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Research Article

A Comprehensive Review On Analytical Methods Used For The Estimation Of Escitalopram

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ABSTRACT

Escitalopram is a selective serotonin-reuptake inhibitor (SSRI) and an antidepressant used to treat Major Depressive Disorder. In 2011, escitalopram was approved in over 100 countries. Different analytical methods are being developed to identify the physicochemical properties of escitalopram in pharmaceutical dosage forms, chemical substances, and synthetic compositions. The Literature Review survey provides the most appropriate techniques for estimating escitalopram and identifies the most efficient solvents used to estimate escitalopram.

INTRODUCTION

Escitalopram is the S-enantiomer of citalopram, a selective serotonin reuptake inhibitor (SSRI) used to treat Major Depressive Disorder with high overall tolerability. Escitalopram medication is less likely than many other antidepressants to result in clinically significant drug interactions. The key isoenzymes involved in escitalopram metabolism are cytochrome P450 (CYP) 2C19, CYP3A4, and CYP2D6. Escitalopram was approved in 100 countries across Europe, North

America, and other regions as of November 2011. Escitalopram is used to treat generalized anxiety disorder, social anxiety disorder, obsessive-compulsive disorder, panic disorder, premenstrual dysphoric disorder, and major depressive disorder. Escitalopram inhibits SERT with great selectivity and dose-dependent efficacy. Its antidepressant properties derive from its suppression of serotonin reuptake into presynaptic nerve endings, which increases serotonin activity in the central nervous

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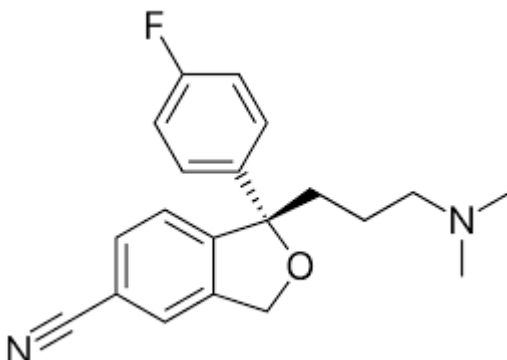
system. Radioligand binding experiments evaluated that escitalopram had significantly higher selectivity for SERT than citalopram and several other SSRIs. Two decision-analytic investigations conducted in Finland and Sweden discovered that when used to treat addiction, escitalopram had a higher cost utility than the other three medicines. Escitalopram should not be used in conjunction with irreversible monoamine oxidase inhibitors (MAOIs), and at least 2 weeks

should pass between discontinuing escitalopram and starting an irreversible MAOI.

Drug Profile[4] :

Escitalopram is an anti-depressant medication used to treat major depressive disorder. Amongst the SSRIs, escitalopram has the highest degree of selectivity for the serotonin transporter (SERT) compared to other off-targets, which may explain why it has lower rates of side effects than other drugs in its class.

Table 1: Drug Profile of Escitalopram

Name	Escitalopram
IUPAC Name	(1S)-1-[3-(dimethylamino)propyl]-1-(4-fluorophenyl)-1,3-dihydro-2-benzofuran-5-carbonitrile
Category	Anti-depressant
Class	selective serotonin reuptake inhibitors (SSRIs)
CAS NO.	128196-01-0
Molecular Formula	C ₂₀ H ₂₁ N ₂ O
Structural Formula	
Molecular weight	324.3919 g/mol
Appearance	white to slightly-yellow powder
Solubility	freely soluble in methanol and dimethyl sulfoxide (DMSO), soluble in isotonic saline solution, sparingly soluble in water and ethanol, slightly soluble in ethyl acetate, and insoluble in heptane.
pKa	9.78
Melting Point	147-152°C
Partition Co-efficient (log p)	3.76

Current studies on Escitalopram

A recent study investigated the cognitive effects of chronic escitalopram administration in healthy volunteers. Another study explored escitalopram's effects on synaptic density in the human brain.

Research has also examined the long-term effects of escitalopram on cardiac outcomes in patients who have experienced acute coronary syndrome (ACS).



