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UV-Spectrophotometric Method for Determination of Imeglimin Hydrochloride in Tablets

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Abstract: A UV spectroscopic method was developed and validated for the estimation of Imeglimin Hydrochloride in tablet dosage forms. methanol and water (50:50 v/v) was used as the solvent, and the absorbance was measured at 241 nm. The method was validated according to ICH guidelines and showed excellent linearity in the concentration range of 0.5–9.5 µg/mL, with a correlation coefficient of 0.9977. It demonstrated good precision, reflected by RSD values below 2%, and offered adequate sensitivity, with LOD and LOQ determined as 0.0809 µg/mL and 0.2451µg/mL, respectively. Recovery studies indicated satisfactory accuracy where percentage recoveries ranges between about 100.36%-101.25% w/w indicate good method accuracy and confirmed that no significant interferences were present. Overall, the validated UV spectrophotometric method proved to be accurate, precise, and sensitive. Its low cost, simplicity, and minimal maintenance requirements make it particularly advantageous for small-scale pharmaceutical industries where both time and economic efficiency are essential for quality control and ensuring therapeutic efficacy.

Keywords: UV Spectroscopy, ICH guidelines, Imeglimin HCl,

1. INTRODUCTION

Type 2 diabetes is the most common form of diabetes and is marked by elevated blood glucose levels. Unlike Type 1 diabetes, individuals with Type 2 diabetes still produce insulin, but either in insufficient amounts or their cells do not respond effectively—a condition known as insulin resistance. It primarily affects middle-aged and older adults, with obesity being the strongest risk factor, though rising childhood obesity has increased cases in younger individuals.

Imeglimin Hydrochloride, approved by CDSCO on January 6, 2023, is an antidiabetic drug used to manage Type 2 diabetes. It lowers blood sugar by enhancing glucose-dependent insulin secretion and is prescribed along with diet and exercise. Imeglimin Hydrochloride, marketed under the brand name IMEXTOR 500, has the IUPAC name (R)-N², N²,6-trimethyl-3,6-dihydro- 1,3,5-triazine-2,4-diamine hydrochloride. It has a molecular formula $C_6H_{14}ClN_5$ and a molecular weight of 155.20 g/mol. The drug appears as a white amorphous powder and is soluble in ethanol, water, and dimethyl sulfoxide. Imeglimin acts through a dual mechanism, enhancing glucose-stimulated insulin secretion (GSIS) while helping preserve pancreatic β-cell mass, and simultaneously improving insulin action by potentially reducing hepatic glucose output and strengthening insulin signaling pathways in both the liver and skeletal muscle. This project focused on developing and validating a new UV spectrophotometric method, following ICH guidelines, for its determination in bulk and tablet formulations.

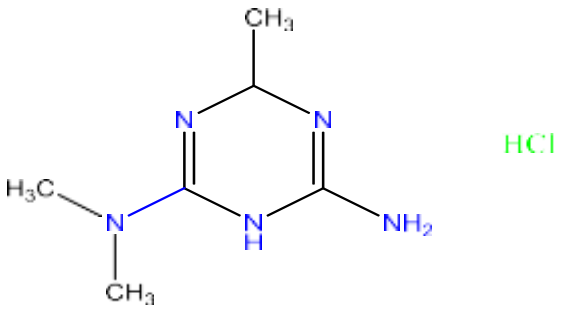

Fig 1: Structure of Imeglimin Hydrochloride

2. NEED OF THE STUDY.

The development of any analytical method requires scientific assurance that the results generated are reliable, accurate, and reproducible, as even minor variability in analytical measurements can significantly impact drug quality, safety, and regulatory compliance in the pharmaceutical industry. Imeglimin hydrochloride, an antidiabetic drug, currently lacks a simple, sensitive, and cost-effective UV-spectrophotometric method for routine estimation. Therefore, there is a need to develop a new UV-spectrophotometric method suitable for its quantification. To ensure the reliability of the developed method, validation using parameters such as linearity, accuracy, precision, specificity, robustness, limit of detection, and limit of quantification, as outlined in ICH guidelines, is essential. A fully validated method will ensure accurate and consistent estimation of Imeglimin hydrochloride in bulk and tablet formulations, thereby supporting quality control activities, ensuring dosage uniformity, and strengthening the overall quality assurance of pharmaceutical products.

RESEARCH METHODOLOGY

3.1 Preliminary analysis of Imeglimin hydrochloride

The drug Imeglimin hydrochloride is not official in any pharmacopeia, Preliminary analysis of Imeglimin hydrochloride was carried out under,

3.11 Description: The sample of Imeglimin hydrochloride was observed for its colour and its texture. It is amorphous powder (white in colour)

3.12 Solubility: The sample of Imeglimin hydrochloride was taken in test tube and observed for solubility in various solvents like water, methanol and dimethyl sulfoxide.

