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A CONCISE REVIEW ON ANALYTICAL PROFILE OF ZOLPIDEM

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ABSTRACT

This is a collective data for Zolpidem from previously published methods either in alone or in combination. Many analytical methods such as HPLC, UV, HPTLC etc, were reported for biological fluids and pharmaceutical formulations. The method proposed was validated statistically. All of the methods proposed are simple, selective, reproducible, sensitive, and precise with high accuracy. This concise review work can guide an analyst to choose most appropriate method for a best analytical method development and validation of Zolpidem alone or in combination with any other formulations.

KEYWORDS: Zolpidem, Analytical Method, HPLC, UV, HPTLC, Biological Fluids.

INTRODUCTION

Every day in human health a revolution found as pharmaceuticals developing. These pharmaceuticals can show best activity if these are free from impurities and pure. Various chemical and instrumental techniques were regularly developed to produce drugs free of impurities. Starting from manufacturing of bulk drug to packaging of finished product and further up to storage the impurities may develop at any stage. Transportation and storage are the two stages where impurities may occur frequently. Impurities must be detected and quantitated in the condition. For detection and measurement purposes, analytical instrumentation and techniques are crucial. Various methods are available to validate bulk drugs and pharmaceuticals such as, HPLC, GC, Titration, UV-Visible spectrophotometry, IR, NMR, Polarimetry, Fluorimetry, AAS, Polarography, Microbiological assay, etc.[1] To be capable of testing bulk drugs, intermediate products, drug formulations, and degradation products, chemical stability makes pharmaceutical analysis a valuable tool.

Insomnia is becoming the concern of health problems. Most patients with insomnia often suffer from daytime dysfunction, emotional problems, etc., which bring serious burdens to patients and their families. Methods of treating insomnia disorder include cognitive behavioural therapy, drug therapy and physical therapy. Early drug treatments were mainly benzodiazepines, but due to their causes of cognitive decline, falls, they were gradually being replaced by non-benzodiazepines. At present, the more commonly used non-benzodiazepine drugs in clinical are Zopiclone, Eszopiclone, Zolpidem and Zaleplon. Among them, Zolpidem is used more. The chemical name for zolpidem is N, N-dimethyl-2-[6-methyl-2-(4-methylphenyl) imidazole [1,2-a] pyridine-3-yl] acetamide, which describes it as a short-acting non-benzodiazepine sedative-hypnotic. Non-benzodiazepines are used to treat chronic and intermittent insomnia. The Food and Drug Administration (FDA) in the United States has certified zolpidem for the short-term treatment of sleep disorders.

Gamma-aminobutyric acid (GABA), a receptor chloride channel agonist that increases GABA inhibitory effects and causes sedation, that is how zolpidem functions. It is also anticonvulsant, anxiolytic, and mildly myorelaxant. GABA-BZ receptors are found in the somatosensory cortex, the plexus pallidus, the inferior colliculus, the pons, the ventral thalamic complex, the olfactory bulb, the cerebellum, and other parts of the brain. The medication activates these receptors, resulting in the sedative effects that help to maintain deep sleep. Benzodiazepines, on the other hand, interact to it and enhance all benzodiazepine (BZ) receptor subgroups, zolpidem binds the BZ1 receptor preferentially in vitro with a high alpha1/alpha5 subunit affinity ratio. The lack of myorelaxant and anticonvulsant effects may be explained by zolpidem's high affinity to the BZ1 receptor. Because of its high potential for abuse, zolpidem is generally not advised for use as a first-line treatment in the general population. In addition to good

sleep hygiene and cognitive behavioural therapy, medications like controlled-release melatonin and doxepin may be used as the first-line therapy for patients with insomnia.

We carried out a systematic review and analysis of the medication zolpidem in order to assess its effectiveness and safety in the treatment of adult insomnia disorder.

