NB: This form should be completed in conjunction with the GMP Audit Report form (FM\_MQL05) for the Core Elements of the cGMP.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Manufacturer** |  | | **Licence No.** |  |
| **Street Address of Facility Audited** |  | | | |
| **Date/s of Audit** |  | **Auditor’s Name** |  | |

**Specific audit findings**

| **Key requirements** | **Compliance rating**  *(Compliant / Non-compliant)* | **Evidence sighted and observations**  ***(Please provide details of observations, documents reviewed, discussions with relevant staff, and any other comments that are relevant to the assessed rating).*** | |
| --- | --- | --- | --- |
| **General comments** |  |  |
| Sterile products manufactured in separate controlled areas with a high standard of hygiene, appropriate air quality control, with special care in accordance with validated procedures **(MP 17(1)).** |  |  |
| Established procedures in place to adequately monitor environmental bioburden in production areas and measure microbiological burden of products to be sterilised**. (MP 17(2)).** |  |  |
| **Premises and production areas** |  |  |
| Premises generally suitable for sterile manufacture **(cGMP A1 001–008)**. |  |  |
| Production areas and fittings designed and laid out to prevent contamination and facilitate cleaning. Access restricted. **(cGMP A1 009-014).** |  |  |
| Appropriate standards of sanitation and hygiene in place **(cGMP A1 015-019).** |  |  |
| **Environmental control** |  |  |
| Air quality suitable for the type of product, and the type of activities carried out in particular areas. Effectively managed and controlled **(cGMP A1 020-029).** |  |  |
| Appropriate levels of environmental monitoring carried out **(cGMP A1 030-035).** |  |  |
| **Personnel** |  |  |
| Key personnel suitably qualified and/or experienced **(cGMP A1-036).** |  |  |
| Personnel adequately trained, supervised, and subjected to medical checks and entry restrictions  **(cGMP A1 037-039).** |  |  |
| Appropriate protective clothing worn and appropriate clean-area entry procedures in place  **(cGMP A1 040-041).** |  |  |
| **Equipment** |  |  |
| Unidirectional airflow equipment regularly tested **(cGMP A1-042).** |  |  |
| All equipment sterilised before use in accordance with documented and validated procedures, using suitable, monitored equipment  **(cGMP A1 043-050)**. |  |  |
| Air and other gases used are appropriately filtered **(cGMP 051).** |  |  |
| Process water quality appropriate and monitored **(cGMP A1 052-053).** |  |  |
| **Specifications** |  |  |
| Adequate specifications for all raw materials including water **(cGMP A1 054-056).** |  |  |
| **Processing** |  |  |
| Processing operations designed to minimise contamination and ensure effective sterilisation **(cGMP A1 057-071).** |  |  |
| Batch records to include all relevant sterilisation records including relevant monitoring records  **(cGMP A1 061-063).** |  |  |
| **Sterilisation** |  |  |
| Heat sterilisation the preferred method unless approved by Registration **(cGMP A1 069).** |  |  |
| Sterilisation procedure appropriate and shown to be effective by monitoring and validation **(cGMP A1 072-095).** |  |  |
| **Finishing (Primary packaging)** |  |  |
| Containers closed by appropriately validated methods and subjected to appropriate levels of testing/inspection. **(cGMP A1 096-098)** |  |  |
| **Quality control** |  |  |
| Each batch tested for sterility, uniformity, potency, pyrogenicity and particulate matter as required for registration **(cGMP A1 099).** |  |  |
| Sampling and testing methods appropriate and relevant records retained by QC  **(cGMP A1 100 -101, 103).** |  |  |
| Parametric release authorised by APVMA and specified calibrations and controls rigorously maintained **( cGMP A1-102).** |  |  |
| Release of sterile product includes review of validation (including media fill runs), environmental and equipment monitoring, batch records, and finished product test results **(cGMP A1-104).** |  |  |
| Other Sterile Manufacture issues. |  |  |
| **Aseptic processing** |  |  |
| **Premises and production areas** |  |  |
| Premises suitable for aseptic processing with suitable clean rooms and airlocks supplied with appropriate grades of filtered air  **(cGMP A1 105-108, 110-111).** |  |  |
| Products manufactured in clean areas up to sterilisation stage, and then processed and filled under aseptic conditions using a double barrier system with appropriate airflow **(cGMP A1-109).** |  |  |
| **Sanitation and hygiene** |  |  |
| Aseptic production areas thoroughly cleaned and disinfected before use using sterilised cleaning and disinfection agents  **(cGMP A1 112 & 115).** |  |  |
| Appropriate protective clothing worn by all personnel in aseptic production areas. **(cGMP A1 113-114).** |  |  |
| **Environmental control and monitoring** |  |  |
| “In operation” and “at rest” states defined for each clean room or suite of clean rooms **(cGMP A1 116-117).** |  |  |
| Appropriate levels of environmental monitoring carried out  **(cGMP A1 118-121)**. |  |  |
| **Personnel** |  |  |
| Access to aseptic production areas restricted to essential personnel, particularly during processing  **(cGMP A1 122).** |  |  |
| Appropriate, cleaned protective clothing worn and no outdoor clothing, watches, jewellery or make-up allowed in clean rooms. Gloves regularly disinfected during processing and masks and gloves changed every working session **(cGMP A1 123-126)**. |  |  |
| **Equipment and processing** |  |  |
| No conveyer belts into clean areas unless continually sterilised  **(cGMP A1-127)**. |  |  |
| All materials (components, containers, equipment, etc) taken into clean room are sterilised and passed in through double ended sterilisers or other appropriate methods **(cGMP Clause A1 129).** |  |  |
| Activities in clean areas during processing are minimised to avoid shedding contaminants. Working environment is comfortable **(cGMP A1-128).** |  |  |
| Appropriate media fill runs carried out. **(GMP Clause A1-130)**. |  |  |
| Other Aseptic Processing issues. |  |  |

***Auditor’s Signature:*** *.............................…………...* ***Date:*** *.........………..…..*

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