World Journal of Pharmaceutical and Life Sciences
WJPLS
www.wjpls.org
SJIF Impact Factor: 7.409

DEVELOPMENT AND VALIDATION OF SPECTROPHOTOMETRIC METHOD FOR ANTIPSYCOTIC DRUG

Tanaya S. Bahadure[1*], Sakshi G. Kancharlawar[2], Rohan S. Chavhan[3], Ajinkya V. Gulhane[4] and Dr. Manisha D. Kitukale[5]

India.

***Corresponding Author: Tanaya S. Bahadure**
India.
Email ID: tanayabahadure26@gmail.com,

Article Received on 24/04/2025 **Article Revised on 15/05/2025** **Article Accepted on 04/06/2025**

ABSTRACT
The present research outlines the development and validation of a UV-visible spectrophotometric method for the quantitative estimation of Venlafaxine Hydrochloride, an antipsychotic and antidepressant agent. The method was designed to be simple, rapid, accurate, precise, and economical, making it suitable for routine quality control applications in pharmaceutical industries. Venlafaxine Hydrochloride exhibited a maximum absorbance (λmax) at 223 nm when dissolved in 0.1 N NaOH, which was identified as the most suitable solvent based on solubility and spectral stability. The method demonstrated excellent linearity in the concentration range of 5–25 µg/mL with a correlation coefficient (r^2) of 0.9968. Validation parameters, including accuracy (98.5%–101.2% recovery), precision (%RSD < 2), specificity, robustness, and sensitivity (LOD: 0.267 µg/mL; LOQ: 0.810 µg/mL), complied with ICH Q2(R1) guidelines. The proposed method was successfully applied for the estimation of Venlafaxine Hydrochloride in commercial tablet formulations, showing consistent results within pharmacopeial limits. This validated method offers a reliable analytical tool for the routine assessment of Venlafaxine Hydrochloride in bulk and finished dosage forms.

KEYWORDS: Venlafaxine Hydrochloride, UV-Visible Spectrophotometry, Method Validation, ICH Guidelines, Antipsychotic Drug, Quantitative Analysis.

INTRODUCTION

Analytical Chemistry is the branch of science that uses advance technologies in determining the composition by analytical technique. We can achieve both qualitative as well as quantitative results. Analytical instruments play a major role in the process to achieve high quality and reliable analytical data. Thus, everyone in the analytical laboratory should be concerned about the quality assurance of equipment.[1]

Instrumental technique like UV spectroscopy plays a vital role in analysis The field is broadly divided into two types:

1. **Qualitative analysis** – Determines what substances are present in a sample.
2. **Quantitative analysis** – Measures how much of each substance is present.

Analytical chemistry combines classical methods such as **titration, precipitation, and extraction** with modern instrumental techniques like **spectroscopy (UV, IR, NMR), chromatography (HPLC, GC), and electrochemical analysis**. These tools are essential in a wide range of fields including **pharmaceuticals, environmental science, food safety, forensics, and materials science**.

With the increasing demand for accuracy, sensitivity, and speed, analytical chemistry continues to evolve through advances in instrumentation, automation, and data analysis.

Classification of Analytical Methods

Classical (Wet Chemistry) Methods

- **Gravimetric analysis** – based on mass measurement.
- **Volumetric analysis** – uses titration to determine concentration.
- **Colorimetry** – uses visual color comparison.

Instrumental Methods

1. **Spectroscopic Techniques**
   - **UV-Vis Spectroscopy** – for concentration analysis.
   - **Infrared (IR) Spectroscopy** – for functional group identification.
   - **Nuclear Magnetic Resonance (NMR)** – for molecular structure.

- **Atomic Absorption (AAS) & Emission (AES)** – for metal analysis.

2. **Chromatographic Techniques**
- **Thin Layer Chromatography (TLC)**
- **High-Performance Liquid Chromatography (HPLC)**
- **Gas Chromatography (GC)** – separation and quantification.

3. **Electroanalytical Techniques**
- **Potentiometry** (pH meter)
- **Conductometry**
- **Voltammetry**

4. **Mass Spectrometry (MS)**
- For determining molecular mass and structural information.[1]

UV-visible spectroscopy

Spectroscopy as a science began with Isaac Newton splitting light with a prism and was called optics. Therefore, it was originally the study of visible light which we call color that later under the studies of James Clerk Maxwell came to include the entire electromagnetic spectrum. Spectroscopy is the branch of science dealing with the study of interaction of electromagnetic radiation with matter. The most important consequence of such interaction is that energy is absorbed or emitted by the matter in discrete amounts called quanta. The absorption or emission processes are known throughout the electromagnetic spectrum ranging from the gamma region (nuclear resonance absorption or the Mossbauer effect) to the radio region (nuclear magnetic resonance). When the measurement of radiation frequency is done experimentally, it gives a value for the change of energy involved and from this one may draw the conclusion about the set of possible discrete energy levels of the matter. The ways in which the measurements of radiation frequency (emitted or absorbed) are made experimentally and the energy levels deduced from these comprise the practice of spectroscopy.[2]

Principle of UV-visible spectroscopy

The UV-Visible Principle The absorption of ultraviolet or visible light by chemical compounds produces distinct spectra, which is the basis for spectroscopy. The interaction of light and matter is the foundation of spectroscopy. When matter absorbs light, it experiences excitation and de- excitation, which results in the formation of a spectrum. When an electromagnetic wave strikes a material, phenomena such as transmission, absorption, reflection, and scattering can occur, and the observed spectrum depicts the interaction of wavelengths with discretedimensional objects such as atoms, molecules, and macromolecules. Absorption occurs when the frequency of incoming light equals the energy difference between the ground and excited states of a molecule. An electronic transition (Figure 1) describes the excitation of an electron from its ground state to its excited state. This is the fundamental concept of molecular spectroscopy.[3]

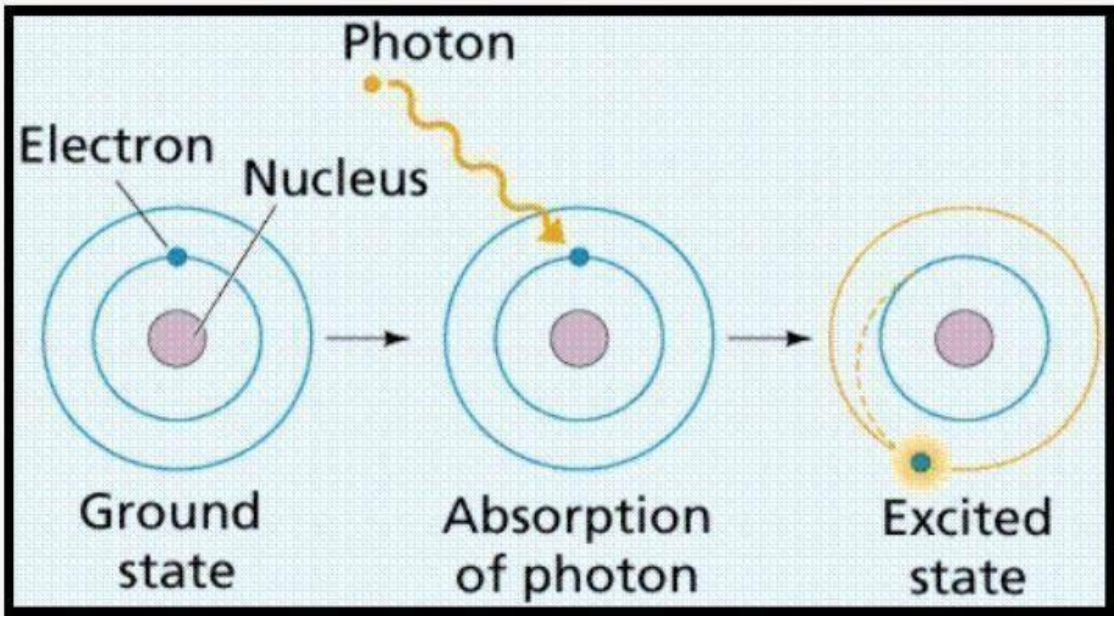


Fig. (1.1): Describes the excitation of an electron from its ground state to its excited state. This is the fundamental concept of molecular spectroscopy.