CHEMICAL STRUCTURE

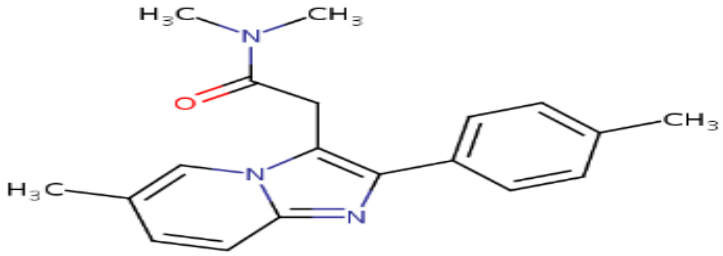
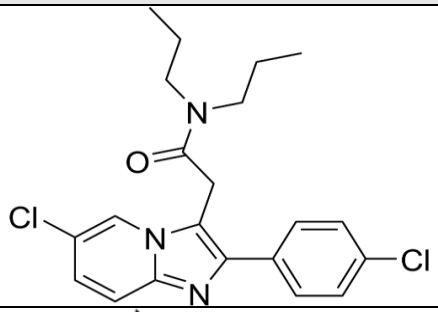
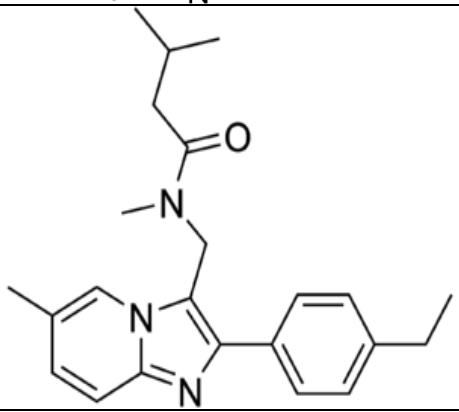
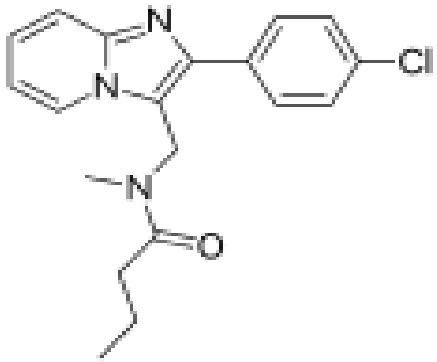
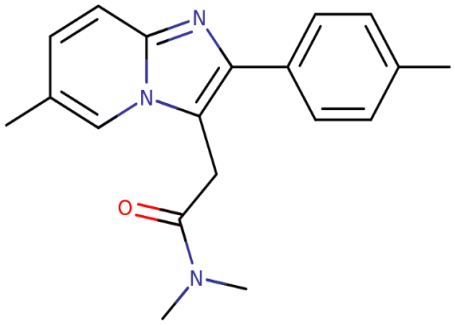
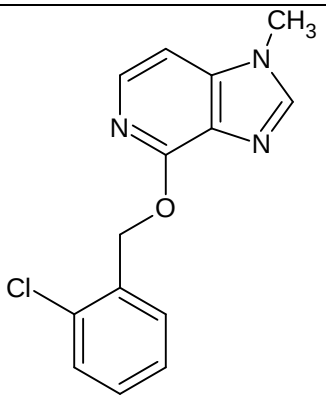
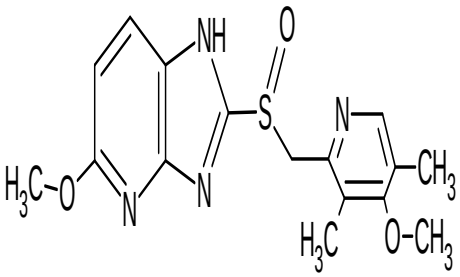
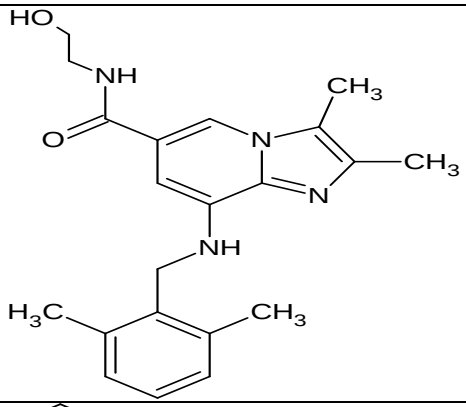
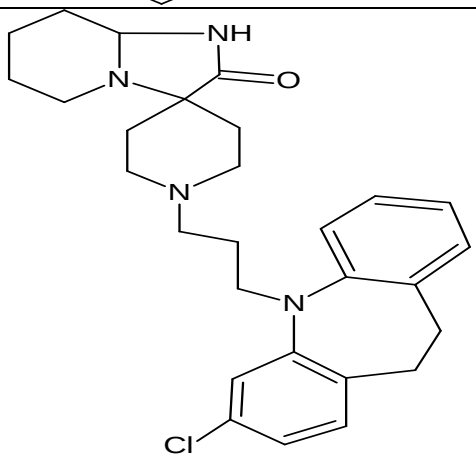
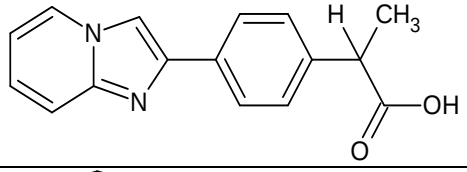
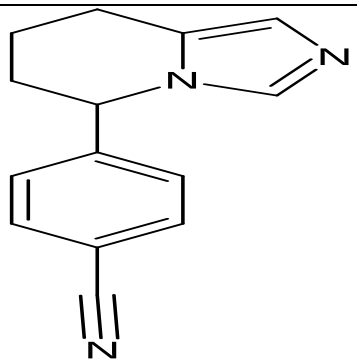


