Pre-Manufacture Checklist

Refer to Procedure QP709: Manufacture of Product

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| --- | --- | --- | --- |
| GMP Batch manufacturing preparation checklist (Complete one checklist for each manufacturing area in which the product is to be made) | | | |
| Manufacturing facility: | | | |
| Previous batch history: | | | |
| Previous product and batch and date manufactured: | | | |
| Facility Cleanliness | | | |
| Area | Actions required / undertaken | Sign | Date |
| Floor |  |  |  |
| Walls |  |  |  |
| Vents |  |  |  |
| Drains |  |  |  |
| Fume hood |  |  |  |
| Services connections |  |  |  |
| Weigh scales |  |  |  |
| Facility Clearance | | | |
| Area | Actions required / undertaken | Sign | Date |
| Movable equipment not required has been removed |  |  |  |
| Area free of raw materials, finished product, wastes and by-products, labels |  |  |  |
| Weigh Scale calibration | | | |
| Weigh scale identity | Confirm calibration and which raw materials will be used | Sign | Date |
|  | Weigh scale calibrated for raw material: |  |  |
|  | Weigh scale calibrated for raw material: |  |  |
|  | Weigh scale calibrated for raw material |  |  |

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| --- | --- | --- | --- |
| Equipment cleanliness | | | |
| Equipment identity/description | Cleaning method used and confirmation that cleaning is complete, clean tags added | Sign | Date |
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|  |  |  |  |
| Personal protective equipment | | | |
| Equipment identity/description | Cleaning method used and confirmation that it is clean and in working order | Sign | Date |
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|  |  |  |  |
| Signage | | | |
| Sign required | Confirmation it is available | Sign | Date |
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Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP709 | Manufacture of Product |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.