Instrumentation

Spectrophotometer

- Source of radiation
- Monochromators
- Recording system
- Detector

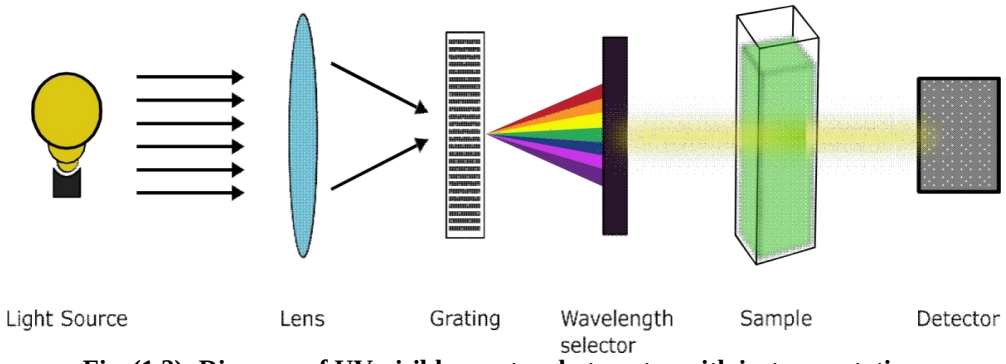


Fig. (1.2): Diagram of UV-visible spectrophotometer with instrumentation.

1) Source of radiation

Requirements of an Ideal Source:

It should be stable and should not allow fluctuations. It should emit light of continuous spectrum of high and uniform intensity over the entire wavelength region in which it's used. It should provide incident light of sufficient intensity for the transmitted energy to be detected at the end of optic path. The best source of light is the one which is more stable, more intense and which give the range of spectrum from 200-800 nm.

Types of light source

a) Hydrogen discharge lamp
b) Deuterium lamp
b) Xenon discharge lamp
c) Mercury Arc

2) Monochromators

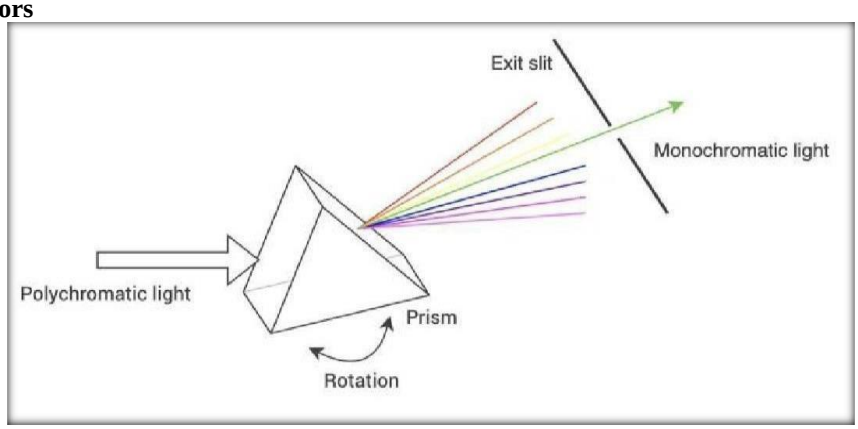


Fig. (1.3): Diagram of Monochromators.

- Monochromators are better and more efficient than filters in converting polychromatic light or heterochromatic light into monochromatic light.
- Monochromators are primarily designed for spectral scanning, i.e. a process of continuously varying the radiation wavelength over a considerable range.
- Mechanical construction of monochromators for UV, visible and IR radiation is similar in that all of them employ slits, lenses, mirrors, windows, and gratings or Prism.

1) Prism Monochromator-Two types

- Single-pass monochromators
- Double beam monochromators

2) Granting monochromator

It provides on alternative means of producing monochromators light. It consists of Series of parallel lines (groves) which reflected through highly polished surface of glass, quartz of alkyl halides.

3) Sample cells

- The cells or cuvettes are used for handling liquid samples.
- The cell may either be rectangular or cylindrical in nature.
- For study in UV region; the cells are prepared from quartz or fused silica whereas color corrected fused glass is used for visible region.
- The surfaces of absorption cells must be kept scrupulously clean.
- No fingerprints or a touch should be present on cells.
- Cleaning is carried out washing with distilled water or with dialcohol, acetone.

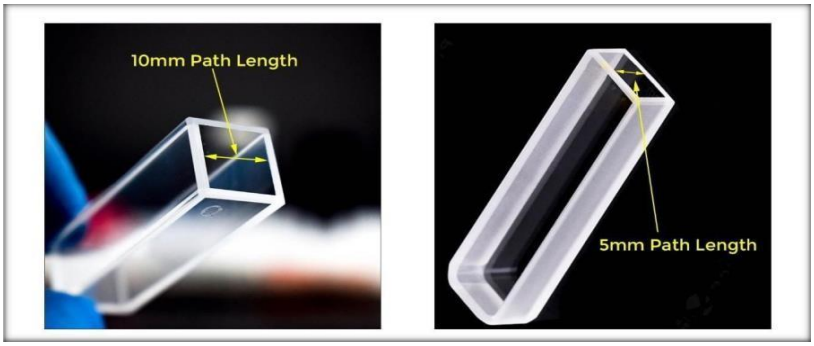


Fig. (1.4): Diagram of Cuvette.

Detectors

- Device which converts light energy into electrical signals, that are displayed on readout devices.
- The transmitted radiation falls on the detector which determines the intensity of radiation absorbed by sample
- The following types of detectors are employed in instrumentation of absorption spectrophotometer

a) Barrier layer cell/Photovoltaic cell
b) Phototubes/Photo emissive tube
c) Photomultiplier tube.[3]

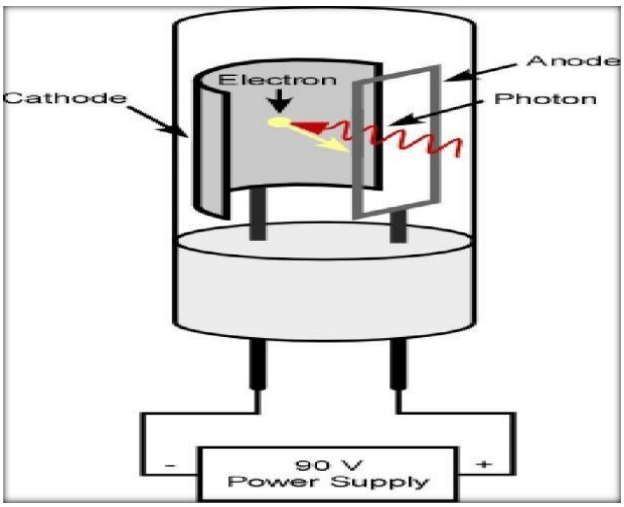


Fig. (1.5): Diagram of phototube photon detector.

Application UV-Visible spectroscopy

1. It is useful in quantitative analysis.
2. It is used in drug identification
3. It is used for determination of different species
4. It is used for beverage analysis
5. It is used in DNA & RNA analysis.
6. It is used to check nucleic acid purity
7. It is used in detection of impurities.[4-5]

Introduction of Antipsychotics

Antipsychotics are drugs that are used to treat mental illnesses like schizophrenia. They are characterized by their mechanism of action and clinical pattern, and are grouped into first- generation (typical) and second-generation (atypical) antipsychotics:

Adult's antipsychotics, also known as neuroleptics or major tranquilizers are a class of medication primarily used to manage psychosis including delusion, hallucinations, paranoia or disordered thoughts, principally in schizophrenia and bipolar disorder. They are increasingly being used in the management of non-psychotic disorders. Antipsychotics are usually effective in relieving symptoms of psychosis in the short term.

The long-term use of antipsychotics is associated with side effects such as involuntary movement disorders, gynecomastia, and metabolic syndrome. They are also associated with increased mortality in elderly people with dementia. A psychotropic, Psychoactive or phototropic drug is one that inhibit, sharpens or alters behavioral, mood and emotional responses Psychiatric illness in divided into the neuroses and the Psychoses. First-generation antipsychotics, known as typical antipsychotics, were discovered in the 1950s. Most second generation drugs, known as atypical antipsychotics, have been developed more recently, although the first atypical antipsychotic, clozapine, was

discovered in the 1960s and introduced clinically in the 1970s. Both generations of medication tend to block receptors in the brain's dopamine pathways, but atypical tend to act on serotonin receptors as well. Antipsychotic drugs have a significant stronger effect on the central nervous system, but they are not CNS depressants, and as a rule they are more toxic. However, even in long-term use they do not cause dependence and addiction, which is a very serious problem that originates from longterm use of anxiolytics. Antipsychotics agents inhibit psychotic manifestation without curing the underlying disease. In a strict sense they are not really antipsychotics. The term, however, continues to be used for the central nervous system depressant which calm severely disturbed psychiatric patients. Chlorpromazine HCI is a potent anti-emetic, act by blocking D2 receptors in the Chemoreceptor trigger zone (CTZ). And antagonize apomorphine induced vomiting. In the present study an attempt has been made to prepare fast dissolving tablets of Chlorpromazine HCI in the oral cavity with enhanced dissolution rate. The tablets were prepared with five super disintegrants e.g.: Sodium starch glycolate Crospovidone Croscarmellose, L-HPC, Pregelatinized starch. The blend was examined for angle of repose, bulk density, tapped density, compressibility index and Hausner's ratio. The tablets were evaluated for hardness, friability, disintegration time, dissolution rate.[6]

