FMEA is systematic, proactive method for evaluating the process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most need to change.

FMEA includes review of the following:

- Steps in Process.
- Failure Modes
- Failure Cause. (Why would the failure happen)
- Failure effect

It can be applied in the design of new product and process in order to prevent errors, accident and adverse reaction. FMEA depends on the product process understanding. It provides evaluation of potential failure mode for process and their likely effect on the product performance. It comprises the assessment of the :(1) Severity Rating, (2) Occurrence rating, and (3) Detection Rating. It can be applied to the equipment and facility and might be used to analyze manufacturing operation and its effect on the product and process. FMEA is classified in three categories (1)Design FMEA, risk analysis for the design of system, (2) Process FMEA, risk analysis for identifying potential product related failure mode, caused by manufacturing process, (3) Machinery FMEA, risk analysis for evaluating the equipments.

FMEA Variables:

Severity: It is a rating corresponding to the seriousness of an effect of a potential failure mode (Scale 1: no effect on out put, 2: moderate effect, 5: hazardous effect).

Occurrence: It is rating corresponding to the rate at which a first level cause and its resultant failure mode will occur over the design life of the system, product. (Scale1: failure unlikely, 2: occasional failure, 5: failure certain).

Detection: It is rating correspond to the likelihood that the detection method or current controls will detect the potential failure mode before the product is released for production for design or for process before it leaves the production facility. (Scale: 1: will detect failure, 2: might detect failure, 5: almost certain not detect failure).

MATERIAL AND METHOD

Material:

Table 1: Equipment used in the various unit operation

Process	Name of Equipment
Shifting Process	Vibrator Shifter
Binder Preparation	Jacketed Paste Cattle
Granulation	RMG
Drying Process	Fluid Bed Dryer
Sizing	Multimill
Compression	Compression Machine
Packaging	Aluminum strip Packaging Machine

For the production of tablet formulation following Steps can be used. It is noted that it is a general procedure and it can't used as an outcome

1. Dispensing of raw material.
2. Shifting
3. Binder Preparation
4. Granulation
5. Drying
6. Sizing
7. Blending and lubrication
8. Compression
9. Packaging

Methods:

1. Selection of the process. The importance of the process in terms impact of potential failure was taken into account as selection criteria. Evaluation using FMEA works best on process that do not have too many sub process.
2. Review of Process: The process was analyzed and described in a step or flow chart and the process design was studied thoroughly for the efficient output.
3. List of potential effects of each failure mode: Cause and effects analyze was used for this step.
4. Assign a severity rating for each effect: Each effect was given its own rating (From 1 to 10; with ten being most severe).
5. Assign an occurrence rating for each failure mode: From 1 to 10 with10 being likelihood of detection.
6. Calculation of risk priority number of each effect
7. Prioritize failure mode of action: Depend upon the calculation
8. Taken action to eliminate the high risk failure modes: The action to be taken for each high risk failure was determined and person was assigned to implement the action

RESULTS

S. No	Failure mode	Failure effect	Failure Cause	Control Measure	S	O	D	RPN	Action
1	Receiving of incorrect material	Contamination, cross contamination in raw material	Incorrect check during receiving of material	Raw material received as per approved vendor list	5	2	1	10	System was in control
2	Temperature and relative humidity	Material fails to meet the specification	Material is not stored as per approved vendor list	Area maintained by HVAC system	5	2	1	10	System was in control
3	Improper cleaning of area	Cross contamination of material and product	SOP not followed	SOP followed for cleaning	5	2	1	10	System was in control
4	Mixing time	Non uniform mixing of batch	Equipment problem, mixing time not followed as per BMR	Followed SOP and BMR for mixing	5	1	1	5	System was in control
5	Granulation Time	Non Uniform Granulation of batch	Equipment problem, granulation time not followed as per BMR	Followed SOP and BMR for granulation	5	1	1	5	System was in control
6	Drying Time	Granules was not proper dried	Equipment problem, drying time not followed as per BMR	Followed SOP and BMR for drying	5	1	1	5	System was in control
7	Compression force	Increase and & decrease hardness and disintegration time of tablet	Equipment error, untrained staff	Set compression force as per BMR, trained operator	5	1	1	5	System was in control
8	Die Fill	Weight Variation Of Tablets	Equipment error, untrained staff	Equipment setting, trained staff	5	1	1	10	System was in control

9	Speed of machine	Shape of tablet	Equipment error, untrained staff	Equipment setting, trained staff	5	1	1	10	System was in control
10	Finished Product Mix up	Market complaint	Transfer of Goods not follow SOP	As per SOP Transfer the goods	5	1	1	10	System was in control
11	Improper carton packing	Market complaint	Untrained Packer	In process check of carton	5	1	1	10	System was in control

CONCLUSION

From the above evaluation of risk assessment based on the FMEA it was concluded that the various critical step that were expected to occur at each stage of the process, were for reduce the associated risk. The method helps to us focusing the various critical steps that important to the quality of the product and process. By doing FMEA analysis includes better quality, increase safety and its contribution towards the cost saving, it also reduces the waste and decrease the development time.

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