

QUALITY ASSURANCEDEPARTMENT

| S. No.                                  | Item /<br>Function  | Potential<br>Failure      | Potential Effect<br>of Failure   | Potential Cause/<br>Mechanism   | Current<br>Control  | Reference document No.  | S | 0 | D | Risk<br>Priority  | Recomme<br>nded   |     |   |    | Risk<br>ation |
|---|---|---------------------------|--|---|---|---|---|---|---|-------------------|---|-----|---|----|---------------|
|   | Tunction  | Mode<br>(Failure<br>Mode) | orranure   | of Failure  | Control   | document 140.   |   |   |   | Number<br>(SxOxD) |   | S   | O | D  | RPN<br>SxOxD  |
|   | RM Receipt  | De-dusting<br>not done    | Contaminatio     n and cross-     contaminatio     n     Ingress of     dust particles             | <ul> <li>SOP not followed properly.</li> <li>Inadequate training.</li> <li>Un availability of facility in working condition</li> </ul>  | <ul> <li>De-dusting procedure is available.</li> <li>Training has been provided of Area cleaning as per SOP.</li> <li>Training has been provided of incoming material cleaning as per SOP.</li> <li>Automatic De-Dusting machine for in the material entry and is maintained.</li> </ul>  | <ul><li>SOP No.</li><li>Training record</li><li>Incoming material checklist</li></ul> | 4 |   | 2 | 16                | Risk is<br>low<br>hence no<br>action<br>plan is<br>required |     | A | NA | NA            |
| ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) | Cleaning (Warehouse, sampling area, dispensing area, manufacturin g area, and packing area) | sanitized.                | Product failure     Contamination & cross contamination.     Area microbial count may be increase. | <ul> <li>Disinfectant preparation procedure not available.</li> <li>Disinfectant rotation schedule not available.</li> <li>Drain point sanitization procedure not available.</li> <li>Area cleaning procedure not available.</li> <li>Filter cleaning procedure not available.</li> <li>Gowning procedure not available.</li> <li>Inadequate training.</li> </ul> | <ul> <li>There is well defined procedure for preparation, filtration, usage and destruction of disinfectant solution.</li> <li>Disinfectant rotation schedule is in place.</li> <li>Procedure of drain sanitization is in place.</li> <li>Training has been provided of all concerned personnel for preparation, filtration, usage and destruction of disinfectant solution.</li> <li>Procedure of cleaning for area cleaning of sampling dispensing area, manufacturing area, and packing area is in place.</li> <li>Training has been provided for area cleaning of sampling dispensing area, manufacturing area, and packing area.</li> <li>Line clearance procedure is in place.</li> <li>Filter transfer from production area to filter cleaning area is in place.</li> <li>Training has been provided of Filter transfer from production area to filter cleaning area.</li> </ul> | SOP No.     Preventive maintenance record.     Environmental monitoring record.       | 4 | 3 | 2 | 24                | Risk is<br>low<br>hence no<br>action<br>plan is<br>required | N A | ı | NA | NA            |



