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Review Article

A Review on Various Analytical Methodologies for Buspirone

Vikas R. Patil¹*, Vinay V. Sarode², Samir B. Tadvi³, Bhushan P. Patil⁴, Vaishali Badgujar⁵, Shweta V. Rane⁶, Kunal M. Jadhav⁷

¹Assistant Professor, Department of Pharmaceutical Chemistry, Smt. Sharadchandrika Suresh Patil College of Pharmacy, Chopda, Maharashtra, India.

²*Research Scholar, Department of Pharmacology, VYWS, Institute of Pharmaceutical Education and Research, Borgaon (Meghe), Wardha, Maharashtra, India.*

³Assistant Professor, Department of Pharmaceutics, Smt. Sharadchandrika Suresh Patil College of Pharmacy, Chopda, Maharashtra, India.

⁴Assistant Professor, Department of Pharmacognosy, Smt. Sharadchandrika Suresh Patil College of Pharmacy, Chopda, Maharashtra, India.

⁵Assistant Professor, Department of Pharmaceutical Chemistry, TSPM's Trimurti Institute of Pharmacy, Paldhi, Jalgaon, Maharashtra, India

⁶*Research Scholar, Department of Pharmaceutical Chemistry, LTJSS, Priyadarshini J. L. College of Pharmacy, Nagpur, Maharashtra, India.*

⁷Student, TSPM's Trimurti Institute of Pharmacy, Paldhi, Jalgaon, Maharashtra, India.

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ABSTRACT

Buspirone is a psychotropic drug which belongs to the class of compounds known as azaspirodecanediones. Buspirone used primarily as an anxiolytic. It specifically used for generalized anxiety disorder. As an anxiolytic drug buspirone is as potent as benzodiazepines, but it does not cause the adverse side effects, for example sedation, anti-convulsion or muscle relaxation. Buspirone was first approved in 1986 by USFDA. Therefore, the main objective of this analysis of Buspirone in pharmaceutical and biological formulation is in both qualitative and quantitative terms. In this review article, we have summarized UV/Vis spectroscopy, high- performance liquid chromatography (HPLC). High-performance thin-layer chromatography (HPTLC), Liquid chromatography-mass spectroscopy-mass spectroscopy (LC-MS/MS) etc. based methods for estimation of Buspirone. In addition to that, we have discussed the bioanalytical methods for Buspirone analysis. In conclusion, this review article will help to research scholars for further method development for drug estimation in pharmaceutical dosage forms and biological fluids.

*Corresponding Author: Vikas R. Patil

Address: Department of Pharmaceutical Chemistry, Smt. Sharadchandrika Suresh Patil College of Pharmacy, Chopda, Maharashtra, India

Email 🖂 : vikaspatil259@gmail.com

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INTRODUCTION

Buspirone is the member of azapirone group of anxiolytic agents which is widely used in anxiolytic therapy ^[1]. BSP does not cause sedation or depression of central nervous system. Buspirone is chemically known as 8-{4-[4-(2pyrimidinyl)-1-piperazinyl] butyl}-8-azaspiro [4,5]decane-7,9-dione (Figure 1) ^[2]. It contains pyrimidinylpiperazine and the azaspirodecanedione linked together ^[3]. BSP is used in several psychological disorders, including generalized anxiety disorder and also treat nonspecific anxiety symptoms with or without associated symptoms of depression ^[4]. BSP having anxiolytic, anticonvulsant, hypnotic, and also muscle relaxant properties ^[3]. Buspirone is belongs to the widely investigated arylpiperazine class of serotonin 5HT1A receptor ligands ^[4].

