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Original Article

Development and Validation of Tofacitinib Citrate in API and Tablet Formulation by UV Spectroscopic and HPTLC Method

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ABSTRACT

Introduction: In the present study, quantification of tofacitinib citrate by UV spectroscopy and HPTLC method were done and validated as per ICH guidelines. Tofacitinib was approved in 2012, it was first JAK inhibitor for the treatment of moderate to severe rheumatoid arthritis. In the UV spectroscopic method tofacitinib citrate was quantified at 287 nm using methanol as a diluent. In HPTLC method, toluene: methanol: acetic acid (7.5:2:0.5% v/v/v) were used as a mobile phase and an HPTLC silica gel 60 F_{254} precoated plate was used as stationary phase. **Materials and Methods:** Double beam UV spectrophotometer UV-1800 shimadzu along with a pair of quartz cells 10 mm and for HPTLC camag TLC scanner 4 with linomat 5 equipped with visionCATS (version 3.2.23095.1) were used. API of tofacitinib citrate was procured from Hetero Healthcare, Hyderabad. Methanol was used as diluent. **Results:** Tofacitinib citrate was quantified by densitometric as absorbance mode at 287 nm and the chromatogram was obtained at the R_f value of 0.428±0.051. The linearity was assessed using UV and HPTLC methods at the concentration range of 1-5 µg/mL and 100-500 ng/spot respectively; with correlation coefficient (r^2) 0.9993 and 0.9906 respectively. The percent recoveries for UV and HPTLC method were calculated as 100.41-100.72% and 99.86-101.3% respectively. The limit of detection and limit of quantitation for UV method was found to be 0.1649 µg/mL and 0.4998 µg/mL respectively and for HPTLC method 58.66 ng/spot and 177.76 ng/spot respectively. The percent purity of tofacitinib citrate was found to be 98.66-101.60% 100.22% for UV and 98.03-100.74% 99.42% for HPTLC method. **Conclusion:** The accuracy, percent recovery and percent purity calculated from both the methods were best compared to other available methods. HPTLC method is more sensitive as its detection limit very less than UV method.

Keywords: UV spectroscopy, HPTLC method, Tofacitinib citrate, Tablet formulation.

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INTRODUCTION

The United States Food and Drug Administration (USFDA) approved tofacitinib in November 2012 for the treatment of moderate to severe rheumatoid arthritis and the first oral small molecule known as Janus Kinase Inhibitor (JAK) which is inhibitor of intracellular tyrosine kinase.[1] Rheumatoid arthritis is a long-term autoimmune disorder which can lead to permanently damaged the joint.[2] In 2017, Pfizer approved the tofacitinib for psoriatic arthritis patients who didn't responds well to other medicine and in 2018 it is used in ulcerative colitis.[3] And recently in 2021, Tofacitinib receives approval to treat patients with ankylosing spondylitis who cannot tolerate or responds to Tumor Necrosis Factor (TNF) inhibitors. JAK1, JAK2, JAK3 and TyK2 are four members of JAK family; in kinase assay tofacitinib inhibits the JAK1 and JAK3 majorly, and JAK2 and TyK2 to the lesser extent.[4] The dose of tofacitinib is 5 mg twice a day and it also modulates the T-cell activation, synovitis and structural joint damage.[5]

Chemically tofacitinib citrate is 3-[(3R,4R)-4-methyl-3-[methyl(7H-pyrrolo[2,3-d] pyrimidin-4-yl)amino]piperidin-1-yl]-3-oxopropanenitrile 2-hydroxypropane- 1,2,3-tricarboxylate having molecular formula $C_{22}H_{28}N_6O_8$ and molecular weight 504.5 g/mol.[6] The structure of tofacitinib citrate showed in Figure 1.