Literature Review

Table 2: Reported UV method for Escitalopram

Sr No.	Title	Description
1	Simultaneous Estimation of Escitalopram oxalate and Etizolam in Bulk and Pharmaceutical Dosage Form by UV. ^[5]	Solvent -Methanol and Water λ_{max} – escitalopram at 236 nm and etizolam at 250 nm Linearity - 10-30 $\mu\text{g/ml}$ for Escitalopram oxalate and 2-10 $\mu\text{g/ml}$ for Etizolam
2	Development of Simple, Precise UV Spectroscopic Method for the Estimation of Escitalopram Oxalate in Bulk and Marketed Tablets. ^[6]	Solvent – methanol and phosphate buffer λ_{max} - 238 nm Linearity - 2-10 $\mu\text{g/ml}$
3	Method Development & Validation of Escitalopram Oxalate & Etizolam By Uv-Spectrophotometry. ^[7]	Solvent – methanol λ_{max} - 238.0 nm and 248.6 nm Linearity - 10.0 - 60.0 $\mu\text{g/ml}$ for Escitalopram oxalate and 1.0 – 6.0 $\mu\text{g/ml}$ for etizolam
4	Development of UV Spectroscopic Method for Nefopam and Escitalopram as INN Drugs in Tablet Dosage Form. ^[8]	Solvent – water λ_{max} - 266nm and 284nm Linearity - 50-400 $\mu\text{g/ml}$ for Nefopam and 25-200 $\mu\text{g/ml}$ for Escitalopram
5	Development and Validation of Spectrophotometric Methods for Simultaneous Estimation of Escitalopram oxalate and Etizolam in their Combined Tablet Dosage Form. ^[9]	Solvent – 0.1 N HCl Method 1: λ_{max} - 238.2 nm and 251.6 nm Method 2: λ_{max} - 238.2 nm and 248.8 nm Method 2: λ_{max} - 238.2 nm and 292.8 nm Linearity - 10-60 $\mu\text{g/ml}$ for Escitalopram oxalate and 5-30 $\mu\text{g/ml}$ for Etizolam
6	Zero order spectrophotometric method for estimation of escitalopram oxalate in tablet formulations. ^[10]	Solvent – 80% v/v methanol in water λ_{max} - 238 nm Linearity - 2-20 $\mu\text{g/ml}$

Table 3: HPLC method of escitalopram

Sr No.	Title	Description
1	Development and Validation of Rp-Hplc Method for The Estimation of Escitalopram Oxalate and Flupentixol Dihydrochloride in Combined Dosage Form and Plasma. ^[11]	Mobile Phase - potassium dihydrogen orthophosphate buffer: methanol: acetonitrile [30:60:10 v/v/v] pH adjusted to 11 Stationary phase = C ₈ [150×4.6 mm] 3.5 μm λ_{max} -230nm Flow Rate : 1.5 ml/min