Figure 1: (N, N-dimethyl-2- [6-methyl-2- (4-methylphenyl) imidazole [1,2-a] pyridine-3yl] acetamide).

Table 1: Details of Imidazopyridines derivatives.

Sr. No.	Drug	Structure	IUPAC Name	Molecular wt.	Solubility
1	Alpidem		2-(6-chloro-2-(4-chlorophenyl) imidazole [1,2-a] pyridin-3-yl)-N, N-dipropylacetamide	404.1 g/mol	Slightly soluble in MeOH, Chloroform,
2	Necopidem		N-[[2-(4-ethylphenyl)-6-methylimidazole [1,2-a] pyridin-3-yl] methyl]-N-3-dimethylbutanamide	363.5 g/mol	Slightly soluble in Chloroform, MeOH.
3	Saripidem		N-[[2-(4-chlorophenyl) imidazole [1,2-a] pyridine-3-yl] methyl]-N-methyl butanamide	341.8 g/mol	Very Soluble in Dimethyl Sulfoxide

4	Zolpidem		N, N-Dimethyl-2-[6-methyl-2- (4-methylphenyl) imidazole [1,2-a] pyridin-3-yl] acetamide	307.4 g/mol	Sparingly soluble in MeOH, Slightly soluble in H_2O
5	Bamaluzole		4- [(2 chlorophenyl) methoxy]-1-methyl imidazole [4,5-c] pyridine	273.71 g/mol	Very Soluble in Dimethyl Sulfoxide
6	Tenatoprazole*		5-methoxy-2- [(4-methoxy-3,5-dimethyl pyridin-2-yl) methyl sulfinyl]-1H-imidazo [4,5-b] pyridine	346.4 g/mol	Soluble in Organic solvents-MeOH
7	Linaprazan*		8- [(2,6-dimethyl phenyl) methylamino] -N-(2-hydroxyethyl)-2,3-dimethylimidazole [1,2-a] pyridine-6-carboxamide	366.5 g/mol	Soluble in Dimethyl Sulfoxide
8	Mosapramine**		1'-[3-(2-chloro-5,6-dihydrobenzo [b] [1] benzazepin-11-yl) propyl] spiro [1,5,6,7,8,8a-hexahydro imidazo [1,2-a] pyridine-3,4'-piperidine]-2-one	479.1 g/mol	Soluble in Dimethyl Sulfoxide

9	Miroprofen***		2-(4-imidazole [1,2-a] pyridine -2-ylphenyl) propanoic acid	266.29 g/mol	Soluble in MeOH, Chloroform
10	Fadrozole****		4- (5,6,7,8-tetrahydro imidazo [1,5-a] pyridin-5-yl) benzonitrile	223.27 g/mol	Soluble in Ethanol, Dimethyl Sulfoxide, Dimethyl formamide

-Gastrointestinal Imidazopyridines; **-Antipsychotic Imidazopyridines; *-Anti-Inflammatory Imidazopyridines; ****-Antineoplastic Imidazopyridines.*

Table 2: Summary of methods related to HPLC technique.