3.13 Identification Test: Light absorption: A 0.001%w/v solution of Imeglimin Hydrochloride was prepared and its absorbance was measured at 241nm.
Acceptance criteria: Absorbance not more than 0.48 at 241nm.

3.2 Methodology for development of UV-spectrophotometric method for Imeglimin hydrochloride

3.2.1 Instruments used:

The instruments used for the development of the UV-spectrophotometric method included an electronic weighing balance (Sartorius – TE214S) for accurate weighing of samples, an ultra sonicator (RC Systems – MU 1700) to ensure proper dissolution of the drug, and a UV-Visible spectrophotometer (Shimadzu – 1700, software version UV-Probe 2.34) for scanning and measuring the absorbance of Imeglimin hydrochloride.

3.2.2 Chemicals and reagents used:

The chemicals and reagents used in the development of the UV-spectrophotometric method included methanol (HPLC grade) and distilled water as solvents, along with Imeglimin hydrochloride standard for preparing calibration solutions, and Imeglimin hydrochloride tablets for analyzing the formulated dosage forms.

3.2.3 Selection of analytical wavelength:

A standard solution of Imeglimin hydrochloride (10 µg/mL) prepared in the selected solvent mixture was scanned in the UV region between 200–400 nm using a Shimadzu-1700 UV-Visible spectrophotometer. The UV spectrum obtained was evaluated, and the wavelength showing maximum absorbance for Imeglimin hydrochloride was selected as the analytical wavelength.

3.2.4 Selection of solvent system:

Imeglimin is marketed as a single-dose formulation. Simple solvents such as water and methanol were initially evaluated, followed by various solvent combinations to obtain optimum solubility and maximum absorbance stability. The solvent system providing clear solubility and consistent absorbance values was selected for further analysis.

3.3 Methodology for validation of UV spectrophotometric method for Imeglimin hydrochloride Preparation of Standard

Solution:

Accurately weight 10mg of Imeglimin standard was transferred into 10ml volumetric flask, methanol and water (50:50) was added and sonicated for 15 min to dissolve it fully, volume was made up with solvent system of methanol and water (50:50) to get 1000µg/ml of standard stock solution of Imeglimin and labelled as Standard stock solution.

Prepare working Standard stock solution by taking 0.1ml of standard stock was withdrawn and transferred to 100ml volumetric flask, volume made up to the mark with solvent system methanol and water (50:50) to get the working standard solution 1µg /ml solution of Imeglimin and was labelled as stock solution.

Prepare solvent system by Accurately measure 50 ml of methanol and transfer it to 100ml volumetric flask and measure 50ml of water and transfer it to 100ml volumetric flask (50:50) and mix.

Preparation of Sample Solution:

Ten tablets were weighted and powdered, average weight of one tablet was calculated and the weight of powder equivalent to 10mg of Imeglimin was transferred to 10ml volumetric flask dissolved in solvent system and the volume was made up to 10 ml with solvent system to set the concentration of 1000 µg g/ml of sample solution. And labelled as sample stock solution.

Prepare working Sample stock solution by taking 0.5ml of sample stock solution, which was diluted to 10ml with solvent methanol and water in ratio of 50:50 to set concentration of 5 µg/mL solution. The solution was scanned and the absorbance was measured at 241nm.

3.3.1 Linearity and range

The linearity of an analytical procedure specifies the ability to obtain test results that are directly proportional to the concentration of the analyte in the sample. Linearity was determined by analysing the absorbance of Imeglimin standard solutions in the

concentration range of 0.1–1.9 µg/mL at 241 nm, using methanol: water as the blank. A calibration curve was plotted using concentration versus absorbance, and the regression equation and correlation coefficient were calculated for the Imeglimin standard solutions.

3.3.2 Calibration curve for Imeglimin HCl

Appropriate aliquots of 0.1, 0.3, 0.5, 0.7, 0.9, 1.1, 1.3, 1.5, 1.7, and 1.9 mL from the working standard stock solution were transferred into separate 10 mL volumetric flasks. The volume in each flask was made up to the mark with methanol and water (50:50), producing final concentrations in the range of 0.1–2 µg/ml. The absorbance of each solution was measured at 241 nm, and the values were recorded. A standard calibration curve was constructed by plotting absorbance versus concentration, and the regression equation was computed. Linear regression data obtained for Imeglimin were tabulated accordingly.