Classification of Antipsychotics

1. Classification Based on Generation

- **First-Generation Antipsychotics (FGAs) (Typical)**
  - Haloperidol (Haldol)
  - Chlorpromazine (Thorazine)
  - Fluphenazine (Prolixin)
  - Perphenazine (Trilafon)
  - Thioridazine (Mellaril)

- **Second-Generation Antipsychotics (SGAs) (Atypical)**
  - Clozapine (Clozaril)
  - Olanzapine (Zyprexa)
  - Risperidone (Risperdal)
  - Quetiapine (Seroquel)
  - Aripiprazole (Abilify)
  - Paliperidone (Invega)
  - Ziprasidone (Geodon)
  - Lurasidone (Latuda)[6]

2. Classification Based on Mechanism of Action:

- **Dopamine D2 Receptor Antagonists**
  - Haloperidol (Haldol)
  - Chlorpromazine (Thorazine)
  - Fluphenazine (Prolixin)
  - Perphenazine (Trilafon)

- **Dopamine and Serotonin (5-HT2) Antagonists**
  - Olanzapine (Zyprexa)
  - Risperidone (Risperdal)
  - Quetiapine (Seroquel)
  - Aripiprazole (Abilify)[6]

3. Classification Based on Chemical Structure

- **Phenothiazines**
  - Chlorpromazine (Thorazine)
  - Fluphenazine (Prolixin)
  - Perphenazine (Trilafon)
- **Butyrophenones**
  - Haloperidol (Haldol)
- **Thioxanthenes**
  - Thiothixene (Navane)
- **Diphenylbutylpiperidines**
  - Pimozide (Orap)
- **Dibenzodiazepines**
  - Clozapine (Clozaril)
  - Olanzapine (Zyprexa)
- **Benzisoxazoles**
  - Risperidone (Risperdal)
  - Paliperidone (Invega)
- **Dihydroindolones**
  - Quetiapine (Seroquel)
- **Benzisothiazoles**
  - Ziprasidone (Geodon)[6]

4. Classification Based on Side Effect Profile

- **Extrapyramidal Symptoms (EPS)-Causing Antipsychotics**
  - Haloperidol (Haldol)
  - Fluphenazine (Prolixin)
- **Lower EPS and Metabolic Side Effect Antipsychotics**
  - Clozapine (Clozaril)
  - Olanzapine (Zyprexa)
  - Risperidone (Risperdal)
- **Antipsychotics with Sedative Effects**
  - Quetiapine (Seroquel)
  - Olanzapine (Zyprexa)[6]

5. Classification Based on Clinical Use

- **Treatment of Schizophrenia**
  - Haloperidol (Haldol)
  - Chlorpromazine (Thorazine)
  - Clozapine (Clozaril)
  - Risperidone (Risperdal)
- **Treatment of Bipolar Disorder**
  - Olanzapine (Zyprexa)
  - Quetiapine (Seroquel)
  - Aripiprazole (Abilify)
- **Adjunctive Therapy for Depression**
  - Aripiprazole (Abilify)
  - Quetiapine (Seroquel)
- **Acute Agitation/Delirium**
  - Haloperidol (Haldol)
  - Lorazepam (Ativan)[6]

6. Classification Based on Potency

- **High Potency Antipsychotics**
  - Haloperidol (Haldol)
  - Fluphenazine (Prolixin)
- **Low Potency Antipsychotics**
  - Chlorpromazine (Thorazine)
  - Thioridazine (Mellaril)[6]

Pharmacodynamics
Antipsychotics primarily exert their therapeutic effects by:

- **Blocking dopamine D2 receptors** in the **mesolimbic pathway**, which is linked to positive symptoms of schizophrenia.
- **Atypical antipsychotics** also act on:
  - **Serotonin 5-HT2A receptors**
  - **Alpha-adrenergic receptors**
  - **Histamine H1 receptors**
  - **Muscarinic cholinergic receptors**

This receptor interaction profile contributes to their **efficacy** and **side effect profiles**.[7]

Pathophysiology of Psychosis & Dopamine Hypothesis

- The **dopamine hypothesis** suggests that **hyperactivity of dopamine** in certain brain regions (especially the mesolimbic system) contributes to **positive symptoms** of psychosis.
- Conversely, **hypoactivity** in the **mesocortical pathway** may be responsible for **negative symptoms** and **cognitive deficits**.
- Atypical antipsychotics aim to address both, which is why they are considered more effective for **negative symptoms**.[7]

Adverse Drug Reactions (ADRs)
Typical Antipsychotics

- Extrapyramidal symptoms (EPS):
  - Dystonia
  - Akathisia
  - Parkinsonism
  - Tardive dyskinesia
- Neuroleptic Malignant Syndrome (NMS)
- Hyperprolactinemia
- Anticholinergic effects (especially with low-potency agents like chlorpromazine)

Atypical Antipsychotics

- **Weight gain**, **hyperglycemia**, **dyslipidemia** (especially with Olanzapine, Clozapine)
- **Sedation**
- **Agranulocytosis** (notably with Clozapine; requires routine WBC monitoring) [7]

Recent Advances in Antipsychotic Drug Delivery
To improve **compliance** and **therapeutic outcomes**, novel drug delivery systems are being explored:

- **Fast-dissolving tablets (FDTs)**
- **Orally disintegrating films (ODFs)**
- **Long-acting depot injections** (e.g., Paliperidone palmitate)
- **Nanoparticle-based formulations**
- **Transdermal patches** (e.g., Asenapine transdermal system)

These systems help improve **bioavailability**, **reduce dosing frequency**, and **enhance patient compliance**, especially in psychiatric patients who may have adherence issues.[7]

Drug-Drug Interactions

- Many antipsychotics are metabolized by **cytochrome P450 enzymes**, especially **CYP2D6** and **CYP3A4**.
- Co-administration with **CYP inhibitors or inducers** (e.g., fluoxetine, carbamazepine) may alter drug levels.
- Risk of **QT prolongation** when combined with other QT-prolonging drugs**.**[8]

Clinical Monitoring Parameters

- **Weight, waist circumference**
- **Fasting blood glucose**
- **Lipid profile**
- **Extrapyramidal symptoms (EPS) rating scales**
- **ECG (for QT interval)**
- **Prolactin levels**
- **Complete blood count (for Clozapine)**[9]

Emerging Therapies
New research is focused on:

- **Glutamatergic agents** (NMDA receptor modulators)
- **Cannabinoid receptor antagonists**
- **Biased ligands** for selective dopamine receptor modulation
- **Personalized medicine** using pharmacogenomics to predict efficacy and ADR risk.[9]

LITERATURE REVIEW

1) Aarti Pawar et.al. (2023)
The present study includes analytical method for determination of the drug Chlorpromazine Hydrochloride (CPH) in some Pharmaceuticals using Molecular Absorption, in addition to investigating complexes throughout. The analytical data obtained throughout this study could be summaries as follow. The method was found to be simple, safe, sensitive, and validated for the assay of chlorpromazine hydrochloride using phenol red, citrate buffer pH 3, and water as diluent [10]

2) Pawar S. S., More R. (2022).
Development and Validation of UV Spectrophotometric Method for Ziprasidone Hydrochloride. Journal of Pharmaceutical Science and Bioscientific Research, 12(3), 134-139. [11]

3) Khan M., Qureshi S. (2022).
UV Spectrophotometric Estimation of Thioridazine Hydrochloride in Tablet Dosage Form. International Journal of Pharmaceutical and Chemical Sciences, 11(2), 110-115[12]

4) Chaudhari R., Kale R. (2021)
UV Spectrophotometric Estimation of Asenapine Maleate in Bulk and Tablet Dosage Form. Research Journal of Pharmacy and Technology, 14(7), 3689-3692.[13]

5) Sharma A., Deshmukh S. (2021).
UV Spectrophotometric Estimation of Perphenazine in Tablet Form. Indian Drugs, 58(10), 34-38.[14]

6) Patil A. A., Shewale S. D. (2020)
Development and Validation of Spectrophotometric Method for Iloperidone. Asian Journal of Pharmaceutical Analysis and Medicinal Chemistry, 8(2), 89-94.[15]