Sl. No.	Stationary Phase (Column)	Mobile Phase (with ratio)	pH	Wavelength	Flow Rate	Reference
1	RP-18	Mixture of Ammonium acetate buffer & methanol (30:70, v/v)	5.0	243nm	0.5mL/min	[2]
2	C18 column (250×4.6mm i.d.,5µm)	Mixture of Isocratic mode Methanol & acetonitrile (50:50, v/v)	---	293nm	1.0 mL/min	[3]
3	C18 column	Mixture of Acetonitrile-ammonium acetate (60:40 v/v)	8.0	245nm	1.0 mL/min	[4]
4	C18 column (100×3.9mm)	Mixture of Acetonitrile-sodium dihydrogen phosphate (35:65 v/v)	7.0	245nm	2.5 mL/min	[5]
5	C18 column	Mixture of Acetonitrile-monopotassium phosphate (40:60 v/v)	3.5±0.1	245nm	1.2 mL/min	[6]
6	Silica-gel 6- F254	Mixture of Ethyl acetate-methanol-ammonia solution (8.5:2.0:1.0, v/v/v)	---	254nm	0.78 mL/min	[7]
7	Silica gel 60 F254 plates	Mixture of Toluene-n-butanol-glacial acetic acid-water (1:4:2:2 v/v/v/v)	---	254nm	0.59±0.01 mL/min	[8]
8	C18 reversed phase column	Mixture of Acetonitrile-potassium dihydrogen phosphate (50:50 v/v)	7.0	254 & 390nm	1.5 mL/min	[9]
9	Reversed phase Kromasil C18 column (150mm & 5µm)	Mixture of Acetonitrile-ammonium acetate	8.0	---	1.0 mL/min	[10]
10	I.D. RP OD-5-100 C18 column (2.1 mm; 5µ m)	Mixture of Methanol-acetonitrile-tetrabutylammonium phosphate (13:10:77 v/v/v)	2.0	240nm	0.07 mL/min	[11]

Table 3: Summary of analysis of Zolpidem by UV-Spectroscopy methods.

SL. No.	Drug	Method	Description	Reference
1	Determination of Zolpidem Tartarate in pharmaceutical dosage form	Spectrophotometric method	Detection wavelength: 230.95nm-254,25nm in phosphate buffer & 231.07nm-254.76 nm in borate buffer Linearity range:1-30 µg/ml Co-relation Co-efficient: 0.9999 in phosphate buffer and 0.999 in borate buffer % Recovery range: 99.7-99.88 & 99.46-99.91 %RSD: <2%	[12]
2	Determination of Zolpidem Tartarate in pure and pharmaceutical formulations	New RP-HPLC method	Detection wavelength:300nm Linearity range:20-60 µg/ml Co-relation Co-efficient:0.999 % Recovery range:98.90-100.87 %RSD:0.14%(intra-day), 0.18%(inter-day), 0.46%(intra-day)	[13]

QUALITY BY DESIGN

For pharmaceuticals, several analytical methods are available to enhance the quality.[14-19] But currently, the Quality by Design technique is widely used to improve the analytical method. For the development and production of pharmaceuticals, quality by design (QbD), which is covered in ICH Q81, Q9, and Q2, is well-established.[20]

BENEFITS OF QUALITY

By Design Method It supports the growth of a reliable methodology. Variability sources can be better controlled according to the design setup. Method When a method is transferred from the quality control department to the research level, the success of the transfer is higher. Through ongoing improvement throughout the lifecycle, this technique creates a space for the development of new techniques.[21]

CONCLUSION

This review depicts the analysis methods; developed for determination of Zolpidem. According to this review it was concluded that for Zolpidem different analytical methods are available for a single component as well as in combination and it was also found that mobile phase of acetonitrile was common for most of the chromatographic methods. For the most spectroscopic methods common solvent id methanol. All of the methods were discovered to be concise, precise, cost-effective, and repeatable.

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