From the literature survey, it revealed that the quantification of tofacitinib citrate in bulk and dosage form by RP-HPLC method,[5,7-13] stability studies by hplc,[14-16] determination of

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tofacitinib citrate cleaning residue in tofacitinib tablet,[17] quantitation of tofacitinib citrate by UV spectroscopic method,[18,19] method development by HPTLC method,[20] and UPLC-MS/MS assay for the quantification of tofacitinib in human plasma.[21]

As far as we know, it was worth exploring the alternative method like HPTLC which is simple, accurate, reproducible and sensitive. The aim of present research is to develop a sensitive method which can detect the tofacitinib citrate to a lesser extent by HPTLC method.

MATERIALS AND METHODS

Instrumentation

UV spectral measurements were recorded on a double beam UV spectrophotometer UV-1800 shimadzu along with a pair of quartz cells 10 mm. For HPTLC camag TLC scanner 4 with linomat 5 equipped with visionCATS (version 3.2.23095.1) were used. Slit dimension 5×0.2 mm, scanning speed 20 mm/s, radiation source-deuterium lamp, absorbance mode as scanning mode used during the operation. Precoated aluminium plates (silica gel 60 F_{254}, merck), TLC-hamilton glass syringe having capacity 100 µL, linomat 5 used as applicator and a twin-trough chamber for development. The chromatogram and data integrated peak area as output. Digital analytical balance Shimadzu ATX224 used for weighing purpose and ultrasonic bath PCi analytics used for sonication.

Materials

API of tofacitinib citrate was procured from Hetero Healthcare, Hyderabad. The marketed tablets of Jaknat (Tofacitinib tablets 5 mg)- each film-coated tablet contains tofacitinib citrate 8.08 mg equivalent to tofacitinib 5 mg (manufactured by MSN laboratories Pvt. Ltd.,) purchased from local market. Methanol, toluene, acetic acid and water for HPLC were HPLC grade, which is purchased from Sisco research laboratories, Mumbai, India. Methanol was used as diluent for preparation of standard and sample.

Method of preparation of standard and sample solution

Standard solution preparation

Accurately weighed 50 mg of tofacitinib citrate and transferred into a 50 mL of volumetric flask and the volume was adjusted with methanol to achieve 1000 µg/mL (stock solution). The stock solution was filtered thoroughly. The prepared stock solution was stable in the refrigerator for 15 days. Pipette out 1 mL of stock solution and transfer it into the 10 mL volumetric flask and bring the volume up to the mark with methanol to get 100 µg/mL solution. Further 1 mL of above solution in 10 mL volumetric flask and volume was made with methanol to get 10 µg/mL solution.

Sample solution Preparation

Approximately 20 tablets were weighed, and average weight was calculated for each tablet. A powder containing 5 mg of tofacitinib citrate was weighed and poured into a 25 mL volumetric flask and added 20 mL of methanol in it, sonicate the flask for 45 min. Volume was adjusted up to the mark to get (200 µg/mL) of sample solution then the solution was filtered through the Whatman filter paper no.41. Withdraw 5 mL of the above solution and transfer it to the 10 mL volumetric flask and adjust the volume with methanol to achieve 100 µg/mL concentration. Further withdraw 1 mL of above solution in 10 mL volumetric flask and adjust the volume with methanol to get 10 µg/mL solution.

RESULTS

Method development and optimization

UV method: Optimization of solvents for maximum absorbance (λ_{max})

The standard solution of tofacitinib citrate was scanned in the region of 200-400 nm. An absorption maximum was found to be 287 nm, which was selected further for analysis. Different solvents like water, methanol and co-solvent (methanol and water) are used to check the absorbance at same wavelength. Methanol showed more absorbance compared to water and co-solvent. So, we chose methanol as a solvent and the spectrum was recorded as shown in Figure 2 and the overlay spectrum 1-5 µg/mL was studied, further the spectrum was recorded.