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| S. No. | Item /                   | Potential   | Potential Effect   |  | Current   | Reference    | S | O | D |                               | Recomme  |   |        |    | Risk         |
|--------|--------------------------|---|--------------------|--|---|--------------|---|---|---|-------------------------------|--|---|--------|----|--------------|
|        | Function                 | Failure<br>Mode<br>(Failure<br>Mode)  | of Failure         | Mechanism<br>of Failure  | Control   | document No. |   |   |   | Priority<br>Number<br>(SxOxD) | nded<br>Actions<br>(if any)                      | S | O      |    | RPN<br>SxOxD |
| 3      | Sampling                 | • Sampling  | Cross-             | • Sampling and   | <ul> <li>Environmental monitoring record is in place.</li> <li>Preventive maintenance procedure is in place.</li> <li>Gowning procedure is in place.</li> <li>Sampling and dispensing accessories</li> </ul>  | • SOP No.    | 4 | 2 | 2 | 16                            | Risk is  | N |        | NA | NA           |
|        | and Dispensing Equipment | and dispensing accessories not cleaned Dynamic Pass box are not cleaned. RLAF is not cleaned Vacuum cleaner is not cleaned. | contamination      | dispensing accessories cleaning procedure not available.  Dynamic pass box cleaning procedure not available.  RLAF cleaning procedure not available.  Vacuum cleaner cleaning procedure not available.  Inadequate training. | cleaning procedure is in place. There is well defining procedure for accessories cleaning is in SOP.  Training has been provided of all concerned personnel for accessories cleaning.  Dynamic pass box cleaning procedure is in place.  Training has been provided of all concerned personnel for dynamic pass box cleaning.  RLAF cleaning procedure is in place.  Training has been provided of all concerned personnel for RLAF cleaning.  Vacuum cleaner cleaning procedure is in place.  Training has been provided of all concerned personnel for RLAF cleaning.  Training has been provided of all concerned personnel for vacuum cleaner cleaning. |              |   |   |   |                               | low<br>hence no<br>action<br>plan is<br>required | A | A      |    |              |
| 4      | Manufacturing equipment  | shifter not   | • Product failure. | • Vibro shifter cleaning procedure   | • Vibro shifter cleaning procedure is in place.   | • SOP No.    | 4 | 3 | 2 | 24                            | low  | , | N<br>A | NA | NA           |
|        | cleaning in              | cleaned.  | • Contaminatio     | not available.   | • Training has been provided of all   |              |   |   |   |                               | hence no   |   |        |    |              |



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|--------|--------------------|---------------------------------|--------------------------------|---|---|------------------------|---|---|---|-------------------|------------------|---|---|---|---------------|
|        |                    | Mode<br>(Failure<br>Mode)       |                                | of Failure                              |   |                        |   |   |   | Number<br>(SxOxD) | Actions (if any) | S | O | D | RPN<br>SxOxD  |
|        | tablet, hard       | • Paste                         | n & cross-                     | Paste kettle cleaning                   | concerned personnel for vibro shifter                         |                        |   |   |   |                   | action           |   |   |   |               |
|        | gelatin capsule    | kettle not                      | contamination                  | procedure not                           | cleaning.   |                        |   |   |   |                   | plan is          |   |   |   |               |
|        | and soft gelatin   |                                 |                                | available.                              | • Paste kettle cleaning procedure is in place.                |                        |   |   |   |                   | required         |   |   |   |               |
|        | capsule.           | <ul><li>Mass</li></ul>          | <ul><li>Microbial</li></ul>    | Mass mixer cleaning                     | • Training has been provided of all                           |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | mixer not                       | count may be                   | procedure not                           | concerned personnel for paste kettle                          |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | clean.                          | increase.                      | available.                              | cleaning.   |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | RMG not                         |                                | <ul> <li>RMG cleaning</li> </ul>        | • Mass mixer cleaning procedure is in                         |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | cleaned.                        |                                | procedure not                           | place.  |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | • Multi mill                    |                                | available.                              | • Training has been provided of all                           |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | not                             |                                | <ul> <li>Multi mill cleaning</li> </ul> | concerned personnel for Mass mixer                            |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | cleaned.                        |                                | procedure not                           | cleaning.   |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | <ul><li>Comminut</li></ul>      |                                | available.                              | •RMG cleaning procedure is in place.                          |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | ing mill                        |                                | •Comminuting mill                       | • Training has been provided of all                           |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | not                             |                                | cleaning procedure                      | concerned personnel for RMG cleaning.                         |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | cleaned.                        |                                | not available.                          | • Multi mill cleaning procedure is in place.                  |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | <ul> <li>Oscillating</li> </ul> |                                | <ul> <li>Oscillating</li> </ul>         | • Training has been provided of all                           |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | granulator                      |                                | granulator cleaning                     | concerned personnel for multi mill                            |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | not                             |                                | procedure not                           | cleaning.   |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | cleaned.                        |                                | available.                              | •Comminuting mill cleaning procedure is                       |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | • Roll                          |                                | <ul> <li>Roll compactor</li> </ul>      | in place.   |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | compactor                       |                                | cleaning procedure                      | • Training has been provided of all                           |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | not                             |                                | not available.                          | concerned personnel for Comminuting                           |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | cleaned.                        |                                | •FBD cleaning                           | mill cleaning.  |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | •FBD not                        |                                | procedure not                           | <ul> <li>Oscillating granulator cleaning procedure</li> </ul> |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | cleaned.                        |                                | available.                              | is in place.  |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | •FBP not                        |                                | •FBP cleaning                           | •Training has been provided of all                            |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | cleaned.                        |                                | procedure not                           | concerned personnel for Oscillating                           |                        |   |   |   |                   |                  |   |   |   |               |
|        |                    | <ul><li>Blender</li></ul>       |                                | available.                              | granulator cleaning.  |                        |   |   |   |                   |                  |   |   |   |               |