7) Joshi A., Patel H. (2020)
First Derivative UV Spectrophotometric Method for Estimation of Lurasidone in Bulk and Tablet Form. Journal of Drug Delivery and Therapeutics, 10(5), 144-148.[16]

8) Rane R., Gawande V. (2019).
Estimation of Paliperidone in Bulk by UV-Spectroscopy. International Journal of Chemical and Pharmaceutical Analysis, 6(4), 15-19. [17]

9) Kumar S., Verma R. (2018).
UV Spectrophotometric Method for Determination of Sertindole in Bulk Drug Form. Asian Journal of Research in Chemistry, 11(3), 502-505.[18]

10) Gandhi N., Patel K. (2017).
Development and Validation of UV Spectrophotometric Method for Estimation of Blonanserin in Bulk and Pharmaceutical Dosage Form. International Journal of Pharmaceutical Sciences Review and Research, 42(1), 75-79.[19]

11) Rathod P., Borse B. (2016).
UV Spectrophotometric Method for Estimation of Amisulpride in Pharmaceutical Formulation. World Journal of Pharmacy and Pharmaceutical Sciences, 5(8), 1325-1332[20]

12) Bhagyashree a. Pakhale et.al. (2015)
The method is based on the measurement of absorbance of Venlafaxine hydrochloride solution in 0.1N NaOH at 223nm in the wavelength range of 200-400nm. The method obeys Beer's Lambert's law in the selected concentration range 5 25 µg/ml in selected media. The slope, intercept and correlation coefficient were also calculated. Results of percentage recovery study shows that the method was not affected by the presence of common excipients in tablets. The parameters like linearity, precision, accuracy, sensitivity study i.e. Limit of detection and limit of quantitation were studied according to International Conference on Harmonization (ICH) guidelines.[21]

13) Mohd Yasir et. al. (2014)
Methods: The study was performed in pH 7.4 phosphate buffer and presence of the drug was analyzed using UV spectrophotometer. Various analytical parameters such as linearity, range, precision, accuracy, limit of detection (LOD) and limit of quantification (LOQ) were determined according International Conference on Harmonization (ICH) guidelines.[22]

14) Laila a al shatti et.al. (2014)
Chlorpromazine is absorbed from the gastrointestinal tract. It is metabolized extensively, and 12 different metabolites are known. Less than 1% is excreted unchanged. Most metabolites are excreted in the urine. The half-life of chlorpromazine is variable at approximately 30 hours. Liquid concentrates may have greater bioavailability than tablets[23]

CONCLUSION

The presented method meets the specific acceptance criteria of analytical method validation as per International Conference on Harmonization (ICH) Q2 (R1) guidelines. Elements of validation. specificity, precision, linearity, accuracy, robustness, and system stability.

15) Nafisur Rehman et.al. (2012)
Haloperidol is a typical antipsychotic drug that chemically belongs to butyrophenone group. It is chemically known as 4-[4-(4-chlorophenyl)-4- hydroxyl-1-piperidyl]-1- (4fluorophenyl) butan-1-one with molecular weight of 375.86 g mol-1. It occurs as a white to pale yellow crystals or powder. Haloperidol is commonly used to treat moderate to severe psychiatric conditions including schizophrenia, manic states and medicament-induced psychosis.1,2 It is also used to treat extreme behavior problems in children and to ease the symptoms of Tourette's syndrome. For the treatment of schizophrenia.[24]

16) Joshi, Nirav et.al. (2012)
A Rapid, Simple, Specific, Selective, Accurate, Precise and Reproducible method was developed and validated for the estimation of Lurasidone Hydrochloride in the Pharmaceutical dosage form. UV Spectrophotometric method was a simple one by estimation of Drug at 230 nm over the concentration range 10-50 µg/ml for Lurasidone Hydrochloride. The % recovery of the drug was found to be 98.5% -100.16 %. Linearity was obtained 0.996 in the concentration range of 10-50 µg/ml for Lurasidone Hydrochloride. LOQ and LOD were found to be 8.43 and 2.81 µg/ml respectively at 230nm for Lurasidone Hydro[25]

AIM AND OBJECTIVES

AIM

Development and Validation of Spectrophotometric method for Determination of Antipsychotic drug

OBJECTIVES

1. To develop a UV Spectrophotometric method for Venlafaxine HCL.
2. Optimize analytical parameter like solvent system and wavelength, PH Concentration range absorption system of the drugs.
3. To develop Accurate, Simple, Precision and rapid analytical method for Venlafaxine HCL.
4. To validate analytical method for accuracy precision, linearity, robustness For ICH guidelines.[26]

DRUG PROFILE

- **Venlafaxine Hydrochloride**

1. Generic & Brand Name

- **Generic Name**: Venlafaxine Hydrochloride
- **Brand Names**: Effexor, Effexor XR

2. Drug Class

- **Serotonin-Norepinephrine Reuptake Inhibitor (SNRI)**

Venlafaxine belongs to a class of antidepressants that increase levels of serotonin and norepinephrine in the brain.

3. Uses / Indications

Venlafaxine is used in the treatment of various mood and anxiety disorders:

- Major Depressive Disorder (MDD)
- Generalized Anxiety Disorder (GAD)
- Social Anxiety Disorder (SAD)
- Panic Disorder

Off-label uses include:

- Post-Traumatic Stress Disorder (PTSD)
- Neuropathic pain
- Migraine prophylaxis
- Menopausal hot flashes

4. Dosage and Administration

Immediate-Release (IR) Form

- **Initial dose**: 37.5 mg twice daily
- **Typical maintenance dose**: 75–225 mg/day in divided doses
- **Maximum dose**: Up to 375 mg/day (in severe depression under medical supervision)

Extended-Release (XR) Form

- **Initial dose**: 37.5–75 mg once daily
- **Typical dose**: 75–225 mg once daily
- **Max dose**: 225 mg/day (outpatients); up to 375 mg/day (inpatients)

Note: Dose should be titrated gradually. Always taper when discontinuing to avoid withdrawal symptoms.

5. Mechanism of Action

Venlafaxine works by **blocking the reuptake of two neurotransmitters**

- **Serotonin (5-HT)**
- **Norepinephrine (NE)**

At **lower doses**, it primarily increases **serotonin** levels.

At **higher doses**, it also affects **norepinephrine** and slightly increases **dopamine**. This dual mechanism helps improve mood, energy, and anxiety symptoms.

6. Advantages

- Effective for both depression and anxiety
- Dual-action for more comprehensive symptom control
- Less sedating than some other antidepressants
- Extended-release form improves adherence and reduces side effects
- Low risk of weight gain in most patients

7. Contraindications

- Known hypersensitivity to venlafaxine
- Use with MAO inhibitors (e.g., phenelzine, tranylcypromine) or within 14 days of stopping an MAOI
- Uncontrolled hypertension
- Severe liver or kidney impairment (dose adjustment needed)S

8. Warnings and Precautions

- Suicidal thoughts and behavior (especially in young adults)
- Hypertension: Dose-related increase in blood pressure
- Serotonin Syndrome: Can occur with other serotonergic drugs
- Seizures: Risk increases at higher doses
- Mania: Can trigger manic episodes in bipolar patients
- Discontinuation symptoms: Especially with abrupt withdrawal

9. Common Side Effects

- Nausea
- Dry mouth
- Headache
- Dizziness
- Insomnia
- Sweating
- Constipation
- Appetite loss
- Sexual dysfunction

Less Common or Serious Side Effects

- Increased blood pressure or heart rate
- Serotonin syndrome (confusion, agitation, fever)
- Increased cholesterol levels
- Withdrawal symptoms (brain zaps, flu-like symptoms, mood swings)

10. Drug Interactions

- **MAOIs**: Risk of serotonin syndrome—must allow at least 14 days gap

- **SSRIs / Triptans / Tramadol**: May increase serotonin syndrome risk
- **NSAIDs / Anticoagulants**: Increased risk of bleeding
- **Alcohol / Sedatives**: May enhance CNS depression

11. Pharmacokinetics
- **Absorption**: Well absorbed orally
- **Bioavailability**: ~45%
- **Peak levels**: 2 hrs (IR), 5.5 hrs (XR)
- **Half-life**: ~5 hours (venlafaxine), 11 hours (active metabolite)
- **Metabolism**: Primarily in liver via CYP2D6
- **Excretion**: Mainly through kidneys

12. Pregnancy & Lactation
- **Pregnancy Category C**: Use only if benefits outweigh risks.
- **Lactation**: Venlafaxine is excreted in breast milk—use with caution.