		Concentration range- 10-50 µg/ml for escitalopram oxalate and 1-5 µg/ml for flupentixol
2	Development and validation of an RP-HPLC method for the simultaneous determination of Escitalopram Oxalate and Clonazepam in bulk and its pharmaceutical formulations. ^[12]	Mobile Phase - buffer and acetonitrile in a ratio of 50:50 % v/v Stationary phase = Hypersil ODS C18 column (250mm X 4.6mm; 5µ) λ_{max} -240nm Flow Rate: 1mL/min Retention time- Escitalopram oxalate-2.840± 0.007min and Clonazepam -4.007±0.006 min Concentration range- 20-120µg/ml and 1-6µg/ml for Escitalopram oxalate and Clonazepam.
3	Development and Validation of a Chiral HPLC Method for Quantitative Analysis of Enantiomeric Escitalopram. ^[13]	Mobile Phase- ammonium acetate/ ethanol/ 2-propanol/ methylene dichloride (100 : 150 : 70 : 30, % v/v) Stationary phase : The Chiral CD-PH λ_{max} -254nm Flow Rate: 0.5 mL/min Concentration range- 20.0-70.0 µg/ml
4	Development and Validation of Stability Indicating Rp-Lc, Short Runtime Method for The Estimation of Escitalopram in Escitalopram Dosage Form. ^[14]	Mobile Phase- 0.01 M potassium dihydrogen orthophosphate buffer (pH 7.0), acetonitrile and methanol, 60:28:12 % V/V/V Stationary phase : Waters BEH C8 (100mm x 2.1mm) 1.7µm λ_{max} - 239nm Flow Rate: 0.4 mL/min Concentration range- 6-18 µg/ml
5	Eco-friendly based stability-indicating RP-HPLC technique for the determination of escitalopram and etizolam by employing QbD approach. ^[15]	Mobile Phase- ethanol and phosphate buffer (60:40 % v/v) Stationary phase : Phenomenex column C ₁₈ λ_{max} - 254nm Flow Rate: 1 mL/min Concentration range- 5–30 µg/mL for ESC, 2–12 µg/mL for ETZ
6	Stability-Indicating RP-HPLC Method for the Simultaneous Determination of Escitalopram Oxalate and Clonazepam. ^[16]	Mobile Phase- acetonitrile –50 mM phosphate buffer 1 10 mM triethylamine (70:30, % v/v) Stationary phase: n ODS Hypersil C18 column (250 X 4.6 mm) λ_{max} - 268nm Flow Rate: 1.5 mL/min Concentration range- ESC- 5.0 to 25.0 µg /mL; CLO - 0.5 to 2.5 µg /mL.
7	Development and Validation of Stability Indicating Rp-Hplc Method for Simultaneous Estimation of Escitalopram and L-Methylfolate In Bulk and Tablet Dosage Form. ^[17]	Mobile Phase- orthophosphoric acid buffer, Acetonitrile, (45:55 % v/v) Stationary phase: DSC18 column (4.6x250mm,5µ λ_{max} - 215nm Flow Rate: 1 mL/min Concentration range- 18.75- 112.5µg/mL of Escitalopram and 25-150µg/mL of L-methyl folate
8	Development and Validation of Analytical Method by Reverse Phase HPLC for the	Stationary phase: Atlantis Hilic Silica, 5m, C-18 column (4.6250mm) λ_{max} - 238nm

	Estimation of Escitalopram oxalate in Bulk and Dosage form. ^[18]	Flow Rate: 1 mL/min Concentration range- 100-600µg/ml Rt Time- 4.7 min
9	Stability Indicating Chromatographic Method Development and Validation for The Simultaneous Estimation of Escitalopram Oxalate and Flupentixol in Its Pharmaceutical Dosage Form by HPLC. ^[19]	Mobile Phase- Potassium Dihydrogen Phosphate Buffer, pH-5.5 & mobile phase B Methanol (35: 65) Stationary phase: C18 Column (25 cm X 0.46 cm) λmax - 302nm Flow Rate: 1 mL/min Concentration range- 20-60 µg/ml for Escitalopram Oxalate and (1-3 µg/ml) for Flupentixol
10	RP-HPLC method for simultaneous determination of escitalopram oxalate and flupentixol HCl in tablet dosage form. ^[20]	Mobile Phase- mixture of acetonitrile and potassium phosphate buffer (pH 7.0 with 0.1% triethylamine) in the ratio 60: 40 %v/v Stationary phase: C18 Grace (250mmX 4.6mm) λmax - 231nm Flow Rate: 1 mL/min Concentration range- ESC-5-25 µg/ml and FLU-10-50 µg/ml
11	A New Stability Indicating Validated RP-HPLC Method for Simultaneous Estimation of Escitalopram and Clonazepam in Bulk and Tablet Dosage Form. ^[21]	Mobile Phase- phosphate buffer and acetonitrile (55: 45 v/v) Stationary phase: C18 λmax - 231nm Flow Rate: 1 mL/min Concentration range- 1–200 µg/mL for escitalopram and 1.5–150µg/mL for clonazepam
12	RP-HPLC method development and validation for simultaneous estimation of escitalopram oxalate and atazanavir sulphate in bulk and dosage form. ^[22]	Mobile Phase- acetonitrile/phosphate buffer (pH =3.55) Stationary phase: C18 Inertsil ODS 3V (250 * 4.6 mm, 5.0 m) λmax - 210nm Flow Rate: 1 mL/min Concentration range- escitalopram oxalate (2.5 - 15 µg/ mL) and atazanavir sulphate (30 - 150.0 µg/mL)
13	Spectrophotometric and Reversed-Phase High-Performance Liquid Chromatographic Methods for Simultaneous Determination of Escitalopram Oxalate and Clonazepam in Combined Tablet Dosage Form. ^[23]	Mobile Phase- acetonitrile–0.005 M tetrabutylammonium hydrogen sulfate (55:45, %v/v) Stationary phase: HiQ SiL C18 column (250 x 4.6 mm id) λmax - 287nm Flow Rate: 1 mL/min Concentration range- 10.0–60.0 µg/mL and 0.5–3.0 µg/mL for ESC and CLO
14	Analytical Method Development and Validation for Simultaneous Estimation of Olanzapine and Escitalopram Oxalate by Using HPLC and UV Spectrophotometric Method. ^[24]	Mobile Phase- methanol: water (60:40 %v/v) Stationary phase: hibarR 250-4.6 HPLC column purosphensR STAR RP-18 λmax - 239nm Flow Rate: 1 mL/min
15	Development and Validation of HPLC Method for The Estimation of Escitalopram Oxalate and Tolterodine	Mobile Phase- acetonitrile : methanol : ammonium acetate buffer pH 3.0 in the ratio 30:20:50 %V/V/V for ESC