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|--------|------|----------------|--------------------------------|--|---|------------------------|---|---|------------------|-----------------|---|-----|--------------------|
|        |      | Mode           | of Fanure                      | of Failure                               | Control   | document No.           |   |   | Number           | Actions         | S | O I | RPN                |
|        |      | (Failure Mode) |                                |  |   |                        |   |   | (SxOxD)          | (if any)        |   |     | SxOxD              |
|        |      | not            |                                | Blender cleaning                         | •Roll compactor cleaning procedure is in                    |                        |   |   |                  |                 |   |     |                    |
|        |      | leaned.        |                                | procedure not                            | place.  |                        |   |   |                  |                 |   |     |                    |
|        | • R  | loto cube      |                                | available.                               | <ul> <li>Training has been provided of all</li> </ul>       |                        |   |   |                  |                 |   |     |                    |
|        |      | nixer not      |                                | •Roto cube mixer                         | concerned personnel for Roll compactor                      |                        |   |   |                  |                 |   |     |                    |
|        |      | eleaned.       |                                | cleaning procedure                       | cleaning.   |                        |   |   |                  |                 |   |     |                    |
|        | •C   | Compressi      |                                | not available.                           | • FBD cleaning procedure is in place.                       |                        |   |   |                  |                 |   |     |                    |
|        |      | on             |                                | <ul> <li>Compression</li> </ul>          | <ul> <li>Training has been provided of all</li> </ul>       |                        |   |   |                  |                 |   |     |                    |
|        | n    | nachine        |                                | machine cleaning                         | concerned personnel for FBD cleaning.                       |                        |   |   |                  |                 |   |     |                    |
|        |      | ot             |                                | procedure not                            | •FBP cleaning procedure is in place.                        |                        |   |   |                  |                 |   |     |                    |
|        |      | eleaned.       |                                | available.                               | <ul> <li>Training has been provided of all</li> </ul>       |                        |   |   |                  |                 |   |     |                    |
|        | • N. | <b>I</b> etal  |                                | <ul><li>Metal detector</li></ul>         | concerned personnel for FBP cleaning.                       |                        |   |   |                  |                 |   |     |                    |
|        | d    | letector       |                                | cleaning procedure                       | <ul> <li>Blender cleaning procedure is in place.</li> </ul> |                        |   |   |                  |                 |   |     |                    |
|        |      | ot             |                                | not available.                           | <ul> <li>Training has been provided of all</li> </ul>       |                        |   |   |                  |                 |   |     |                    |
|        |      | eleaned.       |                                | <ul> <li>Dust extractor</li> </ul>       | concerned personnel for blender cleaning.                   |                        |   |   |                  |                 |   |     |                    |
|        | • D  | Oust           |                                | cleaning procedure                       | • Roto cube mixer cleaning procedure is in                  |                        |   |   |                  |                 |   |     |                    |
|        | e    | extractor      |                                | not available.                           | place.  |                        |   |   |                  |                 |   |     |                    |
|        |      | ot             |                                | <ul> <li>Stirrer cleaning</li> </ul>     | <ul> <li>Training has been provided of all</li> </ul>       |                        |   |   |                  |                 |   |     |                    |
|        |      | eleaned.       |                                | procedure not                            | concerned personnel for Roto cube mixer                     |                        |   |   |                  |                 |   |     |                    |
|        |      | tirrer not     |                                | available.                               | cleaning.   |                        |   |   |                  |                 |   |     |                    |
|        | c    | eleaned.       |                                | <ul> <li>Coating pan cleaning</li> </ul> | <ul> <li>Compression machine cleaning procedure</li> </ul>  |                        |   |   |                  |                 |   |     |                    |
|        | • A  | utocoater      |                                | procedure not                            | is in place.  |                        |   |   |                  |                 |   |     |                    |
|        | n    | ot             |                                | available.                               | • Training has been provided of all                         |                        |   |   |                  |                 |   |     |                    |
|        |      | eleaned.       |                                | <ul> <li>Autocoater cleaning</li> </ul>  | concerned personnel for compression                         |                        |   |   |                  |                 |   |     |                    |
|        | •C   | Coating        |                                | procedure not                            | machine cleaning.   |                        |   |   |                  |                 |   |     |                    |
|        |      | Pan not        |                                | available.                               | • Metal detector cleaning procedure is in                   |                        |   |   |                  |                 |   |     |                    |
|        |      | leaned.        |                                | <ul> <li>Capsule filling</li> </ul>      | place.  |                        |   |   |                  |                 |   |     |                    |
|        |      | Capsule        |                                | machine cleaning                         | • Training has been provided of all                         |                        |   |   |                  |                 |   |     |                    |
|        | fi   | illing         |                                | procedure not                            | concerned personnel for metal detector                      |                        |   |   |                  |                 |   |     |                    |



