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AN OVERVIEW ON ANALYTICAL METHODS FOR ESTIMATION OF VARENICLINE TARTRATE IN PHARMACEUTICAL DOSAGE FORM BY QBD APPROACH

Chaudhari Avan[1*], Dr. Sangita K. Patel[2], Khushbu S. Patel[3], Dr. C. N. Patel

[1]Student of pharmaceutical Quality Assurance, Shri Sarvajanik Pharmacy Collage, Arvind Baug Mehsana-384001, Gujarat, India.

[2]Associate Professor, Department of Pharmacognosy, Shri Sarvajanik Pharmacy Collage, Arvind Baug Mehsana-384001, Gujarat, India.

[3]Assistant Professor, Department of Pharmaceutical Quality Assurance, Shri Sarvajanik Pharmacy Collage, Arvind Baug Mehsana-384001, Gujarat, India.

[4]Principal and Professor, Department of Pharmaceutical Quality Assurance and Pharmaceutical Chemistry, Shri Sarvajanik Pharmacy Collage, Arvind Baug Mehsana-384001, Gujarat, India.

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***Corresponding Author**

Chaudhari Avan

Student of Pharmaceutical Quality Assurance, Shri Sarvajanik Pharmacy Collage, Arvind Baug Mehsana-384001, Gujarat, India.

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ABSTRACT

Varenicline tartrate is a selective partial agonist of the α4β2 nicotinic acetylcholine receptor widely used in smoking cessation therapy. By partially stimulating these receptors while simultaneously blocking the effects of nicotine, varenicline reduces cravings and withdrawal symptoms associated with tobacco dependence. Reliable analytical methods are essential for ensuring the quality, safety, and efficacy of varenicline tartrate in pharmaceutical formulations. Various analytical techniques, particularly chromatographic and spectroscopic methods such as HPLC and UV spectrophotometry, have been reported for its estimation in bulk drug and dosage forms. This article presents a concise overview of nicotine addiction, the pharmacological role of varenicline tartrate, its mechanism of action, and the α4β2 receptor system. In addition, a summarized literature review of reported analytical methods for

varenicline tartrate is discussed. The review highlights the importance of accurate and validated analytical approaches for routine pharmaceutical quality control and provides a foundation for future analytical method development.

KEYWORDS: Varenicline tartrate; Smoking cessation; Nicotinic acetylcholine receptor; Analytical methods; Literature review; Pharmaceutical analysis.

1. INTRODUCTION[1-11]

1.1 Introduction of Varenicline Tartrate[1]

Varenicline is a medicine that helps people stop smoking. It works on special receptors in the brain called nicotinic acetylcholine receptors. Instead of fully activating these receptors, it acts as a partial agonist this means it gives a mild effect while blocking nicotine from cigarettes. As a result, cravings and withdrawal symptoms become weaker, making it easier for people to quit smoking.

Varenicline was first approved in the USA in 2006 and is sold under the brand name Chantix. It is available as 0.5 mg and 1 mg tablets. The usual treatment starts with a small dose (0.5 mg once daily) and is slowly increased to 1 mg twice daily, usually for at least 12 weeks after quitting.

Common side effects were Nausea, Trouble sleeping/vivid dreams, Anxiety, dizziness, or headache, Changes in appetite and dry mouth. Rarely, it can cause serious allergic skin reactions (like Stevens-Johnson syndrome) or mild liver problems.

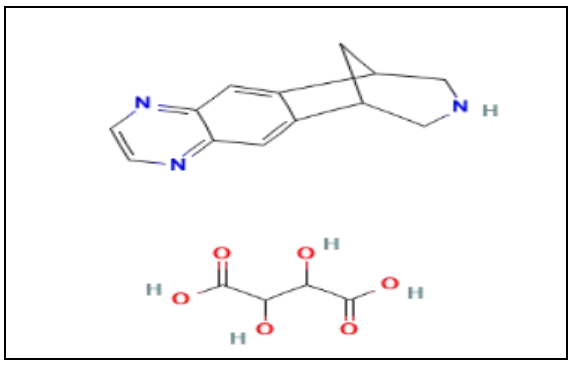

Figure 1: Structure of Varenicline tartrate.

1.1.1 General Introduction of Partial Agonist at Nicotinic Acetylcholine Receptors[2]

Nicotinic receptors are special proteins found in the brain, nerves, and muscles. When nicotine or certain drugs bind to these receptors, they become active and send signals.