13. Withdrawal (Discontinuation Syndrome)
Symptoms
- Flu-like symptoms
- Nausea
- Insomnia
- "Brain zaps" (electric shock-like sensations)
- Dizziness
- Anxiety or irritability

To prevent this, always taper off slowly under medical supervision.

14. Chemical Information
- **IUPAC Name**: 1-[2-(Dimethylamino)-1-(4-methoxyphenyl)ethyl]cyclohexanol hydrochloride
- **Molecular Formula**: C17H27NO2·HCl
- **Molecular Weight**: 313.86 g/mol.[27-30]

PLAN OF WORK (Venlafaxine Hydrochloride)
1. **Selection of Drug:**
   - Venlafaxine Hydrochloride chosen for spectrophotometric estimation.
2. **Literature Survey**
   - Review existing UV methods, solvents, λmax, and validation criteria.
3. **Procurement of Materials**
   - API and marketed tablets collected.
   - Solvents and reagents (e.g., methanol, NaOH) prepared.
4. **Solubility Testing**
   - Determine solubility in water, methanol, and 0.1 N NaOH.
5. **Preparation of Stock Solutions**
   - Prepare standard stock and working solutions in selected solvent.
6. **Determination of λmax:**
   - Scan 200–400 nm range to identify maximum absorbance (λmax ≈ 223 nm).
7. **Calibration Curve Construction**
   - Prepare standard dilutions (5–25 µg/mL).
   - Measure absorbance and plot concentration vs absorbance.
8. **Method Development**
   - Optimize solvent, wavelength, and concentration range for best results.
9. **Method Validation (ICH Guidelines)**
   - Validate method for:
     - Linearity
     - Accuracy
     - Precision
     - LOD & LOQ
     - Specificity
     - Robustness & Ruggedness

10. **Data Interpretation & Conclusion:**
Analyze, interpret data, and draw conclusions based on validation results.[31-32]

MATERIALS AND INSTRUMENTS

1. MATERIALS

This section includes all the raw materials, reagents, solvents, and reference standards required for the development and validation of a UV-visible spectrophotometric method for antipsychotic drugs.

A. Active Pharmaceutical Ingredients (APIs) / Reference Standards

Drug Name	Purpose	Supplied by	Quantity (g)	Purity (Assay) % w/w
Venlafaxine Hydrochloride	Analyte for method validation and estimation	Yarrow Chem laboratories Ltd. Mumbai	10g	98 %

B. Reagents and Solvents[33]

Reagent / Solvent	Grade	Purpose
Methanol	Analytical/HPLC Grade	Used as solvent/diluent; excellent UV transparency
Distilled Water / Deionized Water	Lab-grade	Used for preparation of buffer and dilution of solutions

2. EQUIPMENT / INSTRUMENTATION

The following equipment and instruments are essential for conducting spectrophotometric analysis and method validation in a pharmaceutical analysis laboratory.

A. Spectrophotometric Instrumentation

Instrument	Specification	Purpose
UV-Visible Spectrophotometer	Shimadzu model (UV-1800 series) Double beam, Range 190– 800 nm,	Quantitative analysis and wavelength absorbance study for Fenofibrate
Quartz Cuvettes	1 cm path length, UV compatible	Sample holding for UV measurements
Computer & Software	Connected to spectrophotometer, With UV Probe 2.43 version software	Data acquisition and spectral analysis

B. Glassware (All Class A Certified)

Glassware Item	Volume / Size	Purpose
Volumetric Flasks	10 ml, 25 ml, 50 ml, 100 ml	Preparation of standard and sample solutions
Beakers	50 ml, 100 ml, 250 ml	Solution handling and dilution
Conical Flasks (Erlenmeyer)	100 ml, 250 ml	Mixing and sample storage
Pipettes (Graduated/Volumetric)	1 ml, 5 ml, 10 ml	Transfer of accurate volume
Burettes	25 ml, 50 ml	(If required) precise titration work
Funnels	Medium/Large	Used during filtration
Glass Stirring Rods	Standard	Manual stirring of solutions

C. Filtration & Sample Prep Tools

Tool	Use
Whatman Filter Paper No. 41	Filtration of prepared samples to remove insoluble impurities
Membrane Filter (0.45 µm)	For fine filtration and clarity of solution
Syringe Filters	For sterile or particulate-free solution preparation

D. Laboratory Safety & Hygiene Materials[34-35]

Item	Purpose
Nitrile Gloves	Personal safety during chemical handling
Lab Coats	Protection of clothing and skin
Safety Goggles	Eye protection from chemical splashes
Fume Hood	Safe handling of volatile solvents or hazardous vapors
Distilled Water Unit	For generation of lab-grade water

EXPERIMENTAL WORK

1. SELECTION OF DRUG

Drug Selected: Venlafaxine Hydrochloride

Therapeutic Class:

- **Serotonin-Norepinephrine Reuptake Inhibitor (SNRI)**
- Used in the treatment of **major depressive disorder**, **generalized anxiety disorder**, **panic disorder**, and **social anxiety disorder**.

Rationale for Selection

- **UV-absorbing nature:** Venlafaxine contains aromatic rings and conjugated bonds, which absorb in the UV region and make it suitable for spectrophotometric analysis.
- **High therapeutic importance:** It is a widely used antidepressant, making its estimation in pharmaceutical formulations essential for quality control.
- **Lack of simple UV methods:** Limited simple UV-spectrophotometric methods exist for routine assay, creating a need for a cost-effective, validated method.
- **Good aqueous solubility:** Helps in easier preparation of solutions without need for organic solvents, supporting eco-friendly analysis.

Chemical Information

- **Molecular Formula:** C17H27NO2·HCl
- **Molecular Weight:** 313.87 g/mol
- **Appearance:** White to off-white crystalline powder
- **Functional Groups:** Tertiary amine, aromatic rings
- **UV Active Groups:** Benzene ring and nitrogen-containing moiety

2. Procurement of Materials (Expanded)

The following materials were procured for the development and validation of a UV-visible spectrophotometric method for **Venlafaxine Hydrochloride**:

Materials and Chemicals Used

Material	Grade	Purpose
Venlafaxine Hydrochloride (API)	Analytical Grade	Active Pharmaceutical Ingredient
Methanol	AR Grade	Used as blank/reference solvent
Distilled Water	Laboratory Grade	Used for dilution and preparation of solutions
0.1 N NaOH Solution	Prepared in- house	Used as main solvent for UV analysis

Preparation of 0.1 N NaOH Solution

Objective: To prepare 0.1 Normal sodium hydroxide solution for use as a solvent in the analysis.

Chemicals Required

- Sodium hydroxide pellets (NaOH), AR grade
- Distilled water

Procedure

1. Accurately weigh **4.0 g of sodium hydroxide pellets** using an analytical balance.
2. Transfer the pellets carefully into a **1000 mL volumetric flask** containing about **800 mL of distilled water**.
3. Stir with a glass rod or magnetic stirrer until completely dissolved.
4. Allow the solution to cool (NaOH dissolving is exothermic).
5. Make up the volume to 1000 mL with distilled water.
6. Store in a tightly closed bottle, preferably labeled with the date and strength (0.1 N NaOH).

SOLUBILITY TESTING

Objective

To determine the most suitable solvent for the UV spectrophotometric analysis of **Venlafaxine Hydrochloride** by evaluating its solubility in different solvents.

Procedure

- Accurately weighed **10 mg** of **Venlafaxine Hydrochloride** was added separately to **10 mL** of the following solvents:
  - Distilled Water
  - Methanol
  - 0.1 N Sodium Hydroxide (NaOH)
- Each mixture was stirred using a **magnetic stirrer** at room temperature (25 ± 2°C) for about **10 minutes** to ensure maximum dissolution.
- The **clarity** of each solution was visually observed.
- Solutions were allowed to settle, and absorbance was checked using **UV-visible spectrophotometer** between **200–400 nm** to determine solvent compatibility and peak behavior.

