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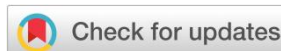
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Research Article

Development And Validation of UV-Spectrophotometric Method for Determination of Upadacitinib Bulk and in Tablet Dosage Form

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Abstract

Upadacitinib is a selective Janus kinase-1 (JAK1) inhibitor widely used in the treatment of autoimmune disorders such as rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, atopic dermatitis, ulcerative colitis, and Crohn's disease. Owing to its therapeutic significance, the development of a simple, accurate, and reliable analytical method for its quantitative estimation is essential for routine quality control. The present study was undertaken to develop and validate a UV-visible spectrophotometric method for the determination of Upadacitinib in bulk drug and tablet dosage form. Methanol was selected as the solvent for the preparation of standard and sample solutions. The absorption spectrum of Upadacitinib was recorded in the ultraviolet region, and the wavelength corresponding to maximum absorbance (λ_{max}) was selected for quantitative analysis. The developed method obeyed Beer-Lambert's law over the concentration range of 2-12 $\mu\text{g/mL}$, exhibiting excellent linearity with a correlation coefficient (R^2) greater than 0.999. The proposed analytical method was validated according to the International Council for Harmonisation (ICH Q2(R2)) guidelines with respect to linearity, accuracy, precision, specificity, robustness, limit of detection (LOD), and limit of quantitation (LOQ). The percentage recovery obtained from accuracy studies was within the acceptable range of 98-102%, while the percentage relative standard deviation (%RSD) for precision studies was found to be less than 2%, indicating good reproducibility and precision. The developed method was successfully applied to the assay of commercial tablet formulations without interference from formulation excipients. The results demonstrated that the proposed UV spectrophotometric method is simple, sensitive, rapid, economical, and suitable for the routine quantitative estimation and quality control analysis of Upadacitinib in bulk drug and pharmaceutical tablet dosage forms.

Keywords: Upadacitinib, UV Spectrophotometry, Method Development, Method Validation, Tablet Dosage Form.

INTRODUCTION

Pharmaceutical analysis is an important branch of pharmaceutical sciences that deals with the identification, characterization, purity testing, and quantitative estimation of drugs and pharmaceutical formulations. It plays a vital role in ensuring that pharmaceutical products meet the required standards of quality, safety, efficacy, and stability before they are released for clinical use¹. The increasing demand for high-quality medicines has led to the development of accurate, precise, and reliable analytical techniques for the analysis of pharmaceutical compounds. Analytical methods are essential during drug discovery, formulation development, manufacturing, quality control, and stability testing. Therefore, the development and validation of suitable analytical methods are indispensable components of pharmaceutical research and industrial quality assurance².

Several analytical techniques are available for the quantitative estimation of drugs, including ultraviolet-

visible (UV-Visible) spectrophotometry, high-performance liquid chromatography (HPLC), high-performance thin-layer chromatography (HPTLC), gas chromatography (GC), infrared (IR) spectroscopy, and mass spectrometry (MS). Among these techniques, UV-visible spectrophotometry is one of the most widely employed methods in pharmaceutical analysis because of its simplicity, rapidity, accuracy, cost-effectiveness, and ease of operation³. It requires minimal sample preparation and relatively inexpensive instrumentation compared to chromatographic methods, making it highly suitable for routine quality control laboratories⁴.

UV-visible spectrophotometry is based on the principle that molecules containing chromophoric groups absorb ultraviolet or visible radiation at specific wavelengths, resulting in electronic transitions from lower to higher energy states. The amount of radiation absorbed by a solution is directly proportional to the concentration of the absorbing species, according to Beer-Lambert's law. This relationship enables the quantitative determination of pharmaceutical compounds with high accuracy and precision. The technique is widely applied

for assay, dissolution studies, impurity estimation, stability studies, and routine quality control of pharmaceutical formulations⁵.

Method development is a systematic process of selecting appropriate analytical conditions to obtain accurate, precise, sensitive, and reproducible results. The success of an analytical method depends upon several factors, including solvent selection, wavelength optimization, concentration range, sample preparation, and instrumental parameters. A properly developed analytical method should provide consistent results while minimizing analytical errors. Once developed, the method must be validated to demonstrate its suitability for the intended analytical purpose. Analytical method validation is a documented process that confirms that an analytical procedure consistently produces reliable and reproducible results. The International Council for Harmonisation (ICH) has established guidelines for analytical method validation to ensure uniformity and scientific reliability. According to ICH Q2(R2) guidelines, validation parameters include specificity, linearity, accuracy, precision, range, robustness, limit of detection (LOD), limit of quantitation (LOQ), and system suitability. Validation ensures that the developed analytical method is capable of providing dependable results during routine pharmaceutical quality control and regulatory compliance⁶.