Agonists are Drugs that fully activate these receptors. Partial agonists were Drugs that only partly activate them while blocking stronger effects from nicotine.

Varenicline is a partial agonist. It slightly stimulates the receptor (reducing withdrawal symptoms) but also prevents nicotine from binding (reducing pleasure from smoking). This makes it useful in smoking cessation therapy.

Varenicline is a quit-smoking drug and Works as a partial agonist (mild stimulation + blocking nicotine). It Helps reduce cravings & relapse. Approved in 2006, marketed as Chantix.

Introduction of Quality by Design (QbD)[3-4]

The expression "Quality by Design" refers to the achievement of a defined and consistent level of quality. Compiling variables and their relationships over the optimal set of tests, known as an Experimental Design, is a very useful component of QbD.

Although quality by design principles have been applied to improve the quality of products and user experiences in all industries, the US Food and Drug Administration (USFDA) has recently adopted them to change the way that pharmaceuticals are discovered, developed, and sold. This was initially published in "Drug cGMPs for the twenty-first century" by the US Food and Drug Administration (USFDA). The International Council for Harmonization (ICH) rules further encourage this approach, which has become significant for the pharmaceutical business.

1.1.2 Mechanism of Action[5-7]

Varenicline acts on α4β2 nicotinic acetylcholine receptors in the brain, which are involved in nicotine addiction. It works as a partial agonist, meaning it stimulates these receptors but less strongly than nicotine. This causes a small release of dopamine, which helps reduce withdrawal symptoms and cravings. At the same time, varenicline blocks nicotine from binding to these receptors. Because of this, smoking becomes less pleasurable and the urge to smoke decreases. This helps people quit smoking and prevents relapse.

The mechanism of action of varenicline tartrate in relation to nicotine addiction. When a person smokes, nicotine enters the brain and binds to α4β2 nicotinic acetylcholine receptors on dopamine neurons in the ventral tegmental area (VTA**)**. This activation causes rapid neuronal firing and leads to a large release of dopamine in the nucleus accumbens, producing

the pleasurable and reinforcing effects of smoking. In the absence of nicotine, these receptors are not strongly stimulated, resulting in low dopamine release and causing withdrawal symptoms and cravings. Varenicline tartrate acts as a partial agonist at the α4β2 receptors. It binds to these receptors and produces a moderate release of dopamine, which helps reduce withdrawal symptoms. At the same time, it blocks nicotine from binding to the receptors, preventing the strong dopamine surge normally caused by smoking. As a result, the pleasure associated with smoking is reduced, helping individuals decrease cravings and quit smoking.

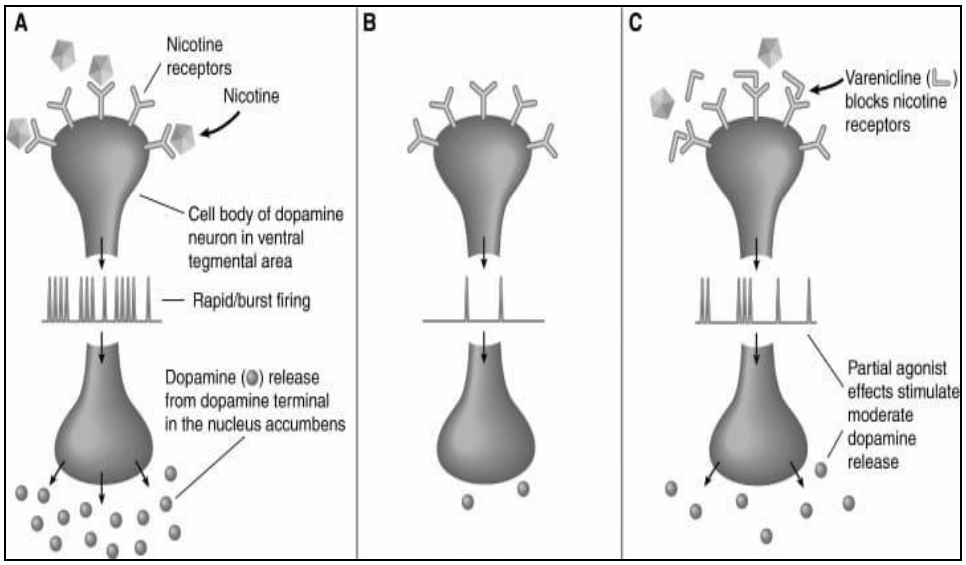

Figure 2: Mechanism of action of Varenicline tartrate.