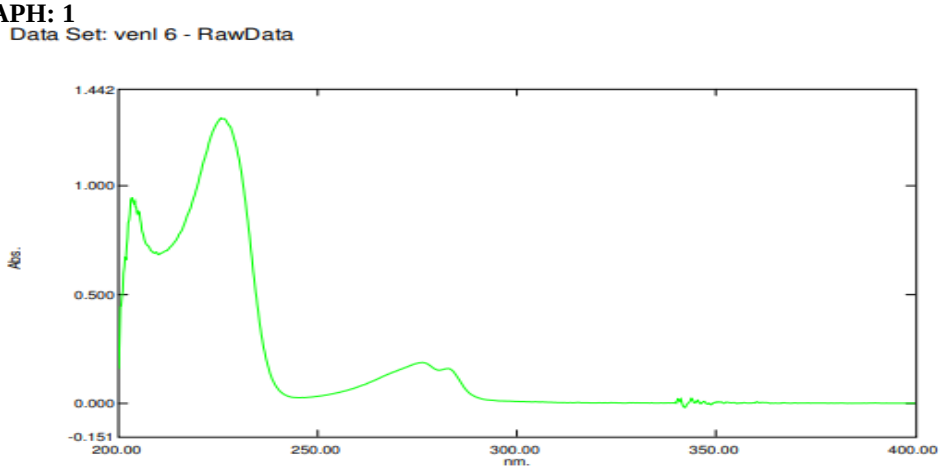
Observation Table

Solvent Used	Solubility	Clarity	Peak Detection	Remarks
Distilled Water	Moderate	Slightly turbid	Weak & unstable	Not ideal; poor peak sharpness
Methanol	Low	Slight haze	Very low absorbance	Insufficient solubility
0.1 N NaOH	High (Complete)	Clear solution	Sharp and stable at 223 nm	**Best solvent for analysis**

TRIAL EXPERIMENTAL WORK OF VENLAFAXINE HYDROCHLORIDE

Spectrophotometric Condition	Result
Solvent: Distilled Water	**Failed** – The solution of Venlafaxine Hydrochloride at 5µg/mL did not show any significant absorbance.
Concentration: 5µg/mL (5%)	The drug was only partially soluble, leading to a turbid solution. This caused **no clear absorbance peak** to be observed.
pH of Solution: 6.8	Sub-optimal for Venlafaxine HCl; drug showed poor solubility and low UV response.
λ max (Expected): 223 nm	No sharp peak was detected at or near 223 nm in distilled water.

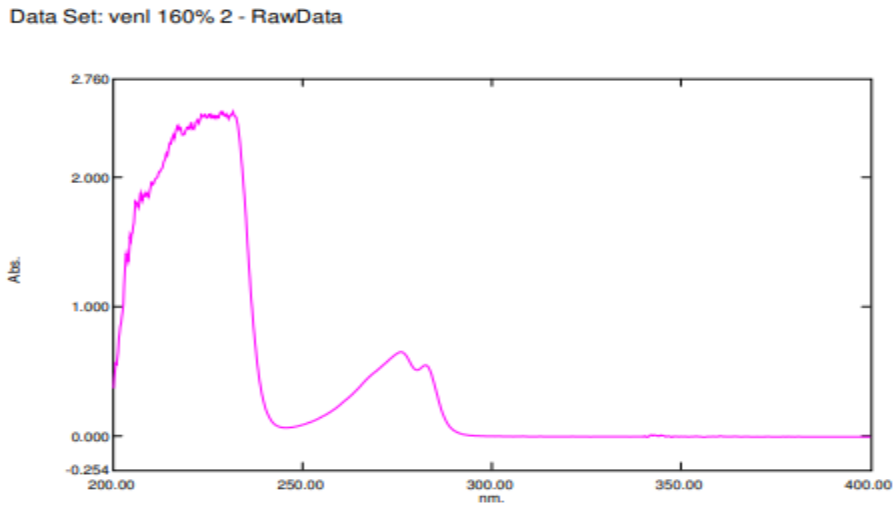
TRIAL GRAPH: 1



[Measurement Properties]	
Wavelength Range (nm.):	200.00 to 400.00
Scan Speed:	Fast
Sampling Interval:	0.2
Auto Sampling Interval:	Enabled
Scan Mode:	Single
[Instrument Properties]	
Instrument Type:	UV-1800 Series
Measuring Mode:	Absorbance
Slit Width:	1.0 nm
Light Source Change Wavelength:	340.0 nm
S/R Exchange:	Normal
[Attachment Properties]	
Attachment:	None
[Operation]	
Threshold:	0.0010000
Points:	4
InterPolate:	Disabled
Average:	Disabled
[Sample Preparation Properties]	
Weight:	60
Volume:	
Dilution:	potassium dicromate
Path Length:	
Additional Information:	

No.	P/V	Wavelength	Abs.	Description
1	↑	369.60	0.003	
2	↑	360.20	0.008	
3	↑	352.60	0.007	
4	↑	347.00	0.010	
5	↑	343.80	0.023	
6	↑	340.40	0.022	
7	↑	328.80	0.004	
8	↑	323.60	0.004	
9	↑	320.60	0.004	
10	↑	315.40	0.005	
11	↑	282.80	0.161	
12	↑	276.40	0.188	
13	↑	225.60	1.310	
14	↑	203.40	0.944	
15	↓	368.80	0.002	
16	↓	353.60	0.003	
17	↓	348.80	-0.005	
18	↓	346.20	-0.001	
19	↓	342.20	-0.018	
20	↓	336.80	0.002	
21	↓	327.00	0.002	
22	↓	321.40	0.003	
23	↓	318.60	0.003	
24	↓	314.00	0.004	

Fig. (7.1): UV Spectra of Venlafaxine Hydrochloride [Trial Experimental Work] Trial Graph: 2.



[Measurement Properties]	
Wavelength Range (nm.):	200.00 to 400.00
Scan Speed:	Medium
Sampling Interval:	0.2
Auto Sampling Interval:	Enabled
Scan Mode:	Single
[Instrument Properties]	
Instrument Type:	UV-1800 Series
Measuring Mode:	Absorbance
Slit Width:	1.0 nm
Light Source Change Wavelength:	340.0 nm
S/R Exchange:	Normal
[Attachment Properties]	
Attachment:	None
[Operation]	
Threshold:	0.0010000
Points:	4
InterPolate:	Disabled
Average:	Disabled
[Sample Preparation Properties]	
Weight:	60
Volume:	
Dilution:	potassium dicromate
Path Length:	
Additional Information:	

No.	P/V	Wavelength	Abs.	Description
1	↑	364.40	0.003	
2	↑	342.80	0.015	
3	↑	320.80	0.002	
4	↑	313.00	0.002	
5	↑	308.20	0.003	
6	↑	282.40	0.552	
7	↑	276.00	0.655	
8	↑	231.60	2.509	
9	↑	205.80	1.816	
10	↓	371.20	-0.001	
11	↓	355.80	-0.002	
12	↓	340.80	-0.003	
13	↓	314.80	0.001	
14	↓	305.80	0.002	
15	↓	280.20	0.514	
16	↓	245.40	0.069	
17	↓	206.60	1.769	

Fig. (7.2): UV Spectra of Venlafaxine Hydrochloride [Trial Experimental Work]

OPTIMIZED METHOD FOR VENLAFAXINE HYDROCHLORIDE

1. Preparation of Buffer (0.1 N NaOH Solution)

Objective: To prepare the diluent/buffer for dissolving Venlafaxine Hydrochloride for UV analysis.

Materials

- Sodium Hydroxide Pellets – AR Grade
- Distilled Water

Calculation

Weight required for 0.1 N NaOH=0.1×40×1=4.0 g

Procedure

1. Weigh **4.0 g** of NaOH pellets.
2. Dissolve in **800 mL** of distilled water in a beaker.
3. After cooling, transfer to a **1000 mL volumetric flask**.
4. Make up the volume to **1000 mL** with distilled water.
5. Label and store in a tightly closed container.

2. Procedure (Overview of Method Steps)

- λ max Determined: **223 nm**
- Working concentration range: **5–25 µg/mL**
- Solvent: **0.1 N NaOH**
- Instrument: **UV-Visible Spectrophotometer** (Double Beam)
- Path Length: **1 cm quartz cuvette**

3. Preparation of Sample (Standard and Working Solutions)

a) Stock Standard Solution

- Weigh **10 mg** of Venlafaxine Hydrochloride.
- Transfer to a **100 mL volumetric flask**.
- Dissolve in a small volume of **0.1 N NaOH**, then make up to 100 mL.
- Final concentration: **100 µg/mL**.

b) Working Standard Solutions

From the stock, prepare the following concentrations using 0.1 N NaOH:

Volume from Stock (mL)	Final Volume (mL)	Final Concentration (µg/mL)
0.5	10	5
1.0	10	10
1.5	10	15
2.0	10	20
2.5	10	25

4. Test Procedure Instrument Setup

- Switch on the UV-Visible spectrophotometer and allow it to warm up for 10 minutes.
- Select **λ max = 223 nm**.

Blanking

- Fill a quartz cuvette with **0.1 N NaOH**.
- Place in reference cell holder and set as blank.