Upadacitinib is a selective and reversible Janus kinase-1 (JAK1) inhibitor belonging to the class of targeted synthetic disease-modifying antirheumatic drugs (tsDMARDs). It is marketed as an extended-release tablet and is indicated for the treatment of several chronic inflammatory and autoimmune disorders, including moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, atopic dermatitis, ulcerative colitis, and Crohn's disease. By selectively inhibiting JAK1-mediated intracellular signalling pathways, Upadacitinib suppresses the production of pro-inflammatory cytokines and reduces inflammatory responses, thereby improving clinical outcomes and quality of life in affected patients⁷.

Following oral administration, Upadacitinib is rapidly absorbed and exhibits good bioavailability. It is primarily metabolized in the liver by the cytochrome P450 enzyme CYP3A4 and is eliminated through both renal and fecal routes. The drug has demonstrated significant clinical efficacy and an acceptable safety profile in long-term treatment of autoimmune diseases. Due to its increasing therapeutic importance and widespread clinical use, accurate analytical methods are required for the estimation of Upadacitinib in bulk drug and pharmaceutical dosage forms to ensure product quality, dosage accuracy, and regulatory compliance⁸.

Although sophisticated chromatographic methods such as HPLC and LC-MS are available for the determination of Upadacitinib, these techniques require expensive instrumentation, skilled personnel, longer analysis time, and higher maintenance costs. In contrast, UV-visible spectrophotometry offers a rapid, economical, and convenient alternative for routine quantitative

analysis, particularly in academic institutions and quality control laboratories where advanced chromatographic instruments may not be readily available. Therefore, the development of a validated UV spectrophotometric method for Upadacitinib is of considerable practical importance⁹.

The present study focuses on the development and validation of a simple, accurate, precise, rapid, and economical UV-visible spectrophotometric method for the quantitative estimation of Upadacitinib in bulk drug and tablet dosage form. Methanol was selected as the solvent for the preparation of standard and sample solutions, and the absorption maximum (λ_{max}) of the drug was determined by scanning in the ultraviolet region. The analytical method was optimized and validated according to ICH Q2(R2) guidelines by evaluating important performance characteristics such as linearity, accuracy, precision, specificity, robustness, limit of detection, and limit of quantitation. Furthermore, the validated method was successfully applied to the assay of commercially available Upadacitinib tablets¹⁰.

The development of a reliable UV spectrophotometric method provides a valuable analytical tool for routine quality control, pharmaceutical research, and academic laboratories. The proposed method offers advantages such as simplicity, reduced analysis time, minimal solvent consumption, cost-effectiveness, and excellent analytical performance. Consequently, it can serve as a suitable alternative to more complex analytical techniques for the routine estimation of Upadacitinib in bulk drug and tablet dosage forms¹¹.

MATERIALS AND METHODS

Materials

Upadacitinib pure drug was obtained as a gift sample from a pharmaceutical manufacturer. Commercially available Upadacitinib tablets (15 mg) were procured from the local market for analysis. Methanol (AR grade) was used as the solvent throughout the study, while distilled water and other analytical grade reagents were used wherever required¹². The analytical work was carried out using a Shimadzu UV-Visible Double Beam Spectrophotometer with 1 cm quartz cells and a Shimadzu AUX-220 digital analytical balance. An ultrasonic bath and standard laboratory glassware were also used during the experimental work¹³.

Methods

A standard stock solution of Upadacitinib (100 $\mu\text{g/mL}$) was prepared by dissolving 10 mg of the drug in methanol and making up the volume to 100 mL. The solution was scanned in the wavelength range of 200-400 nm to determine the maximum absorption wavelength (λ_{max})¹⁴. Working standard solutions in the concentration range of 2-12 $\mu\text{g/mL}$ were prepared, and their absorbance was measured at λ_{max} to construct the calibration curve¹⁵. For tablet analysis, powdered tablets equivalent to 10 mg of Upadacitinib were extracted with methanol, filtered, suitably diluted, and analyzed at the selected wavelength. The

developed method was validated according to ICH Q2(R2) guidelines by evaluating linearity, accuracy, precision, specificity, robustness, limit of detection (LOD), and limit of quantitation (LOQ)¹⁶. Statistical parameters, including mean, standard deviation (SD), percentage relative standard deviation (%RSD), and correlation coefficient (R^2), were calculated to assess the performance of the method¹⁷.