3.3.3 Limit of detection (LOD) and limit of quantification (LOQ)

The limit of detection is the lowest amount of analyte in a sample that can be detected but not necessarily quantified. LOD was estimated using values obtained from six calibration curves used for determining method linearity.

It was calculated using: $$\mathbf{LOD} = \frac{3.3 \times (standard\ deviation\ of\ Y\text{-}intercept)}{mean\ slope}$$

The limit of quantification is the lowest concentration that can be quantitatively determined with suitable accuracy and precision.

LOQ was calculated using: $$\mathbf{LOQ} = \frac{10 \times (standard\ deviation\ of\ Y\text{-}intercept)}{mean\ slope}$$

3.3.4 Accuracy

Accuracy represents the closeness of agreement between the true value and the measured value. Recovery studies were performed using the standard addition method by adding known quantities of Imeglimin standard to pre-analysed samples at three concentration levels—80%, 100%, and 120% of the assay concentration. From the sample stock solution, 0.1 mL was transferred into three 10 mL volumetric flasks, followed by the addition of 0.8, 1.0, and 1.2 mL of standard Imeglimin solution. The volume in each flask was made up with methanol and water (50:50). All samples were filtered using a 0.45 µm membrane filter, and absorbance was measured at 241 nm. Percent recovery values were calculated and tabulated.

Acceptance criteria: 95–105% w/w.

3.3.5 Precision

The precision of the method was determined by Intraday, inter-day, repeatability and reproducibility studies.

Intraday and interday precision

Precision was assessed by measuring absorbance at different time intervals (morning, afternoon, evening) on the same day for intraday precision, and on three separate days for interday precision, using a 0.3 µg/mL Imeglimin solution. Mean absorbance, standard deviation, and %RSD were calculated and tabulated.

Repeatability

A 5 µg/mL standard solution of Imeglimin was prepared and analysed six times on the same day under identical conditions. Absorbance readings were recorded, and mean, standard deviation, and %RSD were calculated.

Reproducibility

Reproducibility was evaluated by preparing a 5 µg/mL solution of Imeglimin independently by two different analysts. Absorbance was measured for each preparation, and mean, SD, and %RSD were calculated. Results were tabulated and graphically represented.

Robustness

Robustness evaluates the method's ability to remain unaffected by small deliberate variations in analytical parameters. This was assessed by altering the solvent system ratio slightly. Accurately weighed Imeglimin was dissolved in methanol and distilled water (50:50) to prepare stock solution. Aliquots were transferred into nine volumetric flasks. Three sets of solutions were prepared using solvent ratios of 49:51, 50:50, and 51:49. Absorbance was measured at 241 nm and results were tabulated.

Sandell's sensitivity:

The sensitivity of the method depends on experimental conditions and is expressed in terms of the smallest amount of analyte detectable. Sandell's sensitivity, molar absorptivity, standard deviation, coefficient of variance, slope, and intercept were calculated.

$$\mathbf{Sandell's\ sensitivity} = \frac{Concentration\ of\ drug}{Absorbance} \times 0.001$$

3.4 Method for determination of Imeglimin hydrochloride in formulation (tablet) {assay of tablets}

The tablet used for the assay was Imextor, containing a label claim of 500 mg of Imeglimin hydrochloride, and manufactured by Torrent Pharmaceuticals Ltd.

Procedure: A 5 µg/mL solution of the sample stock was taken in a 10 mL volumetric flask, and the volume was made up to the mark with the solvent system. The absorbance of the resulting solution was recorded, and the percentage assay and percentage RSD were calculated.

$$\%\text{Assay} = \frac{\text{Absorbance of sample} \times \text{Concentration} \times \text{DF} \times 100}{\text{Absorbance of standard} \times \text{Weight of sample} \times \text{Label claim}}$$

RESULTS AND DISCUSSION

4.1 Result for Preliminary analysis of drug Imeglimin HCl

A UV-Spectrophotometric method was developed for estimation of Imeglimin hydrochloride in bulk and in formulation

Table 1: Observations for preliminary analysis of Imeglimin hydrochloride

Drug	Tests	Observations
Imeglimin HCl	Description	White amorphous powder
	solubility	Freely soluble in Water, methanol, dimethyl sulfoxide, ethanol
	Identification tests	absorbance found < 0.48 at 241nm.

4.2 Result for Development of UV Spectrophotometric Method for Imeglimin HCl

The UV spectrophotometric method was developed for determination of Imeglimin hydrochloride.

4.2.1. Result for Selection of Analytical Wavelength

The selection of analytical wavelength, the standard solution of Imeglimin HCl was scanned in the spectrum mode from 200nm to 400nm with various solvents 2 solvent mixtures, the solvent mixture of methanol and water in the ratio of 50:50 showed good reproducible absorbance. It is presented below.

