

Name of Laboratory -----

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.		

Name of the Laboratory :		Name of laboratory	
Document No.	:	FC-PF-204	Document Name : Flow chart for analysis of AI ----- content, % by mass
Revision No.	:		Issue Date :
Revision Date	:		Next Revision Date :
Prepared By		Checked By	
		Approved By & Issued By	

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6. CALCULATION:

$$\text{AI content, \% by mass} = \frac{A_1 \times A'IS'_2 \times M_1}{A'IS'_1 \times A_2 \times M_2} \times P$$

Where,

- A_1 = 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
 A_2 = Peak area of AI in the standard solution
 M_1 = Mass in 'g' of standard AI in the standard solution
 M_2 = 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	

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