HPTLC method

Mobile phase optimization for HPTLC

Some trials were tried on TLC plate for development of mobile phase of tofacitinib citrate using Toluene: Methanol: Acetic acid at the 7:3:0, 7.5:2.5:0 and 7.5:2:0.5. The mobile phase Toluene: Methanol (7:3 and 7.5:2.5) shows splitting. From the trials data, we select a mobile phase Toluene: Methanol: Acetic Acid (T:M:AA) (7.5:2:0.5% v/v/v) which shows significant spot of tofacitinib citrate on TLC plate. Mobile phase optimised was used for development and validation by HPTLC method.

The standard solution of tofacitinib citrate (100 µg/mL) from that 10 µL solution applied on precoated plate as band of 4 mm under a stream of nitrogen using Linomat 5. After application of band the plate was run in the saturated chamber (chamber saturation time 20 min) which contains mobile phase toluene: methanol: acetic acid (7.5:2:0.5% v/v/v) and plate was run up to 80% distance of plate. The work was performed at a temperature of 20-24°C and the densitometric scanning was recorded at 287 nm. The R_f value start at 0.383 and end at 0.461 and maximum at 0.431. The chromatogram obtained was symmetrical and sharp. The chromatogram of tofacitinib citrate was showed in Figure 3. 3D overlay densitogram of standard tofacitinib citrate and samples

for different concentrations were studied and UV spectrum was studied using visionCATS software for chromatogram.

Method Validation

Linearity

From the standard solution of tofacitinib citrate (100 µg/mL) serially transferred 0.1, 0.2, 0.3, 0.4 and 0.5 mL of solution into a 10 mL volumetric flask and the volume was adjusted with methanol to achieve a different concentrations i.e., 1, 2, 3, 4, and 5 µg/mL respectively and the absorbance of different solution was measured at 287 nm in UV spectrophotometer. For HPTLC, from standard solution (100 µg/mL) pipette out 1, 2, 3, 4 and 5 mL and poured into 10 mL volumetric flask to achieve a concentration of 10, 20, 30, 40 and 50 µg/mL solution respectively. From this solution 10 µL of solution was applied as band on precoated plate then R_f value and area were calculated. The calibration curve data showed in Table 1 and calibration plots in Figures 4 and 5 for UV and HPTLC respectively are depicted below.[22]

Accuracy

Accuracy was performed by standard additional methods, i.e., at 50%, 100% and 150% by spiking a standard solution in a sample solution. Same quantity of sample solution with different quantities of standard solution for UV method and HPTLC method at 50, 100 and 150% level in a triplicate. Absorbance and area were recorded in UV and HPTLC method respectively. % recovery was calculated from the following data shown in Table 2.

Precision

Precision was made about whether the proposed method was precised or not. Intraday and interday assessments were done by UV as well as HPTLC method. Six standard solutions of tofacitinb citrate standard solutions were analyzed. In intraday study, readings at 0 hr of six samples were recorded and the same samples after 6 hr were run then absorbance, area were recorded in UV and HPTLC respectively. In interday precision, six standard solutions of same concentration were taking absorbance and area on 2nd day and 3rd day for UV and HPTLC respectively. The results of precision are within the limit i.e. %RSD less than 2. The precision data of intraday and interday for UV and HPTLC are shown below (Table 3).

Robustness

In the study of robustness, minor but deliberate variations in method parameters were done and expressed as the % RSD. Six standard solutions of same concentration of tofacitinib citrate were used for the analysis. Small variations were performed in wavelength (±2 nm) for UV method. For HPTLC, variations in composition of mobile phase (±0.5 mL) and chamber saturation time (S.T.) (±5 min). S.T. was 15 min which gives the R_f value 0.431 but the area of chromatogram decreases and if the S.T. was 25 min, then R_f value 0.431 but the area of chromatogram increases and when mobile phase variations i.e. toluene: methanol: acetic acid (7:2.5:0.5) then the R_f value 0.497 and toluene: methanol: acetic acid (8:1.5:0.5) then the R_f value 0.379. The robust data are shown in Table 4.