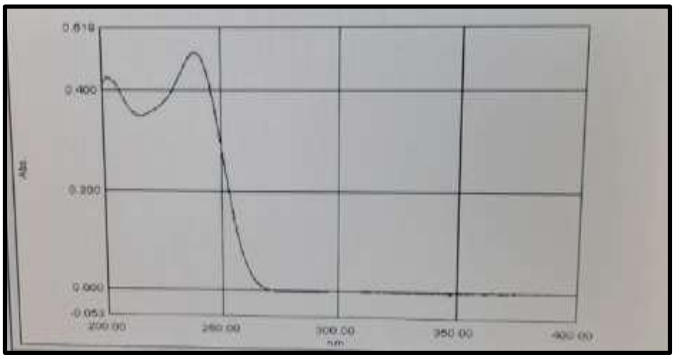

Fig 2: UV Spectra for Imeglimin HCl (5 µg/ml) in methanol: water (50:50) solvent

4.2.2. Result for Selection of Solvent system

Several solvents/solvent systems were tried to good stable absorbance for Imeglimin hydrochloride.

Table 2: Observations for the different solvent systems tried.

Sl. no	Mobile phase	Composition ratio v/v	Absorbance	Observation	Inference
1	Methanol	100	0.42	Moderate absorbance observed in pure methanol	Drug shows good solubility and UV response in methanol, but absorbance is lower compared to methanol–water mixtures
2	Methanol: water	50:50	0.513	Highest absorbance obtained among all compositions	Presence of water enhances drug solubility and UV absorption; this composition is most suitable for analysis
3	Methanol: water	60:40	0.45	Absorbance decreases compared to 50:50 mixture	Higher methanol content reduces polarity, leading to comparatively lower absorbance

From the above result methanol: water in ratio (50:50) at 241nm showed good absorbance hence was selected.

4.3 Result for Validation of UV Spectrophotometric Method for Imeglimin HCl

4.3.1 Linearity and range

The linearity of an analytical procedure specifies the results which are directly proportional to the concentration of analyte in the sample. The linearity and range were determined from coefficient of correlation (R2) obtained by plotting absorbance vs. concentration at 241nm. Slope and Y-intercept was determined and correlation coefficient values of calibration curve was computed.

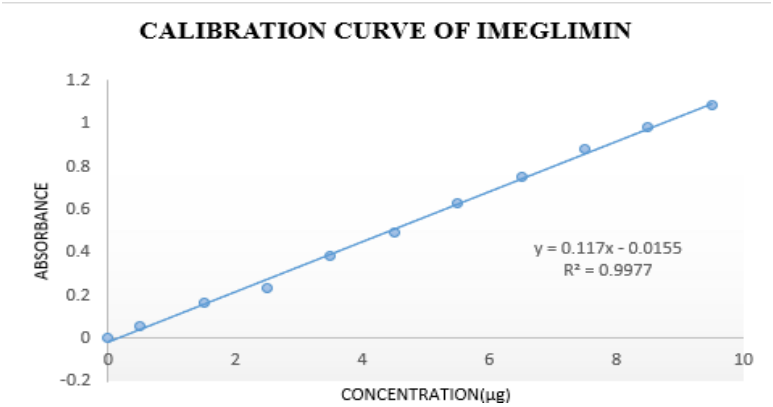

Fig.3 Calibration graph for linearity studies of Imeglimin hydrochloride.

Imeglimin was found to be linear in the range of 0.5-9.5µg /ml and Correlation coefficient was found to be within acceptance criteria of NLT 0.8738.

4.3.2 Limit of detection (LOD) and limit of quantification (LOQ)

The lowest amount of Imeglimin hydrochloride that can be detected and quantified was calculated from the calibration curve by using the formula.

The LOD for Imeglimin hydrochloride was found to be 0.080907(µg /ml) and LOQ was found to be 0.245172 (µg /ml) for Imeglimin hydrochloride.