RESULTS

Based on the validation result the proposed UV method is proven to be suitable as well as found to be simple, precise and accurate for the determination of upadacitinib in bulk and in pharmaceutical dosage form¹⁸.

From the solubility profile methanol and mono basic sodium phosphate buffer pH 4.4 (50:50) was used for the solvent. The spectrum was recorded at wavelength range at 262 nm¹⁹. Beer's law obeys the concentration range 3-27 µg/ml for upadacitinib. The calibration graph was plotted. The correlation values for the drug around found to be 0.999. The optical parameter was calculated²⁰.

Tablet formulation containing 15 mg of upadacitinib was selected for the analysis. The percentage of the drug in the formulation range was found to be 100.73% for upadacitinib. The accuracy of the method was confirmed by recovery studies²¹. To the pre analyzed formulation, the different amount of raw material was added. The number of drugs was calculated. The percentage recovery range was found to be from 99.2 to 101.6% for upadacitinib.

Hence it is suggested the proposed UV spectroscopy method can be effectively applied for the routine analysis of upadacitinib in tablet formulation²².

Table 1: Linearity Concentration

Concentration (µg/ml)	Absorbance
3	0.085
9	0.256
15	0.432
21	0.632
27	0.815

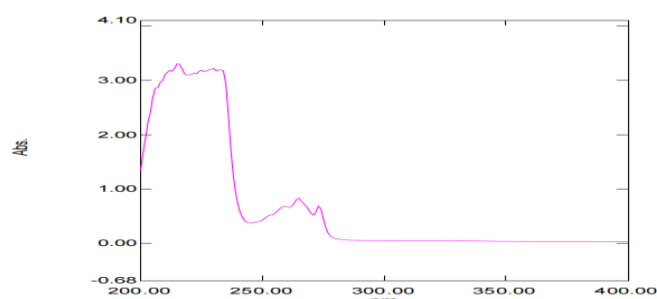


Figure 1: UV Spectrum of Upadacitinib (27 µG/ML)