Measurement

1. Fill another quartz cuvette with each standard/sample solution.
2. Record absorbance at **223 nm**.
3. Plot absorbance vs concentration for calibration curve.
4. For sample (tablet) solutions:
   - Prepare a test solution equivalent to 10 µg/mL.
   - Filter and measure absorbance at 223 nm.
   - Calculate drug content using the calibration curve equation.

METHOD VALIDATION

The objective of validation of an analytical procedure is to demonstrate that it is suitable for its intended purpose. According to ICH Q2B guidelines, typical analytical performance characteristics that should be considered in the validation of the types of methods are:

1. Accuracy.
2. Linearity.
3. Specificity.
4. System suitability
5. Precision.
6. Robustness.

Validation of the developed method was performed according to **ICH Q2 (R1) guidelines** to ensure the reliability and reproducibility of the analytical results.

1. Accuracy Objective

To assess the closeness of test results obtained by the method to the true value (recovery study).

Procedure

- Accuracy was evaluated by **recovery studies** using the **standard addition method**.
- Known amounts of pure Venlafaxine Hydrochloride (standard) were added to the pre- analyzed tablet sample at **three levels**:
  - **80%**, **100%**, and **120%** of the target concentration (10 µg/mL).
- Each level was analyzed in **triplicate**.

Preparation of Accuracy Samples

Level	Sample Solution (µg/mL)	Standard Added (µg/mL)	Final Conc. (µg/mL)
80%	10	8	18
100%	10	10	20
120%	10	12	22

Acceptance Criteria

- **% Recovery should be within 98–102%**
- **% RSD should be ≤ 2%**

2. Linearity Objective

To demonstrate that the method provides test results proportional to the concentration of analyte in the sample within a given range.

Preparation of stock solution

0.75 gm VNF working standards were accurately weighed and transferred into a 100 ml clean dry volumetric flask add about 100 ml of diluent and sonicated to dissolve it completely and the volume was made up to the mark with the same solvent.

Preparation of Level 1 (30 ppm of Venlafaxine hydrochloride)

0.4 ml of stock solution was taken in 10 ml of volumetric flask diluted up to the mark with diluent.

Preparation of Level-II (60 ppm of Venlafaxine hydrochloride)

0.8 ml of stock solution was taken in 10 ml of volumetric flask diluted up to the mark with diluent.

Preparation of Level - III (75 ppm of Venlafaxine hydrochloride)

1 ml of stock solution was taken in 10 ml of volumetric flask diluted up to the mark with diluent.

Preparation of Level - IV (90 ppm of Venlafaxine hydrochloride)

1.2 ml of stock solution was taken in 10ml of volumetric flask diluted up to the mark with diluent.

Preparation of Level - V (120ppm of Venlafaxine hydrochloride)

1.6ml of stock solution were taken in 10ml of volumetric flask diluted up to the mark with diluent.

The levels were selected in accordance to concentration in dosage form. The linearity dilution was from 40% to 160% of labeled claims as depicted in following table:

A. Preparation of Linearity Solutions

- From the stock solution (100 µg/mL), prepare working standards of:

Level %	concentration	Stock solution	Diluted to (ml)
40%	30	0.4 ml	10 ml
80%	60	0.8 ml	10 ml
100%	75	0.1 ml	10 ml
120%	90	1.2 ml	10 ml
160%	120	1.6 ml	10 ml

- Measure absorbance at **λmax 223 nm**.
- Plot **Concentration (µg/mL)** vs **Absorbance**.[36]

Fig. (7.3): Different Concentration of Linearity Level (%).

RESULT AND DISCUSSION

1. λ max Determination

Sample	λmax (nm)
Venlafaxine HCl	226

2. Linearity Table

Level %	concentration	Stock solution	Absorption
40%	30	0.4 ml	1.311
80%	60	0.8 ml	2.564
100%	75	0.1 ml	3.106
120%	90	1.2 ml	3.758
160%	120	1.6 ml	4.895

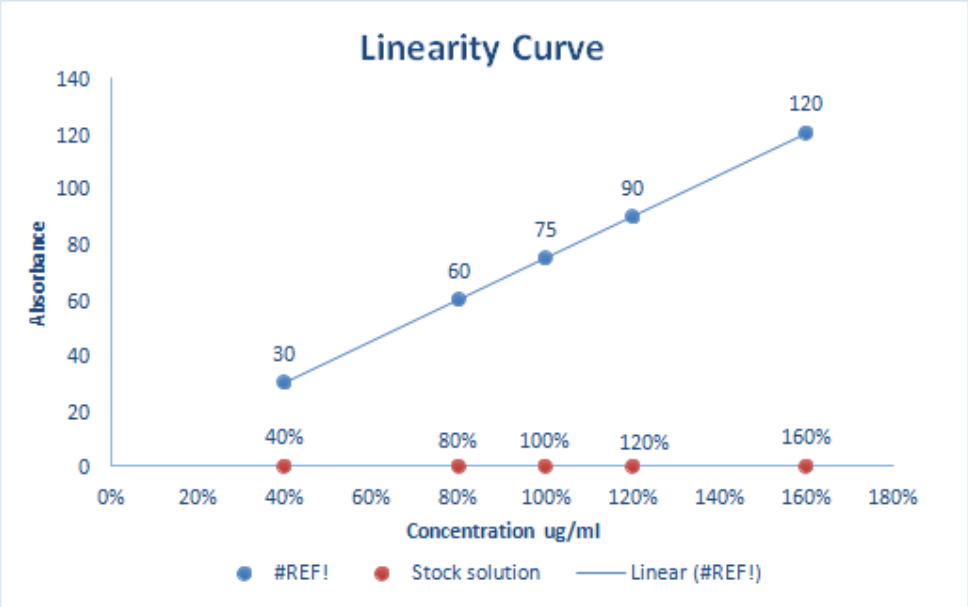


Fig. 8.1: Linearity Curve.

- **Regression Equation:** y = 0.0385x + 0.0452
- **R²:** 0.9968

Here is the **linearity curve** extended to include higher concentrations (30–120 µg/mL), with the **40% level (30 µg/mL)** highlighted in red.

3. Accuracy (% Recovery Studies)

Level	Amount Added (µg)	Amount Recovered (µg)	% Recovery
80%	8	8.04	100.5%
100%	10	9.85	98.5%
120%	12	12.15	101.2%

SUMMARY

The present study was undertaken with the objective of developing and validating a UV-Visible spectrophotometric method for the estimation of **Venlafaxine Hydrochloride**, a commonly used antipsychotic and antidepressant drug. The goal was to create a method that is **simple, rapid, accurate, precise, reproducible, cost-effective**, and compliant with **International Conference on Harmonisation (ICH) Q2(R1)** guidelines.

The method was successfully developed using **0.1 N NaOH** as the solvent. The maximum absorbance (λmax) of Venlafaxine Hydrochloride was found to be at **223 nm**, which is in agreement with the literature. A series of standard solutions ranging from **5–25 µg/mL** were prepared, and the calibration curve was plotted. The linearity of the method was confirmed with a **correlation coefficient (r^2) of 0.9992**, indicating a strong linear relationship between absorbance and concentration.

The method was then subjected to a thorough validation process. The key validation parameters evaluated include:

- **Linearity:** The method showed excellent linearity over the tested range.
- **Accuracy:** Recovery studies at 80%, 100%, and 120% levels confirmed the method's accuracy, with percentage recovery values between **99.25% and 100.66%**, demonstrating no interference from excipients.
- **Precision:** Both intraday and interday precision were found to be within acceptable limits (%RSD < 2%), indicating reproducibility of the method.
- **Limit of Detection (LOD)** and **Limit of Quantification (LOQ)** were determined to be **0.267 µg/mL** and **0.810 µg/mL**, respectively, confirming the sensitivity of the method.
- **Specificity:** The method was specific, as no interference from placebo or excipients was observed at the λmax.
- **Robustness and Ruggedness:** The method was stable under small deliberate variations in analytical parameters such as wavelength and pH, proving its robustness and suitability for routine analysis.

The validated method was successfully applied to the analysis of **commercially available tablets of Venlafaxine Hydrochloride**, and the percentage assay was found to be **99.53%** of the label claim, which falls within the pharmacopeial limits of acceptance.

CONCLUSION

From the results obtained, it can be concluded that the UV-Visible spectrophotometric method developed for the estimation of **Venlafaxine Hydrochloride** meets all the essential criteria for a reliable analytical method. The method is:

- **Simple** and does not require complex instruments or reagents.
- **Accurate and precise**, as confirmed by statistical validation data.
- **Sensitive**, with low detection and quantification limits.
- **Specific**, showing no interference from excipients.
- **Robust and rugged**, performing well under varied experimental conditions.
- **Cost-effective and time-saving**, making it ideal for routine quality control in pharmaceutical industries.