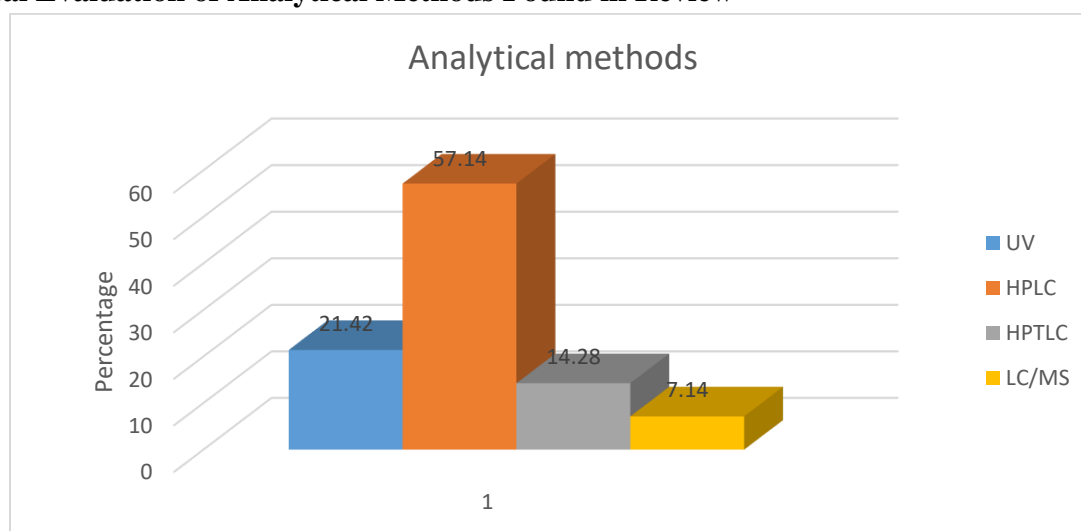
	Tartrate in Oral Dosage Forms. ^[25]	<p>For TOL: acetonitrile: methanol: ammonium acetate buffer pH 3.0 in the ratio 30:30:40 %V/V/V</p> <p>Stationary phase: Kromosil C18 (250 mm x 4.6 mm) 5 μm</p> <p>λ_{\max} - 238nm and 281 nm</p> <p>Flow Rate: 1 mL/min</p> <p>Concentration range- 5-15 μg/ml for ESC, 10-30 μg/ml for TOL</p>
16	Determination of Escitalopram Oxalate and L-Methylfolate in Tablet by Spectrophotometric and Reverse Phase High-Performance Liquid Chromatographic Methods. ^[26]	<p>Mobile Phase- methanol-0.02 M phosphate buffer (pH 5.5) (75:25, %v/v)</p> <p>Stationary phase: Hypersil BDS-C₁₈ Column (5 μm, 250 mm x 4.6 mm i.d.)</p> <p>λ_{\max} - 270 nm</p> <p>Flow Rate: 1 mL/min</p> <p>Concentration range- 3.0–30.0 and 0.75–22.5 μg/mL for ESC and L-MF</p>

