



QUALITY RISK ASSESSMENT FOR PRODUCTION PROCESS

1. Risk Assessment:

Risk Assessment for Blending area

| A. | | Risk Identification | | | Risk Analysis/ Evaluation | | | | |
|-------|--|---|--|---|------------------------------|---|---|-------------|------------|
| S.No. | Item or Process Step | Potential risk and/or Failure mode | Probable impact of potential risk and/or failure mode | Current control measures | S | O | D | R P N | Risk Level |
| 1 | Transferring the granules from the granulation to the blending area and blending area to granules quarantine area. | Product may be contaminate during the transfer from the granulation to the blending area. | Non-conforming product may produce and it may impact to patient health. Product Recall or Market complain may happen. | Final granules transfer to the blend area in double poly bag and well closed with nylon tie with proper status label. | | | | | |
| | | Product may be spillage during the transfer the material. | Yield loss and product may be contaminated. | Material transfer in HDPE drums in double poly bags and poly bag are well closed with nylon tie and material transfer by trained person in supervision of technical person. | | | | | |
| 2. | Secondary Gowning and De-gowning in | Product may be contaminated | Final product may be not of standard quality. Market complaint. | Before the put the material into the bin blender wear the secondary gowning. | | | | | |



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|-------|-------------------------|---------------------------------------|---|---|------------------------------|---|---|-------------|---------------|
| S.No. | Item or Process Step | Potential risk and/or Failure mode | Probable impact of potential risk and/or failure mode | Current control measures | S | O | D | R P N | Risk Level |
| | the blending area. | | | <p>Person in the blending area not move out until the process not completed.</p> <p>After the completion of blending procedure all blended material transfer into the HDPE drums in double poly bag and closed with nylon tie and then with lid and transfer in the quarantine area.</p> <p>Before move out from the blending area, concern person will remove the secondary gowning and put into the “used garments” dedicated racks.</p> <p>Secondary gowning not reused to prevent the contamination or cross contamination.</p> | | | | | |



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| B. | Risk Reduction/ Acceptance | | | | | Risk Review | | | | | |
|--------------|---|-------------------|-------------------------------|----------------------|--|--------------------|----------|----------|------------|-------------------------|----------------------|
| S.No. | Potential risk and/or Failure mode | Risk level | Risk Acceptance Yes/No | Justification | Any action/ Mitigation plan for reduction | S | O | D | RPN | Final Risk Level | Residual Risk |
| | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |



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1. Conclusion: Risk Assessment carried out related to movement of dispensed material from dispensed staging room to granulation material air lock through the outer most corridor. Through proper brainstorming work carried out by the cross functional team for assessment the risk and evaluation the risk and found there are low risk in this activity.

2. Risk Review and Approval:

| S.No. | Name | Designation | Department | Sign/Date |
|-------|------|-------------|----------------|-----------|
| 1. | | | Production | |
| 2. | | | QA | |
| 3. | | | QC | |
| 4. | | | Administration | |
| 5. | | | Ware House | |
| 6. | | | Engineering | |