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| S. No. | Item /<br>Function | nction Failure of Failure Mecha Mode of Fai |  | Potential Cause/<br>Mechanism            | Current<br>Control   | Reference document No. | S | O | D | Priority          | Recomme<br>nded  |   | Ev | alua | Risk<br>ation |
|--------|--------------------|---|--|--|--|------------------------|---|---|---|-------------------|------------------|---|----|------|---------------|
|        |                    | Mode<br>(Failure<br>Mode)                   |  | of Failure                               |  |                        |   |   |   | Number<br>(SxOxD) | Actions (if any) | S | О  | D    | RPN<br>SxOxD  |
|        |                    | machine                                     |  | available.                               | cleaning.  |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | not   |  | •Gelatin melting                         | • Dust extractor cleaning procedure is in                      |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | cleaned.                                    |  | reactor cleaning                         | place.   |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | <ul><li>Gelatin</li></ul>                   |  | procedure not                            | • Training has been provided of all                            |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | melting                                     |  | available.                               | concerned personnel for dust extractor                         |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | reactor not                                 |  | <ul> <li>Encapsulation</li> </ul>        | cleaning.  |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | cleaned.                                    |  | machine cleaning                         | • Stirrer cleaning procedure is in place.                      |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | <ul> <li>Encapsulat</li> </ul>              |  | procedure not                            | • Training has been provided of all                            |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | ion   |  | available.                               | concerned personnel for stirrer cleaning.                      |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | machine                                     |  | • Three stage semi                       | • Coating Pan cleaning procedure is in                         |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | not   |  | drier cleaning                           | place.   |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | cleaned.                                    |  | procedure not                            | • Training has been provided of all                            |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | <ul><li>Three</li></ul>                     |  | available.                               | concerned personnel for coating pan                            |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | stage semi                                  |  | <ul> <li>Gelatin holding tank</li> </ul> | cleaning.  |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | drier not                                   |  | cleaning procedure                       | <ul> <li>Autocoater cleaning procedure is in place.</li> </ul> |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | cleaned.                                    |  | not available.                           | • Training has been provided of all                            |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | <ul><li>Gelatin</li></ul>                   |  | <ul> <li>Triple roller mill</li> </ul>   | concerned personnel for autocoater                             |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | holding                                     |  | cleaning procedure                       | cleaning.  |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | tank not                                    |  | not available.                           | • Capsule filling machine cleaning procedure                   |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | cleaned.                                    |  | <ul><li>Planetary mixer</li></ul>        | is in place.   |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | <ul><li>Triple</li></ul>                    |  | cleaning procedure                       | <ul> <li>Training has been provided of all</li> </ul>          |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | roller mill                                 |  | not available.                           | concerned personnel for capsule filling                        |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | not   |  | <ul> <li>Medicament vessel</li> </ul>    | machine cleaning.  |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | cleaned.                                    |  | cleaning procedure                       | • Gelatin melting reactor cleaning procedure                   |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | <ul><li>Planetary</li></ul>                 |  | not available.                           | is in place.   |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | mixer not                                   |  | <ul><li>Inadequate training.</li></ul>   | • Training has been provided of all                            |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | cleaned.                                    |  |  | concerned personnel for gelatin melting                        |                        |   |   |   |                   |                  |   |    |      |               |
|        |                    | <ul><li>Medicame</li></ul>                  |  |  | reactor cleaning.  |                        |   |   |   |                   |                  |   |    |      |               |