Table 4: HPTLC method of Escitalopram

Sr no.	Title	Description
1	Development and validation of HPTLC method for the estimation of escitalopram oxalate and flupentixol dihydrochloride in pharmaceutical formulation. ^[27]	<p>Mobile Phase- Chloroform: Methanol (4:6% v/v)</p> <p>Stationary phase: silica gel 60 F₂₅₄</p> <p>λ_{\max} -254nm</p> <p>Rf Value : escitalopram-0.24 and flupentixol- 0.44</p> <p>Concentration range= 3-7 μg/spot for ESC and 0.3-0.7μg/spot for FLU</p>
2	Application of Stability Indicating HPTLC Method for Quantitative Determination of Escitalopram Oxalate in Pharmaceutical Dosage Form. ^[28]	<p>Mobile Phase- Ethanol: Water with 0.1% orthophosphoric acid (5:5 v/v)</p> <p>Stationary phase: silica gel 60 F₂₅₄</p> <p>Rf Value: 0.34 and 0.53 in the case of ESC and ETZ</p> <p>Concentration range= 100–600 μg mL⁻¹ for ESC and 300–1800 μg mL⁻¹ for the drug ETZ</p>
3	HPTLC Method for Simultaneous Analysis of Escitalopram Oxalate and Clonazepam in Pharmaceutical Preparations. ^[29]	<p>Mobile Phase- methanol-toluene-triethylamine 1:3.5:0.1 (v/v)</p> <p>Stationary phase: silica gel 60 F₂₅₄</p> <p>λ_{\max} -253nm</p> <p>Rf Value : ESC and CLO were 0.36 and 0.49</p> <p>Concentration range= 50–150 μg mL⁻¹ for ESC and 5–15 μg mL⁻¹ for CLO.</p>
4	Simultaneous HPTLC Determination of Escitalopram Oxalate and Clonazepam in Combined Tablets. ^[30]	<p>Mobile Phase- toluene-ethyl acetate-triethylamine 7:3.5:3 (v/v)</p> <p>Stationary phase: silica gel 60 F₂₅₄</p> <p>λ_{\max} - 258 nm</p> <p>Concentration range= 250–2,500 and 50–500 ng band⁻¹</p>

Table 5 LC/MS method of Escitalopram

Sr No.	Title	Description
1	Liquid chromatography–electrospray ionisation mass spectrometry method for the determination of escitalopram in human plasm, and its application in bioequivalence study. ^[31]	Stationary phase: ODS YMC™ AQ 150 mm × 4.6 mm Mobile Phase: 2.0 mM ammonium acetate (pH 5.0)–acetonitrile (54:46, v/v) Flow rate: 1 ml/min Conc Range: 1.0–200 ng/ml
2	Quantitation of escitalopram and its metabolites by liquid chromatography-tandem mass spectrometry in psychiatric patients: New metabolic ratio establishment. ^[32]	Stationary phase: ACE-3 C 8 (3 μm,3.0 mm 150 mm) Mobile Phase: ammonium formate in methanol:acetonitrile (50:50 v/v) Flow rate: 0.5 ml/min Conc Range: 5.9 to 441.8 ng/ml

Graphical Evaluation of Analytical Methods Found in Review

Escitalopram is the selective serotonin-reuptake inhibitor (SSRI) used as first line medication for the treatment of Major Depressive Disorder. In 2011, escitalopram was approved in 100 countries in Europe, North America, and other regions. There are many analytical methods available for estimation of escitalopram alone or in combination with other drugs. Among these methods HPLC assisted with UV and PDA detector are abundant analytical techniques available in literature review for estimation in pharmaceutical dosage forms as well as in synthetic composition. On the basis of literature review we found that most of the methods are developed using phosphate buffer and methanol as solvents.

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