|  |  |
| --- | --- |
| **Sr. No. in Scope**  | **NABL / NON NABL** |

**Flow chart for analysis of ---------------- in formulation sample**

|  |  |
| --- | --- |
| **Date of Analysis**  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **S.No.** | **Step**  | **Execution** | **Executed By** |
| 1. | Sample No. |  |  |
| 2. | Name of Sample |  |  |
| **3.** | **Procedure** |
| **3.1** | **Preparation of Internal Standard Solution** |
| 3.1.1 | Weigh ---- g of -------------Internal standard in 100 ml volumetric flask |  g |  |
| 3.1.2 | *Note down the S.No. of balance log book* |  |  |
| 3.1.3 | Dissolve and dilute up to the mark with suitable solvent \_\_\_\_\_\_\_\_ |  |  |
| **3.2**  | **Preparation of Standard Solution**  |
| 3.2.1 | Purity of standard |  % |   |
| 3.2.2 | Weigh ------g a.i. of the standard in a ----- ml volumetric flask |  g |  |
| 3.2.3 | *Note down the S.No. of balance log book* |  |  |
| 3.2.4 | Add ---- ml of internal standard solution (3.1.3) |  ml |  |
| 3.2.5 | Dissolve up to the mark with suitable solvent ------------- |  |  |
| **3.3** | **Preparation of Sample Solution**  |
| 3.3.1 | Note down the percent active ingredient content declared on the sample |  % |  |
| 3.3.2 | Weigh sample so as to contain ------ g a.i. in a 25 ml volumetric flask |  g |  |
| 3.3.3 | *Note down the S.No. of balance log book* |  |  |
| 3.3.4 | Add --= ml of internal standard solution (3.1.3) |  ml |  |
| 3.3.5 | Dissolve up to the mark with suitable solvent ---------- |  |  |
| **4.** | **GC Parameters** |
| **4.1** | **Column:** Packed with -------- stationary phase on (---- to ----) mesh |  |  |
| 4.1.1 | **Length x I.D:** ------ cm x ------- mm |  |  |
| **4.2** | **Gas** |  |  |
| 4.2.1 | Carrier:Nitrogen: --- ml/min |  |  |
| 4.2.2 |  Hydrogen: --- ml/min  |  |  |
| 4.2.3 |  Air: ------ ml/min  |  |  |
| **4.3** | **Temperature** |
| 4.3.1 | Oven: -------°C |  |  |
| 4.3.2 | Injector: --------°C |  |  |
| 4.3.3 | Detector: --------°C |  |  |
| **4.4** | **Injection Volume**: 1 µl |  |  |
| **5.** | **Result**  |
| Sample chromatogram no. |  |  |
| Standard chromatogram no. |  |  |

**6. CALCULATION:**

A1 x A’IS’2 x M1

 AI content, % by mass = ---------------------- x P

 A’IS’1 x A2 x M2

**Where,**

A1 = Peak area of AI in the sample solution

A’IS’1 = Peak area of internal standard in the sample solution

A’IS’2 = Peak area of internal standard in the standard solution

A2 = Peak area of AI in the standard solution

M1 = Mass in ’g’ of standard AI in the standard solution

M2 = Mass in ’g’ of sample taken for test

P = Percent purity of ---------------- standard

 **Result:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SI.No.** | **Name of test** | **Result** | **Unit** | **Method of Analysis** |
| 1. | Active ingredient |  | % | No. IS |
| Remark / Reference : name of Method of analysis used to prepare the Flow chart |

|  |  |  |
| --- | --- | --- |
| Analyzed by | Name  |  |
| Dated signature |  |
| Checked by | Name  |  |
| Dated signature |  |