**General Check points**

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| --- | --- | --- |
| **S. No.** | **Check point** |  |
|  | Is the correct sample analysed? | Yes |
|  | Whether any abnormalities observed before / during analysis that could have an impact on analysis? | No |
|  | Is current version of STP followed? | Yes |
|  | Is there any calculation errors? | NO |
|  | Is there any equipment/instrument failure/error? | NO |
|  | Is there any Transcription errors? | NO |
|  | Whether instrument parameters are set properly? | YES |
|  | Whether method parameters are set properly? | YES |
|  | whether any other obvious errors identified that could have an impact on initial analysis? (e.g., wrong standard / sample usage etc.)- If yes, mention the details in the comments section. | NO |
|  | Is the analyst trained on the applicable activity or procedures? | YES |
|  | Is this the first time analyst performed the activity? | NO |
|  | Whether any standard / sample solution preparation error? (Like spillage, incomplete transfer of the material/ incorrect volume / incorrect flask usage etc.), If yes, mention the details in comments section. | NO |
|  | Is the sample storage condition as per requirement? | YES |
|  | Was there any power failure during analysis? | NO |
|  | Did analyst miss any of the step(s)? | NO |

**Discussion with analyst Checkpoints**

|  |  |  |
| --- | --- | --- |
| **Sr. No.** | **Check points** |  |
| 1 | Does the analyst have knowledge about execution of correct procedure? | YES |
| 2 | Did the analyst perform the test as per the current procedure? | YES |
| 3 | Are analyst competent and the relevant training records of the analyst available? | YES |
| 4 | Is this the first-time analyst performing the activity? | NO |
| 5 | Did analyst miss any of the step(s)? | NO |
| 6 | Whether any abnormalities observed before/during analysis that could have an impact on analysis? | NO |

**Sampling Checks Points**

|  |  |  |
| --- | --- | --- |
| **Sr. No.** | **Check points** |  |
| 1 | Was the sampling done as per written procedure? | **yes** |
| 2 | Was the sampling done by a trained person? | **Yes** |
| 3 | Were cleaned sampling tools used for sampling? | **Yes** |
| 4 | Were cleaned containers used for collections of samples? | **Yes** |
| 5 | Was the sample description match as per Standard testing procedure? | **Yes** |
| 6 | Was the sample labelled properly and it is legible? | **Yes** |
| 7 | Was the sample homogeneous? | **Yes** |
| 8 | Was composite sample prepared correctly? | **Yes** |
| 9 | Was the testing sample stored as per the recommended storage condition? | **Yes** |
| 10 | Was the sample integrity including storage condition maintained until testing? | **Yes** |
| 11 | Was the sample pull-out (in case of stability studies) done as per written procedure? | **Na** |

**Data collection / Calculation**

|  |  |  |
| --- | --- | --- |
| **Sr. No.** | **Check points** |  |
| 1 | Was the data collected from instrument in sequential order? | **Yes** |
| 2 | Was there any transcription error? | **NO** |
| 3 | Was there any error in the calculation done? | **NO** |
| 4 | Was correct formula used for calculating the result? | **Yes** |
| 5 | Are correct equivalent factor / correction factor / variables used in calculation? | **Yes** |
| 6 | Is the interpretation of test results done correctly? | **Yes** |
| 7 | Is correct potency of standard applied for calculation? | **Yes** |
| 8 | Is the method adequate as per validation data for recovery, solution stability etc.? | **Yes** |
| 9 | Is the product / material show a history of similar aberrant result for the test under investigation? | **NO** |

**Preparation and Testing**

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| --- | --- | --- |
|  |  |  |
| 1 | Was correct STP used for analysis? | **yes** |
| 2 | Whether precautions (if any) mentioned in the STP were followed? | **Yes** |
| 3 | Was correct weighing from correct portion of sample and standard done? | **Yes** |
| 4 | Was appropriate balance and apparatus/glassware used for sample and standard preparation? | **Yes** |
| 5 | Was adequate size of butter paper used for sample and / or standard weighing? | **Yes** |
| 6 | Was clean and correct capacity of glassware used for analysis? | **Yes** |
| 7 | Were correct and valid standards used and prepared for each test preparation? | **Yes** |
| 8 | Any evidence on usage of other form of In-house Reference standards or working standards (such as form-I or Form-II) or any other salt/base? | **NO** |
| 9 | Is there any evidence of degradation of standards / sample / chemical used for testing | **NO** |
| 10 | Was there any loss of sample and / or standard during preparation? | **NO** |
| 11 | Was the sample and standard prepared as specified in the test procedure? (Properly shaken, sonication or heated /warmed/mixing etc.) | **Yes** |
| 12 | Were the sample and standard dilutions correctly performed as per specification? | **Yes** |
| 13 | Were correct diluents used for preparation of standard / sample? | **Yes** |
| 14 | Were the standard / sample allowed to attain ambient temperature prior to weighing and dilution? | **Yes** |
| 15 | Were the samples and standard correctly labelled for traceability? | **Yes** |
| 16 | Were the sample / standard correctly transferred to vial / auto sampler? | **Yes** |
| 17 | For replicate preparation, were samples / standards treated similarly? | **Yes** |
| 18 | Were correct chemicals / reagents used as per the test method? | **Yes** |
| 19 | Is adequate caution exercised during the handling of material with respect to its characteristics like light sensitive, thermo labile etc.? | **Yes** |

**Instrumentation General Checks Points:**

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| --- | --- | --- |
|  |  |  |
| 1 | Is the instrument calibrated and preventive maintenance done as per schedule? | **YES** |
| 2 | Was analysis performed on correct and calibrated instrument? | **yes** |
| 3 | Is the instrument clean and in good condition? | **yes** |
| 4 | Is any leakage observed? | **NO** |
| 5 | Were instruments used as per written operating procedure? | **yes** |
| 6 | Was there any power supply fluctuation / failure during analysis? | **NO** |
| 8 | Error message in any of the instrument display / software. | **NO** |
| 9 | Is there any instrument failure during analysis? | **NO** |
|  |  |  |

**HPLC Analysis Checks Points:**

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| --- | --- | --- |
| **.** |  |  |
| 1 | Is the mobile phase prepared as per STP? | **yes** |
| 2 | Was the quantity of mobile phase sufficient for total sequence analysis? | **yes** |
| 3 | Were there any pressure fluctuations observed during the analysis? | **No** |
| 4 | Are any air bubbles observed in the mobile phase of instrument flow lines? | **No** |
| 5 | Were correct instrument parameters followed (such as injection volumes, wavelengths, Flow rate, sample temperatures, instrument method, Run time, etc.…)? | **Yes** |
| 6 | Is the response of standard and sample comparable with the trend ? | **No** |
| 7 | Is any buffer deposition observed? | **No** |
| 8 | Is there any abnormality observed in Baseline drift? | **No** |
| 9 | Are there any Extraneous peaks observed in Chromatogram? | **Yes** |
| 10 | Is there any retention time shifting observed in the Chromatogram? | **No** |
| 11 | Is there any Peak splitting / shape distortion observed in the Chromatogram? | **No** |
| 12 | Is any Peak broadening (Fronting / Tailing) observed in the Chromatogram? | **No** |
| 13 | Is there any loss of resolution observed in the Chromatogram? | **No** |