4.3.3 Accuracy

Accuracy studies were performed at 3 different levels (80%, 100%, and 120%) and % recovery of Imeglimin was calculated and presented below

Table 3: Percentage Recovery data for accuracy studies at 3 different levels

Concentration of standard (µg /ml) (A)	Concentration of sample (µg /ml) (B)	Total concentration on (A+B) (µg/ml)	Abs for mixture (Std + sample)	Concentration of std (µg /ml)	Recovery of std (µg/ml)	% recovery of std w/w
5	4	9	1.001	4.050	0.448	101.25
5	5	10	1.105	5.009	0.552	100.18
5	6	11	1.219	6.0217	0.666	100.36

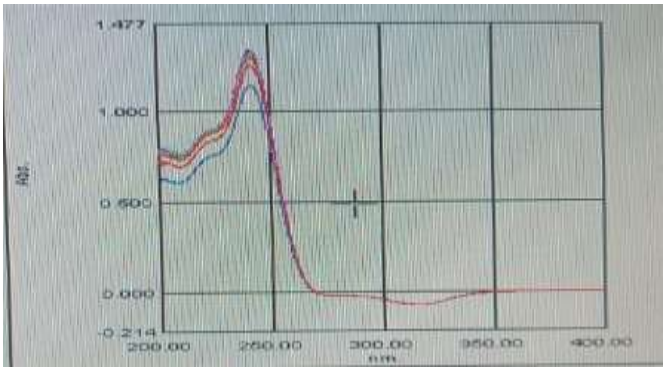

Fig.4: Overlaid UV spectrum for accuracy studies at 3 different levels.

The % recovery for accuracy of proposed method was found to be 100.18 to 101.36%w/w. Hence the method was found to be accurate as the % recovery is within the acceptance criteria limit.

4.3.4 Precision

The precision of an analytical method was studied by performing intra-day, inter-day precision, repeatability and reproducibility studies. Intra-day and inter-day precision was performed to determine whether the developed method gives consistent results at different intervals on the same day and for three consecutive days.

Intraday and interday precision

Intra-day and inter-day precision was performed to determine whether the developed method gives consistent results at different intervals on the same day and for three consecutive days.

From data obtained it can be inferred that as the %RSD for intraday and inter- day studies for Imeglimin hydrochloride was within the acceptance criteria of less than 2%. Hence, it can be concluded that the developed method was found to be precise during intra and inter-day studies.

From data obtained it can be inferred that as the %RSD for intraday and inter- day studies for Imeglimin hydrochloride was within the acceptance criteria of less than 2%. Hence, it can be concluded that the developed method was found to be precise during intra and inter-day studies.

Repeatability

The test for repeatability was performed to check whether the developed method gives consistent results with same solution on the same day and same time.

The %RSD was found to be 0.260 and hence the method was found to be precise during repeatability studies.

Reproducibility

Reproducibility was performed to ensure that the method is precise when different analysts performed the analysis with the same method.

The %RSD values for absorbance by 2 different analysts was found to be within the acceptance criteria, hence the method was found to be reproducible.

Robustness

Robustness is carried out by doing deliberate variation in method parameters is done. Absorbance of any one concentration (i.e.,5ug/ml) is measured at wavelength i.e., 241nm.

From the data obtained %RSD for absorbance was found to be less than 2% which is well within acceptance criteria. Hence the method was found to be robust with small deliberate changes in solvent system ratios.

4.3.5 Sandell's sensitivity

Sandel's sensitivity was calculated to assess the sensitivity of developed and validated UV-spectrophotometric method for Imeglimin Hydrochloride by using the formula.

The Sandell's sensitivity was found to be 0.009009 µg/ cm^2

Table 4: Results for validation of UV Spectrophotometric methods for Imeglimin hydrochloride

Parameters	**Imeglimin Hcl**
Linearity (µg /ml)	0.5-9.5
LOD (µg /ml)	0.080907
LOQ (µg /ml)	0.245172
Correlation coefficient (R^2)	0.9977
Accuracy	100.18 to 101.36%w/w
Precision(%RSD) Intra-day	1.823807
Inter-day	0.872813
Reproducibility	0.244986 & 0.423729
Robustness	1.82
Sandell's Sensitivity (µg/ cm^2)	0.009009

Table 4 displays the developed UV spectrophotometric method was then validated for determination of Imeglimin hydrochloride with various validation parameters as per ICH guidelines.

4.4 Results for determination of Imeglimin hydrochloride in formulation (tablet) {assay of tablets} Table 5: Assay results for Imeglimin hydrochloride in tablet formulation.

SL.NO	ABSORBANCE*(5µg/ml)	%ASSAY(%w/w)
1	0.512	100
2	0.511	99.80
3	0.514	100.58
MEAN	0.512333	100.1267
SD	0.001528	0.405134
%RSD	0.298151	0.404621

The percentage Assay for Imeglimin hydrochloride in tablets was found to be 99.80 to 100.58%w/w which is well within acceptance criteria of 95-105%w/w and the %RSD for Assay value was 0.404621 which is well within the acceptance criteria of not more than 2%. Hence it can be concluded that the developed and validated method can be used for determination of Imeglimin hydrochloride in tablets accurately

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