

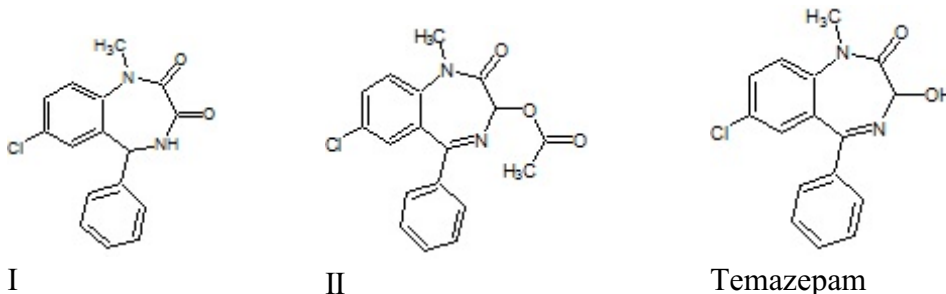
Drug Status Report

Drug: Temazepam Impurities

Drug Name Status: 7-Chloro-1,4-dihydro-1-methyl-5-phenyl-2H,3H-1,4-benzodiazepine-2,3-dione (I) and 3-Acetyloxy-7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepine-2-one (II) are the chemical names.

Chemical Name: 7-Chloro-1,3-dihydro-1-methyl-5-phenyl-2H,3H-1,4-benzodiazepine-2,3-dione (I)
3-Acetyloxy-7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepine-2-one (II)

Chemical structure:



Molecular Formula: I- $C_{16}H_{13}ClN_2O_2$

II- $C_{18}H_{15}ClN_2O_3$

Pharmacological class / Application: pharmaceutical related substance

International status:

US: The substance is not listed on the schedules to the US Controlled Substances Act and is not mentioned on the DEA website.

United Nations: The substance is not listed on the Yellow List - List of Narcotic Drugs under International Control nor on the Green List - List of Psychotropic Substances under International Control.

Canadian Status: Item 18 of Schedule IV to the CDSA is, "Benzodiazepines, their salts and derivatives". Temazepam (structure above) is subitem 30 of this item. Substance I is an isomeric derivative of temazepam; substance II is the acetate ester derivative of temazepam. Both are therefore benzodiazepines.

Recommendation: Temazepam impurities I and II are included in item 18 of Schedule IV to the CDSA and are controlled substances.

April 23, 2008