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NEW ANALYTICAL METHOD DEVELOPMENT FOR INDINAVIR IN SOLID DOSAGE FORM BY RP-HPLC METHOD

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ABSTRACT
Pharmaceutical drug products play a major role on human lives which help in curing the various diseases. Now a day's many of the drugs are synthesized oftenly shows many thereuptic effect in their pharmaceutical formulations. At finally the biologically active substances are formulated into different formulations such as tablets, capsules, suspensions, ointments and an injectables. These drugs deliver the drugs and shows the therapeutic effect. At end the product should ensure the quality can be achieve by various analytical technique. The aim of this study mainly focuses on a powerful analytical technique such as chromatography method as HPLC shows wide application. By literature search it needs to develop new, simple and reliable analytical method development and validations.

KEYWORDS: tablets, capsules, suspensions, ointments and an injectables.

EXPERIMENTAL WORK

INSTRUMENTS USED

S.No	Instruments And Glasswares	Model
1	HPLC	WATERS Alliance 2695 separation module, Software: Empower 2, 996 PDA detector.
2	pH meter	LabIndia
3	Weighing machine	Sartorius
4	Digital ultra sonicator	Labman

CHEMICALS USED

S.No	Chemical	Brand names
1	Indinavir	Sura labs
2	Water and Methanol for HPLC	LICHROSOLV (MERCK)
3	Acetonitrile for HPLC	Merck

Trail 1.

Column : ODS C18 (4.6×250mm) 5µ
Column temperature : 30ºC
Wavelength : 220nm
Mobile phase ratio : Water (100%) V/V
Flow rate : 0.5ml/min
Injection volume : 10µl
Run time : 7minutes

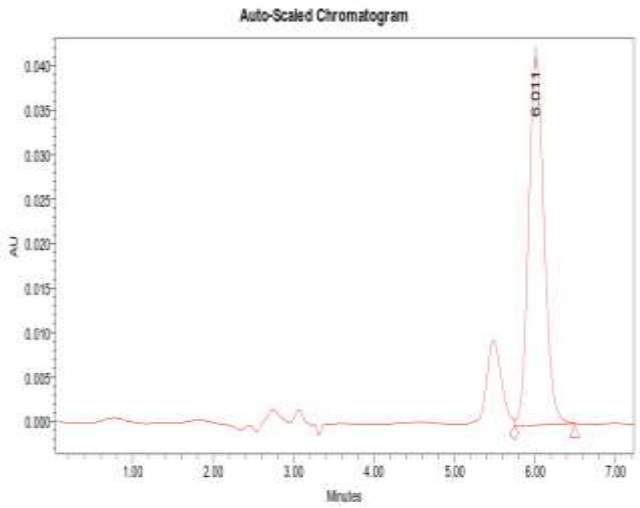

Figure: chromatogram for trail 1

Table: peak results for trail 1

S.No	Peak Name	R_t	Area	Height	USP Tailing	USP Plate count
1	Indinavir	6.011	553927	41393	1.6	849

Observation.
From the above trail it was observed that it shows less platecount and improper baseline in the chromatogram. So go for further trails to get good peak.

Trail 2.

Column : ODS C18 (4.6×250mm) 5µ
Column temperature : 30°C
Wavelength : 220nm
Mobile phase ratio : Methanol: water (15:85%) V/V
Flow rate : 0.8ml/min
Injection volume : 20µl
Run time : 8minutes

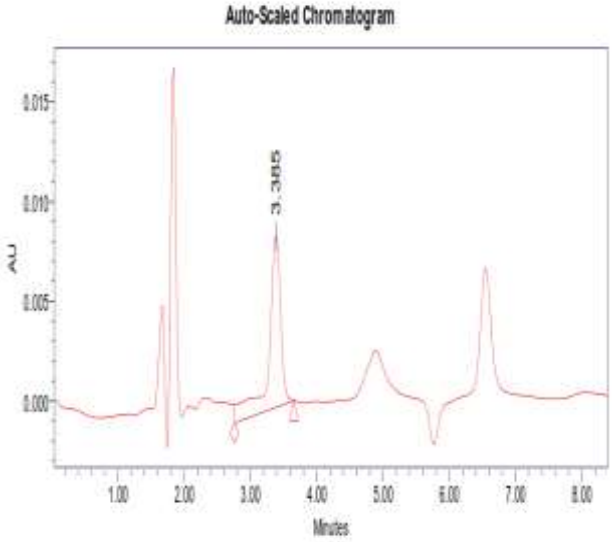

Figure: chromatogram for trail 2

Table: peak results for trail 2

S. No	Peak name	R_t	Area	Height	USP Tailing	USP plate count
1	Indinavir	3.385	110280	8642		2800

Observation.
From the above trail it was observed that it shows improper baseline and peak elution, tailing in the chromatogram. So more trails required to get good chromatogram.

Trail 3.

