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A REVIEW ARTICLE ON ANALYTICAL METHODS FOR DRUG: IMEGLIMIN HYDROCHLORIDE

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ABSTRACT

Imeglimin Hydrochloride is a novel oral antidiabetic agent belonging to the glimins class, designated to target multiple pathways involved in T2DM. This article is a critical examination of the numerous analytical techniques such as the UV spectroscopy method, RP-HPLC, HPTLC, LC-MS methods as well as stability indicating methods that have been demonstrated. This study encompasses, the range of absorbance 237-420nm, solvents like dist water, MeOH, TFAA, phosphate buffers, acetone, toluene, ACN, formic acid, etc and flow rate is achieved between 0.5-1.5ml/min and retention time is range from 0.61-15 min.

KEYWORDS: Imeglimin Hcl, UV, HPLC, HPTLC, LC-MS method, etc.

INTRODUCTION

An Antidiabetic medicine is any drug that helps lower high blood sugar situations, a hallmark of diabetes mellitus. Diabetes arises from the body's incapability to produce or effectively use insulin, a hormone vital for controlling blood glucose situations.

There are two main types: Type 1 Diabetes & Type 2 Diabetes.

Type 1 diabetes happens when your body does not make insulin, a hormone that helps your cells use sugar for energy. It generally begins in the nonage or youthful majority, and people

with Type 1 diabetes have to take insulin every day to stay healthy. Type 1 diabetes, counting for 5- 10% of cases, results from the vulnerable system attacking and destroying pancreatic beta cells, taking insulin remedy for operation.

Type 2 diabetes is more common and frequently begins later in life. With Type 2, your body either does not make enough insulin or cannot use it effectively. This can be managed with life changes like healthy eating, exercise, and occasionally drugs. Type 2 diabetes, comprising 85- of cases, generally affects grown-ups but can do at any age. In type 2 diabetes, the pancreas produces insulin, and the cells within the body turn resistant to insulin, hence its effects on an increase in the blood sugar situations. The cell resistance means insulin is less responsive to the uptake of glucose within the cells therefore taking other medical interventions that are life, oral medicines, or indeed insulin.

Imeglimin Hydrochloride, this is one recently approved oral anti-diabetic medicines under the order of "Glimins" class. Chemical formula(R)-6-imino-N, -tri methyl Hydrochloride having a molecular formula of $C_6H_{14}ClN_5$, importing 191.66 g/ spook. Imeglimin.

This medicine acts substantially on mitochondria It improves their energy product and protects the pancreatic β cells. It reduces liver glucose generation, increases insulin stashing from the pancreatic cells, and improves glucose uptake by the muscles. Hence, Imeglimin targets the root problem in type 2 diabetes mellitus, which is an abecedarian cellular complaint in energy metabolism.[1]

IMEGLIMIN HCL

Imeglimin Hydrochloride (HCl) is an oral medication used in type 2 diabetes mellitus, belonging to the novel class of drugs known as glimin derivatives. It affects mitochondrial bioenergetics that enhance insulin sensitivity, increase secretion of insulin, and decrease the production of hepatic glucose.

Class: Imeglimin is an agent in a new class of antidiabetic drugs called glimins.

Mechanism of Action: It acts through improvement of mitochondrial function, increase in insulin secretion, and reduction of insulin resistance. This drug also reduces glucose production in the liver and increases glucose uptake in muscles.

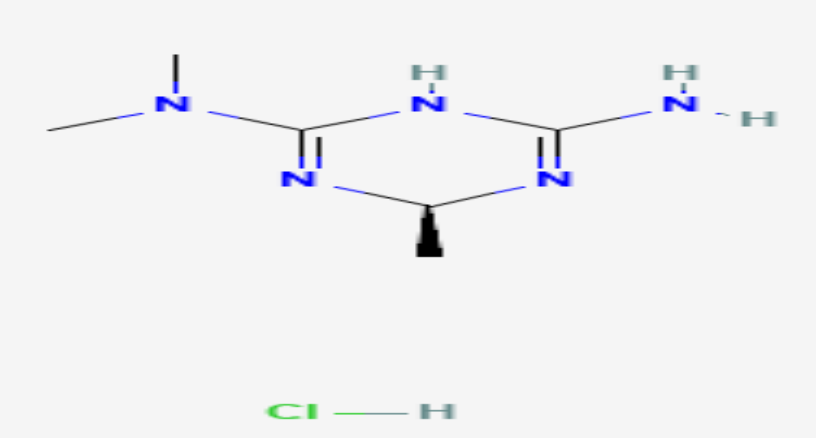
Indication: This primarily is used to manage type 2 diabetes mellitus.

Advantages

- This has a different mechanism compared to other known antidiabetic agents.
- May be useful for patients who have both insulin resistance and beta-cell dysfunction.
- Usually well-tolerated with less risk of hypoglycaemia.

