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NEW ANALYTICAL METHOD DEVELOPMENT FOR SAROGLITAZAR 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 drug 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: Saroglitazar, HPLC, Validation.

INSTRUMENTS USED

S.No	Instruments And Glasswares	Model
1	HPLC	WATERS, software: Empower 2, Alliance 2695 separation module. 996 PDA detector.
2	pH meter	Lab India
3	Weighing machine	Sartorius
4	Volumetric flasks	Borosil
5	Pipettes and Burettes	Borosil
6	Beakers	Borosil
7	Digital ultra sonicator	Labman

CHEMICALS USED

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

HPLC METHOD DEVELOPMENT

Trail 1:

Column : Symmetry C18 (4.6×250mm)5µ

Column temperature : Ambient

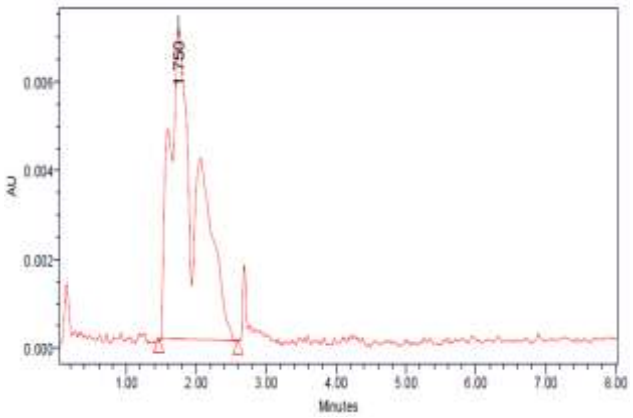
Wavelength : 293nm

Mobile phase ratio : Methanol: Water (10:90%)V/V

Flow rate : 1ml/min

Injection volume : 10µl

Run time : 8min



chromatogram for trail 1.

Trail 1.

S.No	Peak Name	R_t	Area	Height	USP Tailing	USP Plate count
1	Saroglitazar	1.750	192439	7072	2.95	167

OBSERVATION

In this trial it shows less plate count and more tailing and improper separation of peak in the chromatogram. So it requires more trials to obtain good peaks.

Trail 2.

Column : Xterra C18 (4.6×250mm)5µ

Column temperature : 30°C

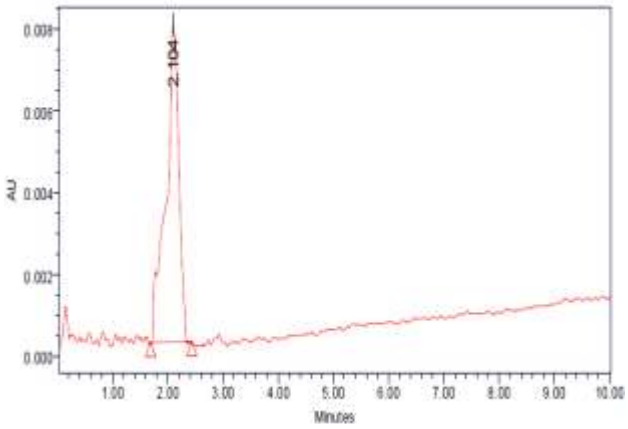
Wavelength : 293nm

Mobile phase ratio : Methanol:Water (20:80%)V/V

Flow rate : 1ml/min

Injection volume : 10µl

Run time : 10min



chromatogram for trail 2.

Trail 2.

S. No	Peak name	R_t	Area	Height	USP Tailing	USP plate count
1	Saroglitazar	2.104	126768	7767	2.79	634

OBSERVATION

In this trial it shows less plate count, more plate count and improper separation of peak in the chromatogram. So it requires more trials to obtain good peaks.

Trail 3.

Column : Inertsil C18 (4.6×250mm)5µ

Column temperature : 30ºC

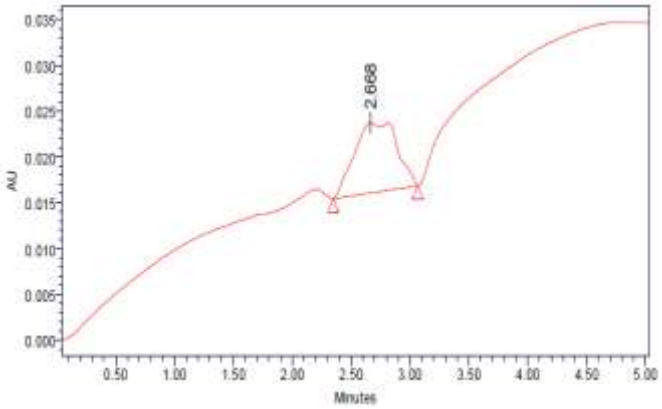
Wavelength : 293nm

Mobile phase ratio : Methanol: Water (30:70%)V/V

Flow rate : 1ml/min

Injection volume : 10µl

Run time : 5min



chromatogram for trail 3.

Trail 3.

S. No	Peak name	R_t	Area	Height	USP Tailing	USP plate count
1	Saroglitazar	2.668	191542	7635	2.14	335

OBSERVATION

In this trial it shows less plate count, more tailing effect and improper separation of peak in the chromatogram. So it requires more trials to obtain good peaks.

Trail 4.