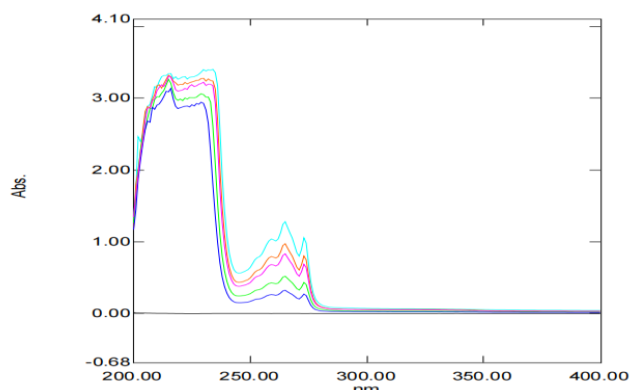


Figure 2: Overlay Spectrum of Upadacitinib

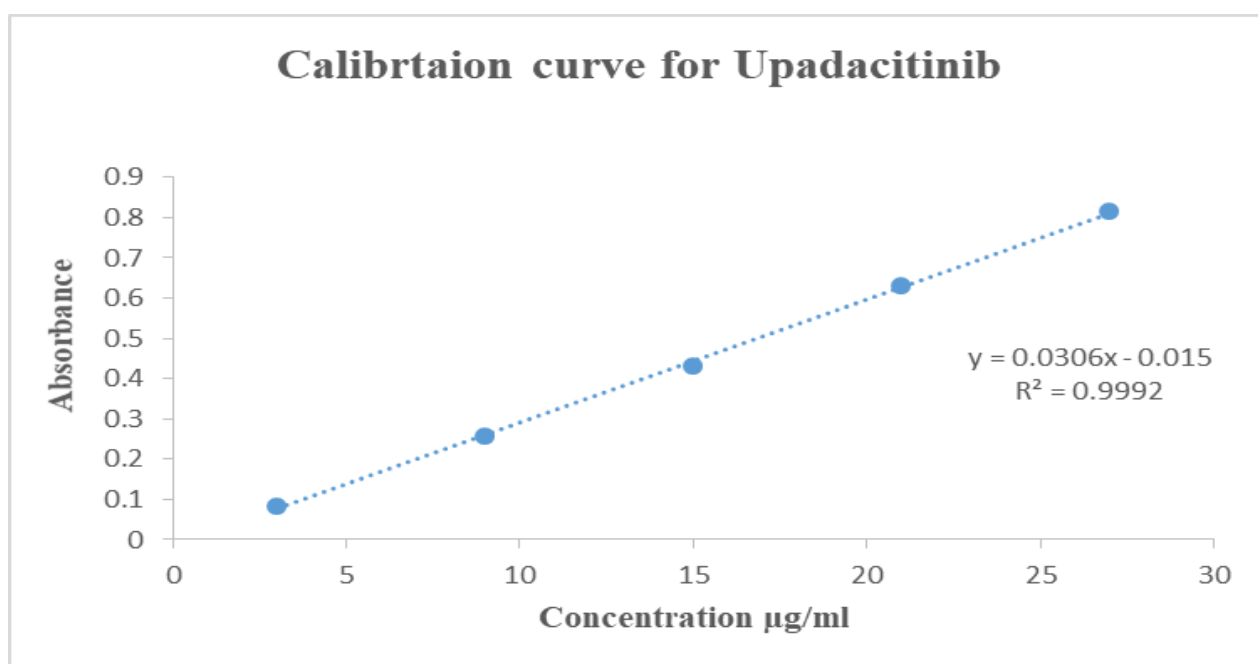


Figure 3: Calibration Curve for Upadacitinib

Table 2: Optical Characteristics of Upadacitinib

Beer's law limit	3-27 µg/ml
Correlation coefficient	0.9992
Regression equation	$Y = 0.0306X + 0.015$
Slope (m)	0.0306
Intercept (c)	0.015
LOD (µg/ml)	0.9422
LOQ (µg/ml)	2.8551

Table 3: Precision Data for Upadacitinib

Sl.No	Concentration of standard (µg/ml)	Amount found (µg/ml)	Percentage (%)	Average (%)	SD	% RSD
1	15.0	15.10	100.66	-	-	-
2	15.0	15.12	100.80	-	-	-
3	15.0	14.95	99.66	100.15	0.6378	0.6368
4	15.0	15.05	100.33	-	-	-
5	15.0	14.90	99.33	-	-	-

Table 4: Quantification Of Tablet Formulation

Drug name	%	Amount present (µg/ml)	Amount Added (µg/ml)	Amount Found (µg/ml)	Amount Recovered	% Recovery	Average	SD	% RSD
Upadacitinib	50	15.00	7.50	22.50	7.48	99.73	99.88	0.7715	0.7724
	75	15.00	11.25	26.25	11.16	99.20			
	100	15.00	15.07	30.07	15.18	100.72			

Table 5: Recovery Study of Pre-Analyzed Formulation

Drug name	%	Amount present (µg/ml)	Amount Added (µg/ml)	Amount Found (µg/ml)	Amount Recovered	% Recovery	Average	SD	% RSD
Upadacitinib	50	15.00	7.50	22.50	7.48	99.73	99.88	0.7715	0.7724
	75	15.00	11.25	26.25	11.16	99.20			
	100	15.00	15.07	30.07	15.18	100.72			

CONCLUSION

A simple, precise and accurate estimation method was developed and validated for upadacitinib in bulk and pharmaceutical tablet dosage form. The solubility of the drug in various polar and non-polar solvent checked as per USP guidelines. The drug was exhibited different solubility character, from the solubility data,

the solvent was found to be methanol and buffer (50:50 dibasic sodium phosphate buffer pH 4.4). Hence, the methanol and buffer (50:50 dibasic sodium phosphate buffer pH 4.4) was selected as solvent and it was used for the preparation of stock solution.

15 µg/ml concentration solutions of upadacitinib were prepared and the spectrum was recorded. 262 nm

wavelengths by observing the spectral character of upadacitinib. The stability of upadacitinib was checked at the selective wavelength. It was found that was stable for 1 hour 45 minutes.

Various aliquots of upadacitinib were prepared in the concentration range from 3-27 µg/ml. The absorbance of these solutions was measured at the selected wavelength (262 nm). The calibration curve was constructed using concentration versus absorbance. The optical parameter like correlation co-efficient, slope, intercept, LOD and LOQ were calculated. The correlation co-efficient value for drug was found to be 0.999. This indicated drug obeys beer's law in the selected concentration ranges. Hence, the concentration was found to be linear. The calibration curve for upadacitinib at 262 nm. The optical characteristic of the solution wavelength at 262 nm. The tablet formulation of upadacitinib (containing 15mg of upadacitinib) was selected for the analysis. The percentage purity of the drug in formulation range was found to be from 99.40 % to 101.8 % for upadacitinib.

The accuracy of the method was confirmed by recovery studies. To the pre-analysed formulation, a known quantity of raw material was added 50 %, 75 %, and 100 % for upadacitinib. The percentage recovery was found to be in the range from 99.2 to 100.72 %. The percentage RSD value was found to be 0.7724.

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