Sensitivity

Sensitivity was determined whether the method is sensitive or not. Standard solution of tofacitinib citrate was measured for the absorbance and area of chromatogram in UV and HPTLC method respectively by regression method. Limit of Detection (LOD) and Limit of Quantitation (LOQ) were determined from the data by regression method. The limit of detection and limit of quantitation for UV method was found to be 0.1649 µg/mL and

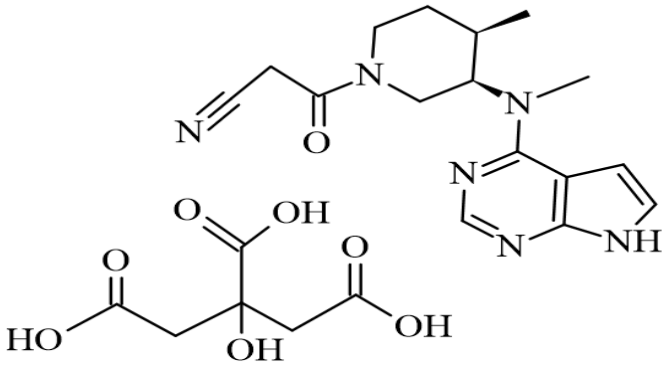

Figure 1: Structure of tofacitinib citrate.

Table 1: Calibration curve data of tofacitinib citrate by UV and HPTLC method.

UV method		HPTLC method	
Conc (µg/mL)	*Mean Absorbance	Conc (ng/spot)	*Mean Area
1	0.061	100	0.01409
2	0.121	200	0.01895
3	0.186	300	0.02237
4	0.239	400	0.02552
5	0.301	500	0.02865
r^2	0.9993	r^2	0.9906

*All the readings were taken in triplicates.

Table 2: Accuracy data of tofacitinib citrate by UV method and HPTLC method.

Level (%)	Expected amount (µg/mL)	UV method			HPTLC method			
		The actual amount found (µg/mL)	% Recovery	Mean	Expected amount (ng/spot)	The actual amount found (ng/spot)	% Recovery	Mean
50	6	5.9196	98.66	100.41	500	492	98.4	99.86
50	6	6.0396	100.66		500	496	99.2	
50	6	6.1158	101.93		500	510	102	
100	12	12.11	100.91	100.72	1000	1020	102	101.3
100	12	12.09	100.75		1000	1018	101.8	
100	12	12.06	100.5		1000	1001	100.1	
150	18	18.0198	100.11	100.57	1500	1518	101.2	100.93
150	18	18.36	102		1500	1497	99.8	
150	18	17.9298	99.61		1500	1527	101.8	

