Health Canada
Santé Canada

STATUS DECISION OF CONTROLLED AND NON-CONTROLLED SUBSTANCE(S)

Substance: I- Zolpidem hydroxy metabolite
II- Zolpidem acid metabolite

Based on the current information available to the Office of Controlled Substances, it appears that the above substance is:

Controlled ☐

Not Controlled ✓

under the schedules of the *Controlled Drugs and Substances Act* (CDSA) for the following reason(s):

- The substances are metabolites of zolpidem and are not captured under the heading of item 25 of Schedule IV to the CDSA.

Prepared by: _____ Date: _____
Vincent Marleau

Verified by: _____ Date: _____
Mark Kozlowski

Approved by: _____ Date: _____
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: "third party information removed as per agreement with applicant"

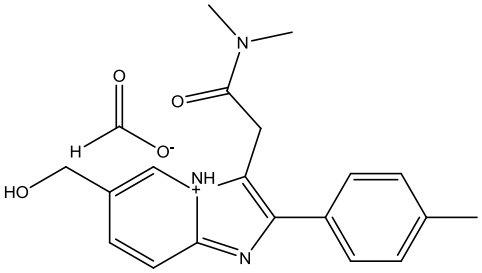
Drug Status Report

Drug: I- Zolpidem hydroxy metabolite
II- Zolpidem acid metabolite

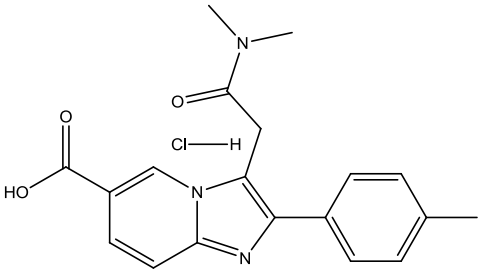
Drug Name Status: I- Zolpidem hydroxy metabolite
II- Zolpidem acid metabolite are the common names.

Chemical Name:
I- 3-(2-(dimethylamino)-2-oxoethyl)-6-(hydroxymethyl)-2-(p-tolyl)-4H-imidazo[1,2-a]pyridin-4-ium formate
II- 3-(2-(dimethylamino)-2-oxoethyl)-2-(p-tolyl)imidazo[1,2-a]pyridine-6-carboxylic acid hydrochloride

Chemical structure:



I



II

Molecular Formula: I-$C_{20}H_{23}N_3O_4$; II- $C_{19}H_{20}ClN_3O_3$

Pharmacological class / Application: Pharmaceutical-related substance

CAS-RN: I- 109461-67-8; **II-** 109461-15-6.

International status:

US: Zolpidem hydroxy metabolite and zolpidem acid metabolite are not listed specifically in the Schedules to the US *Controlled Substances Act* and are not mentioned anywhere on the DEA website.

United Nations: The substances are not listed on the Yellow List - List of Narcotic Drugs under International Control, the Green List - List of Psychotropic Substances under International Control, nor the Red List - List of Precursors and Chemicals Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances under International Control.

Canadian Status: Zolpidem hydroxy metabolite and zolpidem acid metabolite are not listed in the schedules to the CDSA. These substances are metabolites of zolpidem, which is currently listed as item 25 in Schedule IV to the CDSA as "Zolpidem (N,N,6-trimethyl-2-(4-methylphenyl)imidazo[1,2-a]pyridine-3-acetamide) and any salt thereof". Since zolpidem hydroxy metabolite and zolpidem acid metabolite are not salts of the parent drug, they do not fall

under item 25 of Schedule IV to the CDSA. It is noteworthy that a review of 6-Methyl-2-(4-methylphenyl)imidazol[1,2-a]-pyridine-3-acetic acid, zolpidic acid also found that the substance could not be included under item 25 of Schedule IV to the CDSA.

Recommendation: Zolpidem hydroxy metabolite and zolpidem acid metabolite are not included in the schedules to the CDSA and are not controlled substances.

Date: October 22nd, 2012.