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|--------|----------|-------------------|------------------|-------------------------|--|--------------|---|--------------------|-----------------|---|--|--------------|
|        | Function | Failure<br>Mode   | of Failure       | Mechanism<br>of Failure | Control  | document No. |   | Priority<br>Number | nded<br>Actions | S |  | ation<br>RPN |
|        |          | (Failure<br>Mode) |                  | V <b>. 2 W</b> V        |  |              |   | (SxOxD)            | (if any)        | 5 |  | SxOxD        |
|        |          | nt vessel         |                  |                         | • Encapsulation machine cleaning procedure                   |              |   |                    |                 |   |  |              |
|        |          | not               |                  |                         | is in place.   |              |   |                    |                 |   |  |              |
|        |          | cleaned.          |                  |                         | <ul> <li>Training has been provided of all</li> </ul>        |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | concerned personnel for encapsulation                        |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | machine cleaning.  |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | • Three stage semi drier cleaning procedure                  |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | is in place.   |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | • Training has been provided of all                          |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | concerned personnel for three stage semi                     |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | drier cleaning.  |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | • Gelatin holding tank cleaning procedure is                 |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | in place.  |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | • Training has been provided of all                          |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | concerned personnel for gelatin holding                      |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | tank cleaning.   |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | • Triple roller mill cleaning procedure is in                |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | place.   |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | • Training has been provided of all                          |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | concerned personnel for triple roller mill                   |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | cleaning.  |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | <ul> <li>Planetary mixer cleaning procedure is in</li> </ul> |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | place.   |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | <ul> <li>Training has been provided of all</li> </ul>        |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | concerned personnel for planetary mixer                      |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | cleaning.  |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | • Medicament vessel cleaning procedure is in                 |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | place.   |              |   |                    |                 |   |  |              |
|        |          |                   |                  |                         | <ul> <li>Training has been provided of all</li> </ul>        |              |   |                    |                 |   |  |              |



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|--------|-----------------------------|--|--|---|--|------------------------|---|---|---|-------------------|---------------------|-----|-----|----|---------------|
|        | runction                    | Mode<br>(Failure<br>Mode)  | of Fandre  | of Failure  | Control  | document No.           |   |   |   | Number<br>(SxOxD) | Actions<br>(if any) | S   | O   |    | RPN<br>SxOxD  |
|        |                             |  |  |   | concerned personnel for medicament vessel cleaning.  |                        |   |   |   |                   |                     |     |     |    |               |
| 5      | Packing equipment cleaning. | Blister machine not cleaned. Alu-alu machine not cleaned. Strip machine not cleaned. Powder filling machine not cleaned. Sachet filling machine not cleaned. Cleaned. Change part not cleaned. | contamination.  • Microbial count may be increase. | <ul> <li>Blister machine cleaning procedure not available.</li> <li>Alu-alu machine cleaning procedure not available.</li> <li>Strip machine cleaning procedure not available.</li> <li>Powder filling machine cleaning procedure not available.</li> <li>Sachet filling machine cleaning procedure not available.</li> <li>Change part cleaning procedure not available.</li> <li>Change part cleaning procedure not available.</li> <li>Inadequate training.</li> </ul> | <ul> <li>Blister machine cleaning procedure is in place.</li> <li>Training has been provided of all concerned personnel for blister machine cleaning.</li> <li>Alu-alu machine cleaning procedure is in place.</li> <li>Training has been provided of all concerned personnel for alu-alu machine cleaning.</li> <li>Strip machine cleaning procedure is in place.</li> <li>Training has been provided of all concerned personnel for strip machine cleaning.</li> <li>Powder filling machine cleaning procedure is in place.</li> <li>Training has been provided of all concerned personnel for powder filling machine cleaning.</li> <li>Sachet filling machine cleaning procedure is in place.</li> <li>Training has been provided of all concerned personnel for sachet filling machine cleaning.</li> <li>Change part cleaning procedure is in</li> </ul> | • SOP No.              |   | 2 | 2 | 16                | TUBIC IS            | i.' | N A | NA | NA            |