Column : XBridge C18 (4.6×150mm) 5µ
Column temperature : 35ºC
Wavelength : 220nm
Mobile phase ratio : Methanol: water (40:60%) V/V
Flow rate : 0.9ml/min
Injection volume : 10µl
Run time : 6minutes

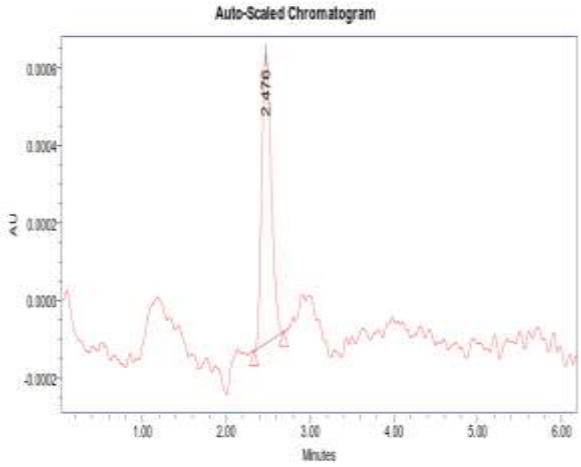

Figure- chromatogram for trail 3

Table: - peak results for trail 3

S. No	Peak name	R_t	Area	Height	USP Tailing	USP plate count
1	Indinavir	2.476	5909	753	1.2	2213

Observation.
In this above trail it shows improper baseline and peak shape in the chromatogram. Its required further trail to get proper chromatogram.

Trail 4: Optimized Chromatogram (Standard).

Mobile phase ratio : Methanol: water (50:50% v/v)
Column : Apollo C18 (4.6×150mm) 5µ
Column temperature : 35ºC
Wavelength : 220nm
Flow rate : 1.0ml/min
Injection volume : 10µl
Run time : 5minutes

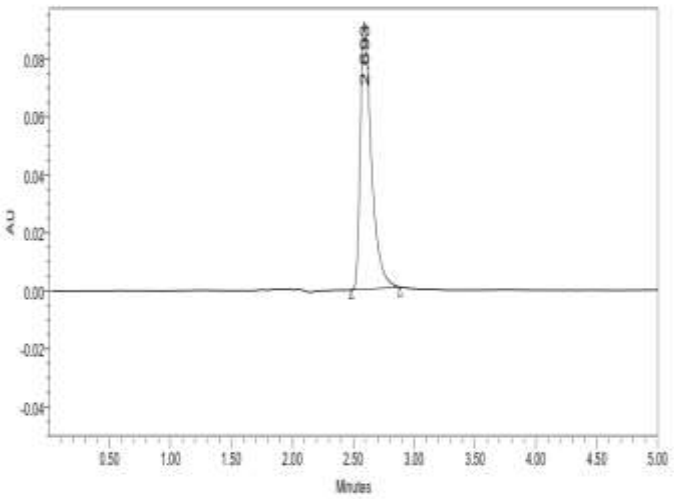

Figure: Optimized Chromatogram (Standard)

Table: Optimized Chromatogram (Standard)

S.No	Name	RT	Area	Height	USP Tailing	USP Plate Count
1	Indinavir	2.693	631521	92254	1.12	9544

Observation: In this trail it shows well peak shape and proper plate count and tailing under limit in the chromatogram. So it's optimized chromatogram.

Optimized Chromatogram (Sample)

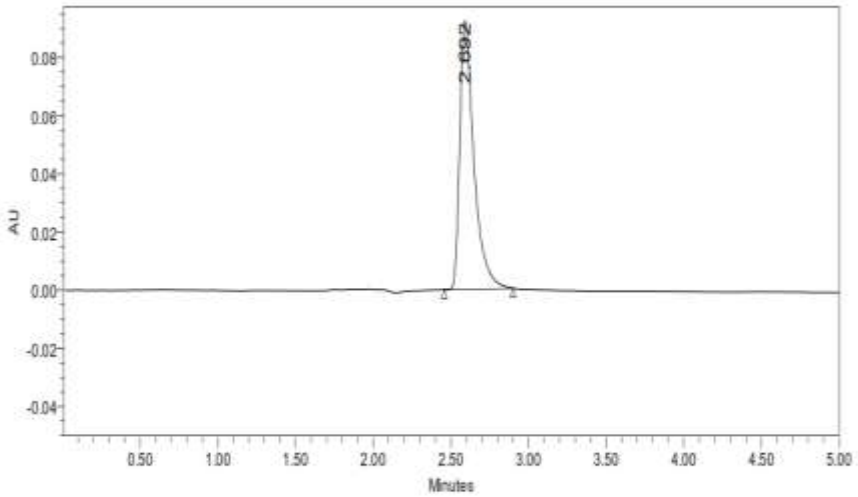

Figure: Optimized Chromatogram (Sample)

Table: Optimized Chromatogram (Sample)

S.No	Name	RT	Area	Height	USP Tailing	USP Plate Count
1	Indinavir	2.692	631644	92264	1.12	9573

Acceptance criteria.

- Theoretical plates must be not less than 2000
- Tailing factor must be not less than 2.
- It was found from above data that all the system suitability parameters for developed method were within the limit.

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