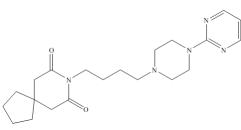


Figure 1: Chemical structure of BSP MECHANISM OF ACTION

In the generalized anxiety disorder the therapeutic action of buspirone is to be mainly interaction with two major subtypes of 5-HT1A receptor. These receptors are involved in the brain's anxiety and fear circuitry which enhances the serotonergic activity in the brain areas. At presynaptic 5-HT1A receptors or at 5-HT1A auto receptors BSP acts as a full agonist, while at the postsynaptic 5-HT1A receptors acting as a partial agonist. 5-HT1A receptors is inhibitory auto receptors which is Gprotein coupled receptors that couple to Gi/Go proteins. When the presynaptic 5-HT1A auto activates receptors it causes neuron hyperpolarization and it reduces the firing rate of the serotonergic neuron, it decreases the extracellular serotonin levels in the neuron's projection areas. Activated 5-HT1A receptors present in postsynaptically promotes hyperpolarization to released serotonin neurons. The main pharmacological action of Buspirone i.e. anxiolytic action is arises due to presynaptic 5-HT1A auto receptors. BUSP act as a potent agonist of presynaptic 5-HT1A auto receptors, it initially causes activation of these auto receptors and inhibits the release of serotonin ^[5].

PHARMACOKINETICS Absorption

Buspirone is rapidly absorbed in empty stomach. Due to extensive first pass metabolism its bioavailability is low and variable (approximately 5%). While taken with food the absorption of buspirone is decreased, the first-pass metabolism of the BSP is also decreases, which results the bioavailability increases as well as Cmax and AUC also increases^[5].

Distribution

The volume of distribution of buspirone was 5.3 L/kg. The buspirone bound to plasma proteins is approx. 86%. BSP is mainly bound to human serum albumin and alpha-1-acid glycoprotein ^[6].

Metabolism

Buspirone is highly metabolized after administered orally, where BSP primarily undergoes hepatic oxidation which is CYP3A4 enzyme mediated. After that metabolism hydroxylated derivatives are produced, including 1-pyrimidinylpiperazine (1-PP) which is a pharmacologically active metabolite. In the studies of animals. 1-PP possessed about 1/4th pharmacological activity of buspirone [6].

Elimination

29-63% of administered dose of buspirone was excreted in the urine within 24 hours, primarily in the form of metabolites. About 18% to 38% of the dose of buspirone was excreted via fecal elimination [5].

PHARMACODYNAMICS



Buspirone has high affinity with agonistic action of the serotonin 5-HT1A receptor [7]. At presynaptic 5-HT1A receptors or at 5-HT1A auto receptors BSP acts as a full agonist, while at the postsynaptic 5-HT1A receptors acting as a partial agonist [5]. The main actions of buspirone are mediated by the interaction with the presynaptic serotonergic (5-HT1A) receptor, which reduces the firing of serotonin producing neurons. Buspirone also have lower affinities for the serotonin 5-HT2A, 5-HT2B, 5-HT2C, 5-HT6, and 5-HT7 receptors.

In addition to that buspirone has also an antagonistic property on the dopamine D2 receptor with weak affinity. It blocks inhibitory presynaptic D2 auto receptors preferentially, and postsynaptic D2 receptors antagonizes only at higher doses. At low doses the buspirone increase dopaminergic neurotransmission in the nigrostriatal pathway. At higher dose of buspirone it blocks the postsynaptic and produces anti-dopaminergic effects. Buspirone has also antagonistic action at the dopamine D3 and D4 receptors with higher affinity [7].

ANALYTICAL ACCOUNT OF BSP

For the determination of BSP in bulk and pharmaceutical formulations, an exhaustive

literature search found numerous analytical techniques such as UV/Visible Spectrophotometry, HPLC, HPTLC, LC-MS/MS, and bioanalytical approaches. BSP is measured as a single constituent and in combination with fluoxetine (FLU), escitalopram (ESCI), paroxetine (PAR) and buspirone (BSP). **Figure 2** shows different analytical methods implemented for the estimation of BSP.

