**Inspection Report**

 **General Information.**

|  |  |
| --- | --- |
| Name of Manufacturer |  |
| Physical Address |  |
| Drug Manufacturing License No. and validity |  |
| Date of Inspection. |  |
| Purpose of Inspection |  |
| Name of Inspector |  |
| Name of firm Representatives present during the course of inspection |  |

Details of the inspection are as follows:

|  |  |  |
| --- | --- | --- |
| **Sr. No.** | **Questions** | **Observations of the panel** |
|  | Do you have documents confirming the import of API including approval from DRAP? |  |
|
|  | What was the rationale behind selecting the particular manufacturer of API? |  |
|  | Do you have documents confirming the import of reference standard and impurity standards? |  |
|
|  | Do you have certificate of Analysis of the API, reference standards and impurity standards? |  |
|  | Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin? |  |
|  | Do you use API manufacturer method of testing for testing API? |  |
|  | Do you have stability studies reports on API? |  |
|  | If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified? |  |
|  | Do you have method for quantifying the impurities in the API? |  |
|  | Do you have some remaining quantities of the API, its reference standard and impurities standards? |  |
|  | Have you used pharmaceutical grade excipients? |  |
|  | Do you have documents confirming the import of the used excipients? |  |
|  | Do you have test reports and other records on the excipient used? |  |
|  | Do you have written and authorized protocols for the development of applied product? |  |
|  | Have you performed Drug-excipients compatibility studies? |  |
|  | Have you performed comparative dissolution studies? |  |
|  | Do you have product development (R&D) section |  |
|  | Do you have necessary equipments available in product development section for development of applied product? |  |
|  | Are the equipments in product development section qualified? |  |
|  | Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section? |  |
|  | Do you have qualified staff in product development section with proper knowledge and training in product development? |  |
|  | Have you manufactured three stability batches for the stability studies of applied product as required? |  |
|  | Do you have any criteria for fixing the batch size of stability batches? |  |
|  | Do you have complete record of production of stability batches? |  |
|  | Do you have protocols for stability testing of stability batches? |  |
|  | Do you have developed and validated the method for testing of stability batches? |  |
|  | Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab? |  |
|  | Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug? |  |
|  | Is your method of analysis stability indicating? |  |
|  | Is your HPLC software is 21CFR compliant?(Details of Model, software, description/version (i.e. software validation report for 21 CFR Part 11 compliance including audit trail, password protection, date & time lock and user authorizations shall also be reported.) |  |
|  | Can you show Audit Trail reports on stability studies testing? |  |
|  | Do you have some remaining quantities of degradation products and stability batches? |  |
|  | Do you have stability batches kept on stability testing? |  |
|  | Do you have valid calibration status for the equipments used in production and analysis? |  |
|  | Do proper and continuous monitoring and control are available for stability chamber? |  |
|  | Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant? |  |

**Remarks:**

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| --- | --- | --- |
| **Name** | **Designation** | **Signature** |