QUALITY ASSURANCEDEPARTMENT

#### RISK ANALYSIS STUDY FOR CLEANING & SANITIZATION OF EQUIPMENT & AREA

| S. No. | Item /<br>Function | Potential<br>Failure<br>Mode<br>(Failure<br>Mode) | Potential Effect<br>of Failure | Potential Cause/<br>Mechanism<br>of Failure | Current<br>Control  | Reference<br>document No. | SO | Priority<br>Number | Recomme<br>nded<br>Actions<br>(if any) | S | Evalu | Risk<br>nation<br>RPN<br>SxOxD |
|--------|--------------------|---|--------------------------------|---|---|---------------------------|----|--------------------|--|---|-------|--------------------------------|
|        |                    |   |                                |   | place.  Training has been provided of all concerned personnel for change part cleaning. |                           |    |                    |  |   |       |                                |

#### **Rating Scale – Severity**

- 1= No Effect
- 2= Minor Effect
- 3= Moderate Effect
- 4= Serious Effect
- 5= Hazardous Effect

#### **Rating Scale - Occurrence**

- 1= Unlikely
- 2= Very Rare
- 3= Possible
- 4= Likely
- 5= Almost Certain (every time)

#### **Rating Scale - Detection**

- 1= Always Detected
- 2= Will Detect Failure
- 3= Might Detect Failure
- 4= Almost certain not to Detect Failure
- 5= Lack of Detection Control

#### **Acceptance Criteria**

 $51 \text{ to} \le 125 = \text{High Categories}$ 

26 to 50 = Medium Categories

Upto25 = Low Categories

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

#### **Remarks:**

- 1.0 For RPN rating  $\leq$  25, No action plan required, however, for the improvement purpose action plan can be proposed for RPN rating  $\leq$  25, if required.
- **2.0** Action plan is required if any of individual Severity and occurrence is high. (Even if RPN is within acceptance criteria).

Conclusion:- On the basis of above risk assessment the Cleaning and Sanitization of equipment and area leads to low risk, all evaluated risk during assessment in all concern department like warehouse ,manufacturing (Tablet, hard gelatin and soft gelatin) area and packing area, which can be lower down after follow above mentioned controls hence no recommended action required.



QUALITY ASSURANCEDEPARTMENT

#### RISK ANALYSIS STUDY FOR CLEANING & SANITIZATION OF EQUIPMENT & AREA

| S. No. | Recommended Action | Responsible Person | Target Date of Completion |
|--------|--------------------|--------------------|---------------------------|
|        | NA                 | NA                 | NA                        |

CAPA (Required / Not Required): Not required

If required, mention CAPA No.: NA

| <b>Quality Risk Management Team</b> | m          |             | Reviewed By                      | Approved By              |
|-------------------------------------|------------|-------------|----------------------------------|--------------------------|
| Name                                | Department | Sign & Date | Head Operations<br>(Sign & Date) | Head QA<br>(Sign & Date) |
|                                     |            |             |                                  |                          |
|                                     |            |             |                                  |                          |
|                                     |            |             |                                  |                          |
|                                     |            |             |                                  |                          |

### QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Procedure: Cleaning and Sanitization of equipment and area.

**Verification of Recommended Action: NA** 

Remarks (if any): NA

Verified By Officer/Executive QA (Sign & Date) Approved By Head QA (Sign & Date)