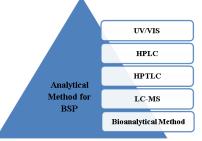


Figure 2: Analytical methods of BSP BIO-ANALYTICAL METHOD FOR BSP

Bio-analysis is a sub-discipline of analytical chemistry covering the quantitative measurement of xenobiotics (drugs and their metabolites, and biological molecules in unnatural locations or concentrations) and biotics (macromolecules, proteins, DNA, large molecule drugs, metabolites) in biological systems ^[8]. The summary of the reported bioanalytical methods is shown in **Table 1.**

Sr. No.	Drug	Sample Matrix	Method	Column	Detection	Internal Standard	Ref
1	BSP	Human Plasma	HPLC	Hypersil BDS CN5 µm	238 nm 1-Phenylpiperazine		9
2	BSP	Human Plasma	HPLC	Nucleosil C18 column	235 nm	35 nm Citalopram	
3	BSP	Human plasma	HPLC	Spherisorb S5 C8 analytical column	240 nm Quinupramine		11
4	BSP	Human Plasma	HPLC	Carboxypropyl (CBA) solid phase column	***	Desmethylimipramine hydrochloride	12
5	BSP	Human plasma	HPLC	Supelcosil ABZ + plus C18 reversed-phase column	*** Prazosin		13
6	BSP	Human serum	HPLC	C18 column.	235 nm ***		14
7	BSP	Rabbit serum	HPLC	Kromasil C8 column	235 nm Diltiazem Hydrochloride		15
8	BSP	Rat plasma	HPLC	Kinetex C8 column	237 nm	Naproxen	16

Table 1: Bioanalytical determination of BSP



9	BSP	Rat plasma	HPLC	Spherisorb ODS-2 column.	248 nm.	1-phenylpiperazine	17
10	BSP	Rat plasma and brain tissue	HPLC	Cyanonitrile Analytical column	***	Gepirone	18
11	BSP	Rat and dog plasma	HPLC	A stainless-steel column	254 nm	L-phenylpiperazine	19
12	BSP	Human plasma	HPLC- MS	Luna C18 guard column	***	Prazosin	20
13	BSP	Human plasma	LC-MS	Column packed with Luna Phenyl-Hexyl	*** 1-(2-pyrimidinyl) piperazine & 1(2 pyridyl)-piperazin		21
14	BSP	Rat bile, urine and liver S9 samples	LC-MS	Zorbax RX C18 reversed phase Column	260 nm	***	22
15	BSP	Human plasma	LC-ESI- MS/MS	Reversed phase C18 supelco ascentis express Column	***	Buspirone D8	23
16	BSP	Human plasma	GC	C8 Column	***	Zolpidem	24
17	BSP	Rat brain	GC-NPD	A fused-silica capillary column	***	Alprazolam	25

***Not provided

UV-VISIBLE SPECTROSCOPY METHOD FOR BSP

The spectrophotometric methods have been accounted for the determination of BSP. The

details of Spectrophotometry determination of basic principle, sample matrix, lambda max, solvent linearity range and the correlation coefficient are summarized in **Table 2**.

Table 2: Summary of	'UV	methods for	r the de	etermination	of BSP
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Sr. No.	Drug	Matrix	Solvent	Lambda Max (nm)	Linearity (µg/mL)	Correlation Coefficient(R2)	Ref.
1	BSP	Bulk and Pharmaceutical Dosage	Chloroform at pH 3.4	408 nm	2.5 - 25 μg/ml	0.997	26
2	BSP	Solid dosage form	Chloroform at pH 2.3	415 nm	1.5 - 6 μg/ml	0.9991	27
3	BSP	Bulk and tablets	Method A - Water Method B - Methanol	236 nm	5 - 25 μg/ml 10- 50 μg/ml	0.9866 0.9905	28
4	BSP	Bulk and tablet	Water	531 nm	10 - 100 μg/ml	0.999	29
5	BSP HCl	Commercial Dosage Form	disodium hydrogen phosphate and citric acid buffer solution of pH 4.0	412 nm	1.25-30 μg/ml	0.9999	30

***Not provided



HPLC METHOD FOR BSP

The specificity of the HPLC method is excellent and simultaneously sufficient precision is also attainable. However, it has to be stated that the astonishing specificity, precision, and accuracy are attainable only if wide-ranging system suitability tests are carried before the HPLC analysis. For this reason, the expense to be paid for the high specificity, precision, and accuracy is also high. The summary of the reported HPLC methods is shown in **Table 3**.

