

# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

### FAILURE MODE EFFECT ANALYSIS FOR COATING PROCESS OF LEVOFLOXACIN TABLETS

| S.<br>No. | Item /<br>Function   | Potential<br>Failure Mode  | Potential Effect<br>of Failure<br>(Effect)   | Potential Cause/<br>Mechanism<br>of Failure   | Current<br>Control   | Reference   | Risk with Current<br>control Measure |   | Recommended<br>Actions<br>(if any) | Risk after<br>control<br>measure      |    | RPN<br>(S*O*D) |    |    |    |
|-----------|--|--|--|---|--|---|--------------------------------------|---|------------------------------------|---------------------------------------|----|----------------|----|----|----|
|           |  |  |  |   |  |   | S                                    | o | D                                  | Risk<br>Priority<br>Number<br>(S*O*D) |    | S              | o  | D  |    |
| 1.        | Coating<br>Process<br>Parameter  Coating<br>Process<br>Parameter | Atomizing air pressure limit in process validation (3.0kg/cm²) were differ from BMR Atomizing air pressure limit (5-6kg/cm²)  Pressure mention in Batch was differing from | ➤ Improper coating of Tablets at 3.0kg/cm² Atomizing air pressure.  ➤ Product may be fail in DT, Dissolution due to improper | <ul> <li>➤ Spray of coating solution may not be uniformly traveled up to the tablets bed at 3.0 kg/cm²         Atomizing air pressure.</li> <li>➤ Spray rate of solution reduced.</li> <li>➤ Time duration of tablets coating increased.</li> <li>➤ Standard operating procedure is not available for Coating machine.</li> <li>➤ Typological error in validation protocol ignored during document review.</li> </ul> | <ul> <li>Film coating solution having low viscosity (1 to 10 mpa.s).         3.0 kg/cm² atomizing air pressure for spray gun is sufficient to maintain the uniform distribution of solution for uniform coating.</li> <li>Spray rate of solution is directly proportional to RPM of Coating Pan.         So we can reduce the spray rate of solution by reduction of Pan RPM up to maintain the tablets friction from coating pan.</li> <li>Complete coating solution to be used up to weight gain.</li> <li>Procedure is available for Operation of coating machine.</li> <li>Wrong limit mentioned in procedure due to typological error but correct limit of pressure 5-6 kg/cm² was followed during</li> </ul> | Batch Manufacturing Record  Standard Operating Procedure for Operation of Coating Machine  Approved Process validation Protocol | 4                                    | 2 | 3                                  | 24                                    | NA | NA             | NA | NA | NA |

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Remarks (if any):

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|-----------|--------------------|---------------------------------|--|---|--------------------|-----------|--------------------------------------|---|---------------------------------------|----|----------------------------------|---|----------------|--|
|           |                    |                                 |  |   |                    |           | S                                    | o | Risk<br>Priority<br>Number<br>(S*O*D) |    | S                                | 0 | D              |  |
|           |                    | mention in validation protocol. | coating.                                   |   | Production.        |           |                                      |   |                                       |    |                                  |   |                |  |

Note: Action shall be taken if Risk Priority Number is more than 64.

Where: S=Severity; O=Occurrence Probability; D=Detection

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| Quality Risk M | Ianagement Team |             | Reviewed By     | Approved By |
|----------------|-----------------|-------------|-----------------|-------------|
| Name           | Department      | Sign & Date | Head Operations | Head QA     |
|                |                 |             | Sign & Date     | Sign & Date |
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#### **QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT**

| Name of Facilit                  | y / Equipment / Utility / System / Activity / Procedure / Unit Operation:  | Coating Process                    |                           |  |  |  |  |  |  |  |
|----------------------------------|--|------------------------------------|---------------------------|--|--|--|--|--|--|--|
| S.No.                            | Recommended Action   | Responsible Person                 | Target Date of Completion |  |  |  |  |  |  |  |
|                                  |  |                                    |                           |  |  |  |  |  |  |  |
|                                  |  |                                    |                           |  |  |  |  |  |  |  |
| All the above agree              | Verification of Action Plan: All the above agreed actions completed, Not Completed. **incase any recommendations Not completed, to be tracked through CAPA System) |                                    |                           |  |  |  |  |  |  |  |
| Remarks (if any):                |  |                                    |                           |  |  |  |  |  |  |  |
|                                  |  |                                    |                           |  |  |  |  |  |  |  |
| Verified By<br>QA<br>Sign & Date |  | Approved I<br>Head QA<br>Sign & Da |                           |  |  |  |  |  |  |  |

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