Side Effects: The most common side effects are gastrointestinal in nature, including nausea, diarrhoea, and abdominal discomfort.[2]

Table 1: Drug profile.[3]

Chemical formula	$C_6H_{14}ClN_5$
Category	an oral antidiabetic drug used in the treatment of type 2 diabetes
IUPAC	(4R)-6-N,6-N,4-trimethyl-1,4-dihydro-1,3,5-triazine-2,6-diamine hydrochloride
CAS NUMBER	775351-61-6
CDSCO approval	As of now, there is no publicly available information regarding the approval of Imeglimin hydrochloride by the Central Drugs Standard Control Organization (CDSCO) in India
Chemical structure	
Molecular weight	191.66 g/mol
Appearance	white to off-white solid
pKa	10.21
Solubility	≥29.9 mg/ml in DMSO ≥50.3 mg/ml in ethanol ≥62.7 mg/ml in water
Pharmacokinetic	Absorption: Rapidly absorbed Metabolism: Minimal hepatic metabolism Excretion: Primarily renal Half-life: Approximately 18-20 hours
Brand Name	Twymeeg Tablets 500 mg
Dosage Form	Film-coated tablets, each containing 500 mg of Imeglimin Hydrochloride
Route	Oral
Melting point	223-225˚C
Combination with other drugs	None

REPORTED METHOD FOR ESTIMATION OF IMEGLIMIN HCL

<table>
<tr><th>Drug</th><th>Method</th><th>Description</th><th>Ref</th></tr>
<tr><td>IME HCL</td><td>UV method</td><td>Solvent: distil water
ʎ max: 237nm</td><td>[4]</td></tr>
<tr><td>IME HCL</td><td>UV method</td><td>Solvent: alizarine red s (ARS), bromophenol blue (BPB) and methyl orange (MO)
ʎ max: 410, 420 and 420nm, respectively</td><td>[5]</td></tr>
<tr><td>IME HCL</td><td>RP-HPLC method</td><td>Stationary phase: Phenomenox C18 (250 mm X 4.6 mm, 5 µm) column
Mobile phase: MeOH: 0.05% TFAA (20:80% v/v)
ʎ max: 240 nm
flow rate: 1 ml/min
retention time: 0.983 min</td><td>[6]</td></tr>
<tr><td>IME HCL</td><td>RP-HPLC method</td><td>Stationary phase: Agilent C18
Mobile phase: MeOH: 0.1% OPA (40:60% v/v)
ʎ max: 240nm
flow rate: 0.7ml/min
retention time: 4.718 min</td><td>[7]</td></tr>
<tr><td>IME HCL</td><td>RP-HPLC method</td><td>Stationary phase: BRISA LC^2 C18 (25mm x 0.46mm, 5 µm)
Mobile phase: MeOH: phosphate buffer (10mM) pH 6 (80:20% v/v)
ʎ max: 243nm
flow rate: 1ml/min
retention time: 3.097 min</td><td>[8]</td></tr>
<tr><td>IME HCL</td><td>HPTLC method</td><td>Stationary phase: Merck TLC plates precoated with silica gel 60 F254 (10 cm × 10 cm with a 250 µm)
Mobile phase: acetone: MeOH: toluene: formic acid (4:3:2:1% v/v/v/v)
ʎ max: 244nm
retention time: 0.61 min</td><td>[9]</td></tr>
<tr><td>IME HCL</td><td>Stability indicating RP-HPLC method
Stress Conditions: % Degraded
Acidic: 6.19
Alkali: 24.93
Oxidation: 17.50
Light: 10.01
Thermal: 0</td><td>Stationary phase: Credchrom C18 column (250mm x 4.6mm x 5µm)
Mobile phase: Phosphate Buffer: ACN (80:20% v/v)
ʎ max: 241nm
flow rate: 1 ml/min
retention time: 2.5 min</td><td>[1]</td></tr>
<tr><td>IME HCL</td><td>Stability indicating LC-ESI/APSI-MS method
Stress Conditions: % Degraded
Acidic: 1.63
Basic: 3.612</td><td>Stationary phase: Xtimate C-18 column
Mobile phase: 10 mM Ammonium format buffer (pH 3): MeOH (75:25% v/v)
ʎ max: 234 nm
flow rate: 0.8 ml/min
retention time: 15 min</td><td>[10]</td></tr>
</table>

	Oxidation	3.685		
	Photolytic	7.7		
	Thermal	1.25		
IME HCL	Stability indicating RP-UHPLC method		Stationary phase: Hypersil gold ODS ((150 x 4.6 mm, 3µm) Mobile phase: Water: ACN (15:85% v/v) ʎ max: 240 nm flow rate: 1 ml/min retention time: 3.831 min	[11]
	Stress Conditions	% Degraded		
	Acidic	4.9		
	Alkali	0		
	Oxidation	10.7		
	Photolytic	5.7		
	Thermal	0		
IME HCL	Stability indicating HPLC method		Stationary phase: Thermo hypersile BDS C18 reversed phase column (150 mm × 4.6 mm, particle size 5 µm) Mobile phase: MeOH: 0.05M phosphate buffer pH 3.0 (20:80% v/v) ʎ max: 240 nm flow rate: 1.5 ml/min retention time: 2.9 min	[12]
	Stress Conditions	% Degraded		
	Acidic	2.64		
	Alkali	8.77		
	Oxidation	14.83		
	Photolytic	1.18		
	Thermal	2.65		
IME HCL	LC-MS Method		Stationary phase: Chiralpak IG-3 (100 × 4.6 mm, 3 µm) Mobile phase: MeOH: 10 mM ammonium acetate (95:5% v/v) flow rate: 0.5 ml/min retention time: 5 min	[13]

CONCLUSION

The analytical techniques for the quantification and characterization of Imeglimin HCl are essential for maintaining its quality, efficacy, and safety. Several techniques, such as chromatographic (HPLC, UPLC), UV spectroscopic, and mass spectrometric (LC-MS) techniques, have been utilized for its analysis in bulk and pharmaceutical formulations. These techniques provide high sensitivity, selectivity, and accuracy for the detection and quantification of Imeglimin HCl in various matrices. Nevertheless, additional improvements in method development, such as green analytical techniques and hyphenated methods, can improve efficiency and sustainability of drug analysis. The future should be directed toward validating these methods under various conditions to provide robust and reliable measurement of Imeglimin HCl in pharmaceutical and biological matrices.

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