Sr. No.	Drug name	Column	Mobile phase	Lambda max (nm)	Linearity (µg/mL)	Retention time (min)	Flow rate (mL/min)	Detector	Ref.
1	BSP	C ₁₈	Water : Acetonitrile : Methanol (45 : 35 : 20) (V/V)	210 nm	5.0 - 25.0 μg/ml	7.057 min	1.0 ml/min	UV	31
2	BSP	RP C18 column	70:30 (v/v) Methanol - 0.01 M Sodium dihydrogen phosphate buffer (pH 3.5)	244 nm	0.05 - 20 μg/ml	7.72 min	0.8 ml/min	UV	32
3	BSP	Semi- micro xterra MS C18	0.010M Ammonium acetate (pH 4.0) Methanol (55:45 v/v)	245 nm	1.00 to 5.00 μg/ml	7.72 min	0.30 ml/min	UV	33
4	BSP	Ultra sphere C ₁₈ column	Acetonitrile - Methanol mixture (13:17)	244 nm	5 and 200 ng/μl	23.60 min	1.4 ml/min	DAD	34
5	BSP	Reversed Phase C18 column	70:30 (v/v) methanol- 0.01M NaH2PO4 buffer	240 nm	0.5-20 μg/ml	***	0.8 ml/min	UV	35

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LIQUID-CHROMATOGRAPHY-MASS SPECTROSCOPY METHOD (LC-MS) FOR BSP

In recent years, the combination of LC/MS has gained a lot of attention for the analysis of interest analytes in complex samples with improved performance. In brief, after a thorough examination, LC/MS interfaces are divided into two categories namely interfaces for indirect and direct input of column effluent. Murat Kartal et. al., established Liquid Chromatographic Method for the Analysis of Buspirone HCl and Its Potential Impurities. The separation was carried out by stationary phase μ Bondapack C18 column with 90:10 (v/v) 10mM KH2PO4 (pH 6.1)-acetonitrile as a mobile phase. Detection was carried out Lambda max at 210 nm^[36].

HPTLC METHOD FOR BSP

Thin-layer chromatography is a popular technique for the analysis of a wide variety of organic and inorganic materials, because of its distinctive advantages such as minimal sample clean-up, a wide choice of mobile phases, flexibility in sample distinction, high sample loading capacity and low cost. Pilvenytė Greta, Kazlauskienė Daiva, Marksa



Mindaugas and Bezruk Ivan established HPTLC method Determination of buspirone, fluoxetine, escitalopram and paroxetine by HPTLC after SPE extraction. They analyses buspirone (BUSP), fluoxetine (FLU), escitalopram (ESCI) and paroxetine (PAR). TLC was carried out by stationary phase silica gel 60 F254 plates with acetonitrile: methanol: 25% ammonia solution (85:10:05) as mobile phase. The HPTLC determination was made with UV detector at 254 nm^[37].

CONCLUSION

The review article provides present comprehensive data of various analytical and bioanalytical methods developed for BSP alone and in combinations. For analysis purpose, different analytical methods have been reported that includes HPLC, HPTLC, LC-MS and UV spectroscopy, etc. The method along with their details concerning the mobile phase, stationary phase, retention time, etc., have been summarized in tabular form that will more helpful for the for further analytical researchers method development for estimation of BSP in dosage form and pure form. In the future, enlisted data can be used for the development of analytical methods bio-analysis of BSP in pharmaceutical and biological formulations. Finally, it presents an opportunity for greater information on what has already been done and what new methods and changes can be developed to get a better estimation of BSP.

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CONFLICT OF INTEREST

The authors declare that no conflict of interest. **ABBREVIATION**

- 1) BSP Buspirone
- 2) USFDA United states of Food and Drug Administration
- 3) UV/VIS Ultra violet/visible spectroscopy
- 4) HPLC High-performance liquid chromatography
- 5) HPTLC High-performance thin layer chromatography
- 6) LC-MS/MS Liquid chromatography-mass spectroscopy-mass spectroscopy
- 7) RP Reverse phase
- 8) nm Nanometer
- 9) µg/mL Micro gram per Milliliter
- 10) DAD Diode array detector
- 11) FLU Fluoxetine
- 12) ESCI Escitalopram
- 13) PAR Paroxetine

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