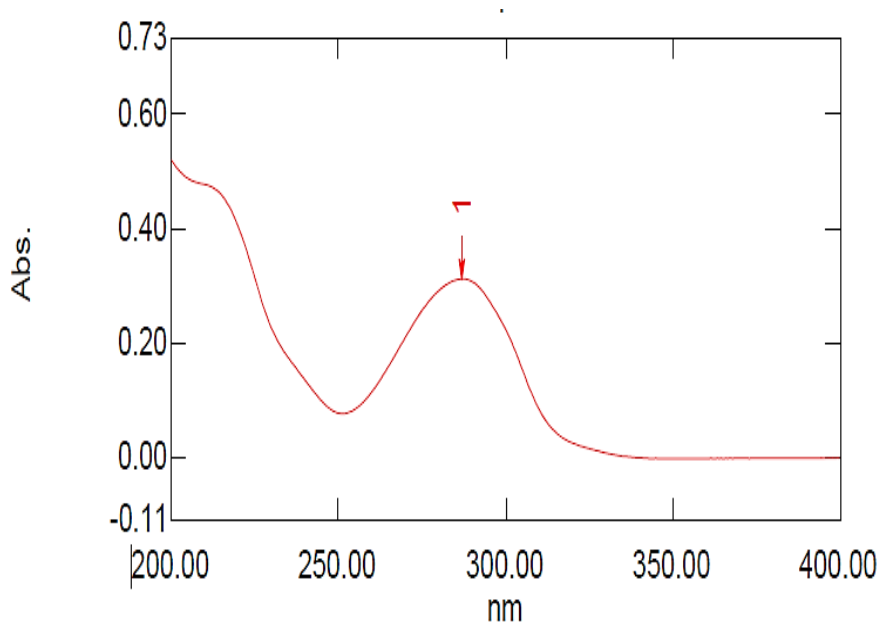

Figure 2: UV spectrum of tofacitinib citrate.

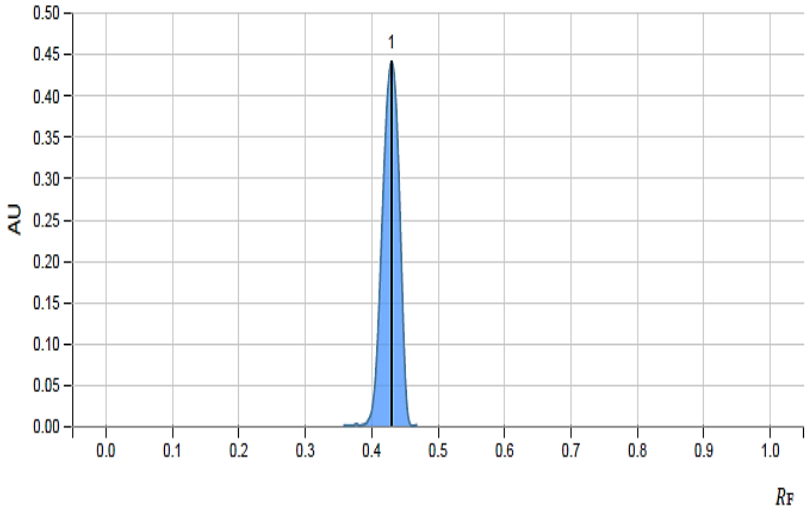

Figure 3: Chromatogram of tofacitinib citrate.

0.4998 µg/mL respectively and for HPTLC method 58.66 ng/spot and 177.76 ng/spot respectively

Assay

Analysis of tablet of tofacitinib citrate by UV and HPTLC method

Standard solution (3 µg/mL) and sample solution (3 µg/mL) of tofacitinib citrate measured the absorbance individually at 287 nm. And calculate the percent content present in tablet by using absorbance in UV method. In HPTLC method, the standard solution (200 µg/mL) and sample solution (200 µg/mL) of tofacitinib citrate employed 10 µL on precoated plate of HPTLC and measured the area and then calculated the percent content present in tablet. The percent purity of tofacitinib citrate was found to be 100.22% for UV and 99.42% for HPTLC method.

DISCUSSION

UV spectroscopic and HPTLC method were developed for quantification of tofacitinib citrate and validated according to ICH guidelines. In the UV spectroscopic method, tofacitinib citrate was quantified at 287 nm using methanol as a diluting solvent. In HPTLC method, the chromatogram was developed using mobile phase toluene: methanol: acetic acid (7.5:2:0.5% v/v/v) which is quantified at 287 nm as absorbance mode having R_f value 0.428±0.051. The linearity of tofacitinib citrate was 1-5 µg/mL for UV and 100-500 ng/spot for HPTLC method as depicted in Table 1. The limit of detection and limit of quantitation for UV method was found to be 0.1649 µg/mL and 0.4998 µg/mL respectively and for HPTLC method 58.66 ng/spot and 177.76 ng/spot respectively. The percent purity of tofacitinib citrate was found to be 98.66-101.60% 100.22% for UV and 98.03-100.74% 99.42% for HPTLC method. The percentage recoveries for UV

Table 3: Intraday and Interday precision data.