Column : ODS C18 (4.6×250mm)5µ

Column temperature : 30ºC

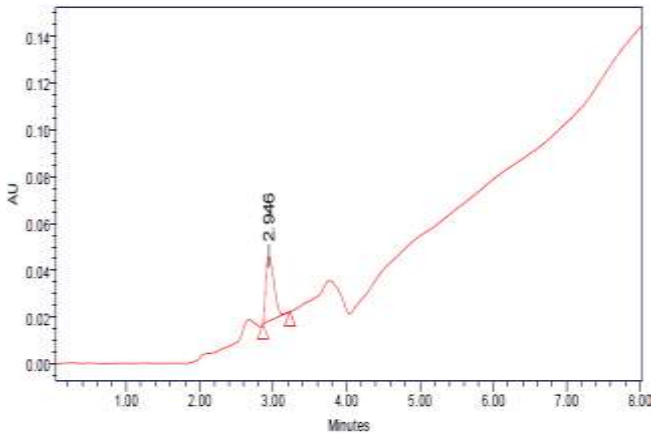
Wavelength : 293nm

Mobile phase ratio : Methanol: Water (40:60%)V/V

Flow rate : 1ml/min

Injection volume : 10µl

Run time : 8min



Trail 4.

S.No	Peak name	R_t	Area	Height	USP Tailing	USP plate count
1	Saroglitazar	2.946	210113	27694	1.31	1235

OBSERVATION

In this trial it shows less plate count and improper separation of peak in the chromatogram. So it requires more trials to obtain good peaks.

Optimized Chromatogram (Standard)

Mobile phase ratio : Methanol: Water (44:56%v/v)

Column : Sunfire C18 (4.6×250mm)5µ

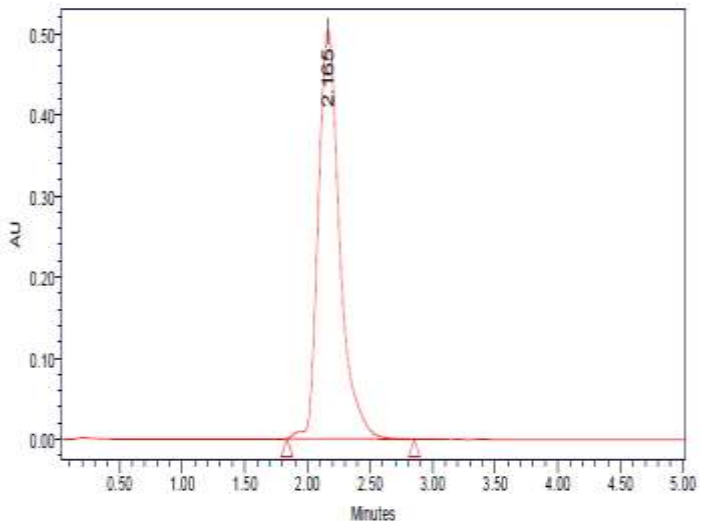
Column temperature : 40ºC

Wavelength : 293nm

Flow rate : 0.9ml/min

Injection volume : 10µl

Run time : 5min



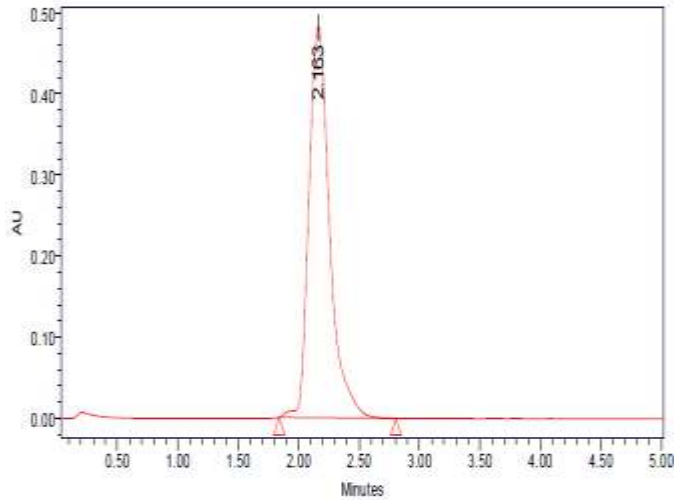
Table

S.no	Name	RT	Area	Height	USP Tailing	USP Plate Count
1	Saroglitazar	2.165	576012	505117	1.41	5846

OBSERVATION

In this chromatogram, the peak is well separated and theoretical plate count is within the limit. So, this chromatogram is optimized.

Optimized Chromatogram (Sample)



Table

S.No	Name	RT	Area	Height	USP Tailing	USP Plate Count
1	Saroglitazar	2.163	575224	483391	1.43	5839

Acceptance criteria

- Theoretical plates must be not less than 2000.
- Tailing factor must be not less than 0.9 and not more than 2.
- It was found from above data that all the system suitability parameters for developed method were within the limit.

REFERENCES

1. Sureshbabu Kapavarapu., Ramu Golkonda., Rambabu Chintala., (2015), Validated Stability Indicating Rp – Hplc Method Development For The Determination Of Saroglitazar In Bulk and Pharmaceutical Dosage Form, Indo American Journal of Pharmaceutical Research, 5(03): 1255-1264.
2. B. Siddartha., Dr. I. Sudheer Babu., (2014), Method Development and Validation for The Estimation Of Saroglitazar In Bulk And Pharmaceutical Dosage Form By Rp-Hplc, World Journal Of Pharmacy and Pharmaceutical Sciences, 3(9): 567-575.
3. Ekta H. Amin., Dr. Dilip G., Maheshwari., (2014), Development and Validation of UV Spectrophotometric Method for Saroglitazar Tablets, Journal Of Pharmaceutical Science And Bioscientific Research, 4(5): 312-315.