Literature review of Varenicline tartrate[8-15]

- Official method for Varenicline tartrate is not available in pharmacopoeia.
- Only reported are available for Varenicline tartrate.

Table 1: Reported method for assessment of Varenicline Tartrate.

Sr. No	Title	Description	Ref. No
HPLC (High Performance Liquid Chromatography) Methods			
1.	Development and validation of **RP HPLC Method** for Estimation of **Varenicline Tartrate** in Bulk Drug and Tablet Dosage Form	**Stationary Phase**: C_{18} column (250 x 4.6 mm, 5 µm) **Mobile Phase:** Methanol: Potassium dihydrogen orthophosphate (pH 3.5) (50:50% v/v) **Detection:** 237 nm **Flow rate:** 0.6 mL/min	08
2.	Development and validation of **Analytical Method** for Simultaneous Estimation of Varenicline Tartrate and Bupropion Hydrochloride	**Stationary Phase:** C_{18} column (250 x 4.6 mm, 5 µm) **Mobile Phase:** Methanol:phosphate with (pH 3) (65:35% v/v) **Detection:** 244 nm **Flow rate:** 1 mL/min	09

3.	A Novel Stability Indicating **RP-HPLC** Assay Method for the Determination **Varenicline** in Pharmaceutical Formulations	**Stationary Phase:** Inertsil ODS 3 V (150 x 4.6 mm, 5µm) **Mobile Phase**: Tri fluro acetic acid:Methanol:Acetonitrile (pH 2.1) (8:1:1 %v/v/v) **Detection:** 235 nm **Flow rate**: 1 mL/min	10
4.	Stress Degradation Studies on **Varenicline Tartrate** and Development of a Validated Stability Indicating **HPLC Method**	**Stationary Phase:** C_{18} column (250 x 4.6 mm, 5µm) **Mobile Phase:** Water: Acetonitrile with (pH 4) (1:1% v/v) **Detection:** 237 nm **Flow rate:** 1 mL/min	11
5.	A Validated Stability Indicating **HPLC Method** for Determination of **Varenicline** in its Bulk and Tablets	**Stationary Phase:** C_8 column (150 x 4.6 mm, 5 µm) **Mobile Phase:** Acetonitrile: Potassium dihydrogen phosphate with (pH 3.5) (10:90% v/v) **Detection:** 235 nm **Flow rate**: 1 mL/min	12
6.	Development and Validation of the **HPLC Method** for **Varenicline** Determination in Pharmaceutical Preparation	**Stationary Phase:** $RP_{18}e$ column (100×4.6 mm, 2 µm, mesopores 13µm) **Mobile Phase:** Sodium benzoate: Trifluoroacetic acid with (pH 3.5) (55:45% v/v) **Detection:** 320 nm **Flow rate:** 1.2 mL/min	13
7.	Novel Liquid **Chromatographic Methods** for the Determination of **Varenicline Tartrate**	**Stationary Phase:** C_{18} column (100 × 2.1 mm, 5 µm) **Mobile Phase:** Potassium dihydrogen phosphate:Octane sulphonic acid with (pH 5) (86:14% v/v) **Detection:** 474 nm and 539 nm **Flow rate:** 1 mL/min	14
8.	Development and Validation of the **UV Spectroscopic Method** for **Varenicline** Determination in Pharmaceutical Preparation	**Solvent:** Sodium benzoate **Wavelength:** 236nm and 319nm **Linearity:** 5-40 µg/mL	15

CONCLUSION

Varenicline tartrate is an important therapeutic agent used in the management of nicotine dependence and smoking cessation. Due to its pharmacological significance, accurate and reliable analytical methods are required for its determination in bulk drugs and pharmaceutical formulations. Various chromatographic and spectroscopic techniques have been reported in the literature for the estimation of varenicline tartrate. The reviewed studies demonstrate ongoing efforts to develop sensitive, precise, and validated analytical methods suitable for routine quality control. As that all work releted to Method at Overall, these article given Information about as that literature review summary that may useful for our research work.

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