	Conc	Intraday study		Interday study	
		0 hr	6 hr	2nd day	3rd day
UV method (Abs)	3 µg/mL	0.186	0.188	0.186	0.212
		0.184	0.186	0.184	0.214
		0.183	0.186	0.183	0.208
		0.184	0.188	0.184	0.208
		0.178	0.188	0.178	0.212
		0.186	0.189	0.186	0.214
%RSD		1.6073	0.6531	1.6073	1.2929
HPTLC method (Area)	300 ng/spot	0.02287	0.02291	0.02329	0.02319
		0.02244	0.02253	0.02322	0.02325
		0.02261	0.02294	0.02321	0.02331
		0.02216	0.02248	0.02375	0.02325
		0.02239	0.02273	0.02335	0.02325
		0.02247	0.02253	0.02264	0.02264
%RSD		1.0542	0.8984	1.5343	1.0882

Table 4: Robustness data.

UV method (Abs)	Conc 3 µg/mL	Conc 3 µg/mL	Conc 3 µg/mL	Conc 3 µg/mL	Conc 3 µg/mL	Conc 3 µg/mL	%RSD
285 nm	0.184	0.186	0.187	0.181	0.178	0.184	1.8145
289 nm	0.183	0.185	0.189	0.184	0.182	0.186	1.3435
HPTLC method (Area)	Conc 300 ng/spot	Conc 300 ng/spot	Conc 300 ng/spot	Conc 300 ng/spot	Conc 300 ng/spot	Conc 300 ng/spot	%RSD
(T:M:AA% v/v/v) 7:2.5:0.5	0.02894	0.02818	0.02909	0.02840	0.02838	0.02851	1.2388
(T:M:AA% v/v/v) 8:1.5:0.5	0.02999	0.02909	0.02956	0.02951	0.02937	0.02988	1.1182
S.T-15 min	0.02338	0.02309	0.02366	0.02318	0.02317	0.02396	1.4534
S.T-25 min	0.02683	0.02661	0.02635	0.02603	0.02713	0.02603	1.6726

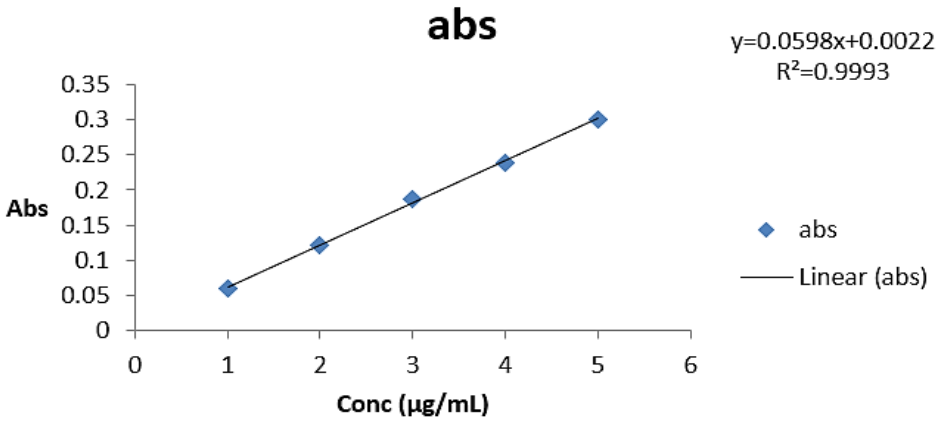

Figure 4: Calibration plot of tofacitinib citrate by UV method.