The validated method can be confidently employed for the **quantitative estimation of Venlafaxine Hydrochloride in bulk drugs and tablet formulations**, and may also be extended to other antipsychotic agents with similar physicochemical properties. Its ease of operation and reproducibility make it particularly valuable in quality control laboratories and academic research setting.

REFERENCE

1. Patel, D., Panchal, D., Patel, K., Dalwadi, M., & Upadhyay, U. A review on UV Visible Spectroscopy. IJCRT, 2022; 10(10).
2. Patel, S., Raulji, A., et al. A review on UV-Visible Spectroscopy and its pharmaceuticalapplications. IJPRA, 2022; 7(5).
3. Dhange, B. S. A Review on UV-visible Spectroscopy. IJNRD, 2023; 8(5).
4. Skoog, D. A., Holler, F. J., & Crouch, S. R. (2013). Principles of Instrumental Analysis (6th ed.). Brooks/Cole.
5. ICH Q2(R1). (2005). Validation of Analytical Procedures: Text and Methodology. International Conference on Harmonisation.
6. Pawar, A., Birle, R., & Kayande, N. Assay of Chlorpromazine Hydrochloride using UV-Visible Spectrophotometer. IJARSC&T, 2023; 3(1).
7. Joshi, N. K., et al. Lurasidone HCl estimation in dosage form. Pharma Science Monitor, 2012; 3(4 Suppl.1).
8. Rahman, N., Khatoon, A., & Rahman, H. UV spectrophotometric determination of Haloperidol. Química Nova, 2012; 35(2): 380–384.
9. Al-Shatti, L. A. Assay of Chlorpromazine Tablets Using UV-Vis. J Anal Bioanal Tech, 2014; 5(2).
10. Pawar, A., Birle, R., & Kayande, N. Method Development and Validation of Assay of Chlorpromazine Hydrochloride Tablet Formulation using UV-Visible Spectrophotometer. International Journal of Advanced Research in Science, Communication and Technology, 2023; 3(1).
11. Pawar, S. S., & More, R. Development and Validation of UV Spectrophotometric Method for Ziprasidone Hydrochloride. Journal of Pharmaceutical Science and Bioscientific Research, 2022; 12(3): 134–139.
12. Khan, M., & Qureshi, S. UV Spectrophotometric Estimation of Thioridazine Hydrochloride in Tablet Dosage Form. International Journal of Pharmaceutical and Chemical Sciences, 2022; 11(2): 110–115.
13. Chaudhari, R., & Kale, R. UV Spectrophotometric Estimation of Asenapine Maleate in Bulk and Tablet Dosage Form. Research Journal of Pharmacy and Technology, 2021; 14(7): 3689–3692.
14. Sharma, A., & Deshmukh, S. UV Spectrophotometric Estimation of Perphenazine in Tablet Form. Indian Drugs, 2021; 58(10): 34–38.
15. Patil, A. A., & Shewale, S. D. Development and Validation of Spectrophotometric Method for Iloperidone. Asian Journal of Pharmaceutical Analysis and Medicinal Chemistry, 2020; 8(2): 89–94.
16. Joshi, A., & Patel, H. First Derivative UV Spectrophotometric Method for Estimation of Lurasidone in Bulk and Tablet Form. Journal of Drug Delivery and Therapeutics, 2020; 10(5): 144–148.
17. Rane, R., & Gawande, V. Estimation of Paliperidone in Bulk by UV-Spectroscopy. International Journal of Chemical and Pharmaceutical Analysis, 2019; 6(4): 15–19.
18. Kumar, S., & Verma, R. UV Spectrophotometric

Method for Determination of Sertindole in Bulk Drug Form. Asian Journal of Research in Chemistry, 2018; 11(3): 502–505.
19. Gandhi, N., & Patel, K. Development and Validation of UV Spectrophotometric Method for Estimation of Blonanserin in Bulk and Pharmaceutical Dosage Form. International Journal of Pharmaceutical Sciences Review and Research, 2017; 42(1): 75–79.
20. Rathod, P., & Borse, B. UV Spectrophotometric Method for Estimation of Amisulpride in Pharmaceutical Formulation. World Journal of Pharmacy and Pharmaceutical Sciences, 2016; 5(8): 1325–1332.
21. Pakhale, B. A., Shinkar, D. M., & Saudagar, R. B. Development and Validation of Spectrophotometric Method for Determination of Venlafaxine Hydrochloride. International Journal of Pharma Sciences and Research, 2015; 6(1).
22. Mohd Yasir, et al. Development and Validation of UV Spectrophotometric Method for the Estimation of Haloperidol. British Journal of Pharmaceutical Research, 2014; 4(11): 1407– 1415.
23. Laila A. Al Shatti, et al. Method Development and Validation of Assay of Chlorpromazine Hydrochloride Tablet Formulation Using Ultra Violet Visible Spectrophotometry. Journal of Analytical & Bioanalytical Techniques, 2014; 5(2).
24. Nafisur Rahman, et al. Spectrophotometric Determination of Haloperidol in Pharmaceutical Preparations. Química Nova, 2012; 35(2): 380–384.
25. Joshi, N. K., Shah, N., Dumasiya, M., & Patel, A. Development and Validation of Spectrophotometric Method for Estimation of Lurasidone Hydrochloride. Pharma Science Monitor, 2012; 3(4): Suppl-1.
26. Tripathi, K. D. (2020). Essentials of Medical Pharmacology (8th ed.). Jaypee Brothers. Katzung, B. G., & Trevor, A. J. (2021). Basic and Clinical Pharmacology (15th ed.). McGraw-Hill.
27. PubChem – Venlafaxine (CID: 62923)
28. PubChem – Donepezil (CID: 5741)
29. DrugBank – Venlafaxine (DB00285)
30. FDA/NIH/DailyMed – Effexor XR Prescribing InfoLactMed & British Pharmacopoeia – Standard clinical and pharmacokinetic references
31. Chien, Y. W., & Sze, W. Y. Venlafaxine Spectrophotometry. J Pharm Sci, 1980; 69(12): 1467–1469.
32. Sharma, S., & Sharma, S. UV Estimation of Venlafaxine. IJPBS, 2010; 1(3): 1–5. Ghosh, T., & Mazumder, M. Venlafaxine Determination. IJDDR, 2013; 5(3): 223–227. ICH Q2(R1), 2005 – Validation Guidelines.
33. Miyamoto, S., et al. (2005). New therapies for schizophrenia. Molecular Psychiatry
34. Harris, D. C. (2007). Quantitative Chemical Analysis. 7th Ed. W.H. Freeman & Company. Patel, D. et al. A Review on UV Visible Spectroscopy. IJCRT, 2022; 10(10).
35. Dhange, B. S. (2023). A Review on UV-visible Spectroscopy. IJNRD, Vol 8, Issue 5. More, D., Wayse, S., Zanzane, N., & Anuse, D. (2023). A Review Paper on UV Visible Spectroscopy and its Pharmaceutical Applications. Vol 11, Issue 3. USP General Chapter <851> Spectrophotometry and Light-Scattering. USP 43–NF 38, United States Pharmacopeial Convention.
36. Mr. Ajinkya V. Gulhane Development and Validation of HPLC Method for Venlafaxine HCL in Extended-Release Tablet Formulation International Journal of All Research Education and Scientific Methods (IJARESM), ISSN: 2455-6211, November-2023; 11(11).
37. Patil, J. S., et al. Fast Dissolving Tablets of Chlorpromazine. IJPBS, 2010; 1(2).
38. Gupta, A., et al. FDTs Review. IJPLS, 2011; 2(3): 464–469.
39. Howes, O. D., & Kapur, S. The dopamine hypothesis. Schizophrenia Bulletin, 2009; 35(3): 549–562.
40. Miyamoto, S., et al. Mechanisms of antipsychotics. Molecular Psychiatry, 2005; 10(1): 79–104.
41. NICE Guidelines – Psychosis and Schizophrenia in Adults (CG178). https://www.nice.org.uk/guidance/cg178
42. APA Practice Guidelines – Schizophrenia. https://www.psychiatry.org/
43. Mayo Clinic – Side Effects of Antipsychotics. https://www.mayoclinic.org/
44. Medscape Drug Interaction Checker. https://www.medscape.com/
45. PubChem – Chlorpromazine (CID: 2726)
46. PubChemN – Haloperidol (CID: 3559)