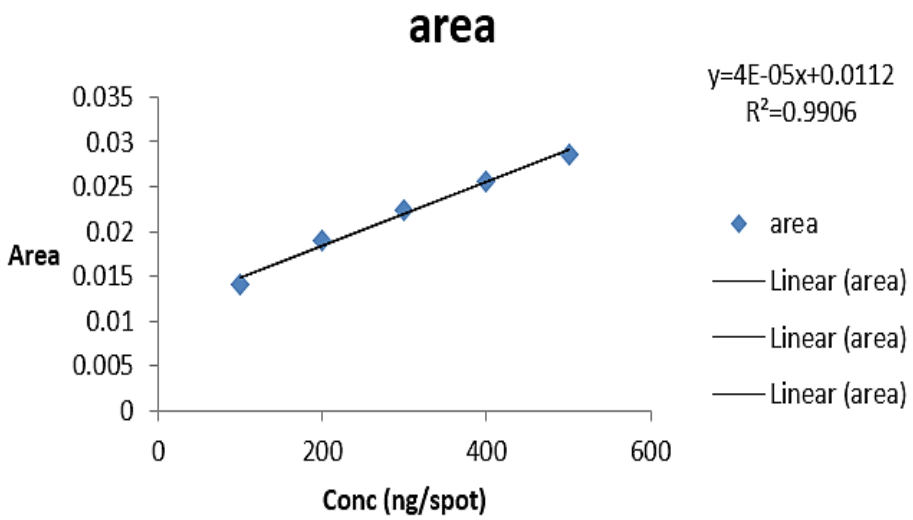

Figure 5: Calibration plot of tofacitinib citrate by HPTLC method.

and HPTLC method were calculated as per ICH guidelines which found 100.41-100.72% and 99.86-101.3% respectively as shown in Table 2 and percentage Relative Standard Deviation (%RSD) less than 2% showing that the methods were precise, robust and accurate. The inference from the study, the UV method can be implemented in laboratories which lacks high technical analytical instruments and does not require a skilled person. And in HPTLC method the detection limit was very low so we can use this sensitive method for detection of very low concentration. HPTLC requires only 20 mL of mobile phase which is less and requires an average of 45 min which is less as compared to HPLC method. Both methods were eco-friendly in nature.

CONCLUSION

The proposed UV spectroscopic and HPTLC methods for quantification of tofacitinib citrate in API as well as in tablet formulation were linear having a concentration range of 1-5 µg/mL. The sensitivity, accuracy, percent recovery and percent purity calculated from both the methods were best compared to other available methods. UV and HPTLC methods are method of choice which is cheapest, less time consuming as compared to HPLC and UPLC method which is expensive and time-consuming. In the current research work requires less solvent thus it is promising the cost-efficiency of the present method, also the total analysis time is less hence rapid analysis of a greater number of samples could be done. Both methods can be implemented in laboratories. This simple procedure is an alternative to other reported methods. The proposed methods are free from interference due to excipients in tablets and thus could be used for regular quantification of tofacitinib citrate in tablets. Also, the current research work provides an alternative method where toluene is used which is good solvent.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

UV: Ultraviolet; **HPTLC:** High performance thin layer chromatography; **JAK:** Janus kinase inhibitor; **ICH:** International conference on harmonization; **R_f:** Retention factor; **%RSD:** Percent relative standard deviation; **T:M:AA:** Toluene:Methanol:Acetic acid; **S.T.:** Saturation time; **API:** Active pharmaceutical ingredient; **RP-HPLC:** Reverse Phase-High performance liquid chromatography; **UPLC:** Ultra performance liquid chromatography; **LOD:** Limit of detection; **LOQ:** Limit of quantitation.

SUMMARY

The chromatogram obtained by HPTLC method was sharp and symmetrical in the mobile phase ratio toluene: methanol: acetic acid (7.5:2:0.5% v/v/v) and it shows the R_f value 0.428±0.051. Tofacitinib citrate was quantified by UV method at 287 nm using methanol as a solvent which shows better results. A percent recovery by UV and HPTLC method was found in an acceptable range as per ICH guidelines (98-102%) which shows the methods were accurate and % RSD less than 2% shows the method was precise and robust. Both the UV and HPTLC methods are cost effective, less time-consuming compare to other.

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