SAFETY DATA SHEET (SDS)

Olanzapine Tablets USP, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg

Revision Date: 02-March-2023 Version 1.0

1. IDENTIFICATION

Product Name: Olanzapine Tablets, USP- 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg

Product Information: Olanzapine Tablets

Company Name: Cadila Pharmaceuticals Limited

Address: 1389, Dholka – 382225, District: Ahmedabad, Gujarat State, India.

Phone No.: 02714/221481

Fax No.: 02714/220315

2. HAZARD(S) IDENTIFICATION:

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Serious eye damage/eye irritation	Category 2B
	Sensitization, skin	Category 1
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
	Specific target organ toxicity, repeated exposure	Category 2 (Blood)
OSHA defined hazards	Not classified.	

Label elements

Signal word	Warning
Hazard statement	H302: Harmful if swallowed
	H320: Causes eye irritation
	H317: May cause an allergic skin reaction
	H336: May cause drowsiness or dizziness
	H373: May cause damage to organs (Blood) through prolonged or repeated exposure

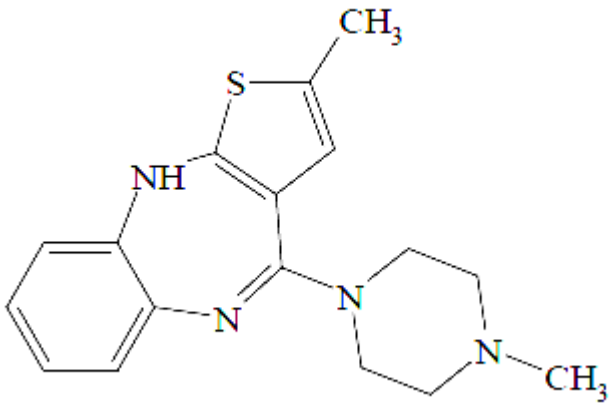
Precautionary statement

Prevention	P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response	P333 + P313: If skin irritation or rash occurs: Get medical advice/attention P337 + P313: If eye irritation persists: Get medical advice/attention P363: Wash contaminated clothing before reuse. P314: Get medical advice/attention if you feel unwell.
Storage	Store olanzapine tablets, at controlled room temperature, 20° to 25°C (68° to 77°F) [see USP].
Disposal	None available.
Hazard(s) not otherwise classified (HNOC)	None known.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name: 2-Methyl-4-(4-methyl-1-piperazinyl)-10H-thieno [2,3-b][1,5] benzodiazepine



Olanzapine, USP (Form – I)

Product Code: Not applicable

Hazardous Ingredients / Components: Not Applicable

CAS No.: 132539-06-1

Other Components:

Inactive Ingredients	Exposure Limit	CAS No.
Crospovidone (Polyplasdone Ultra)	Not Found	9003-39-8
Hydroxypropyl Cellulose (Klucel-LF)	Not Found	9004-64-2
Lactose Monohydrate (Pharmatose 200M)	Not Found	5989-81-1
Magnesium stearate	Not Found	557-04-0
Microcrystalline Cellulose	Not Found	9004-34-6
HPMC 2910/ Hypromellose (6mPas)	Not Found	9004-65-3
Titanium Dioxide	Not Found	13463-67-7
Triacetin	Not Found	102-76-1

4. FIRST – AID MEASURES

Inhalation: Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

Skin Contact: Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

Eye Contact: Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.

Ingestion: Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

5. FIRE-FIGHTING MEASURES

5.1 Suitable Extinguishing Media: Alcohol-resistant foam, Carbon dioxide, Water, Dry chemical spray, water spray to cool fire-exposed containers.

	Unsuitable extinguishing media:	A solid water stream may be inefficient.
5.2	**Flammable Properties and Hazards:**	No data available
	Flash Pt:	No data
	Explosive Limits:	LEL: No data, UEL: No data.
	Autoignition Pt:	No data
5.3	**Fire Fighting Instructions:**	As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

Protective precautions, Protective Equipment and Emergency Procedures: Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

Environmental precautions: Take steps to avoid release into the environment, if safe to do so.

Methods and Material for Containment and Cleaning Up: Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure.

Storage: Store olanzapine tablets, at controlled room temperature, 20° to 25°C (68° to 77°F) [see USP].

8. EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Controls: Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

Personal protection equipment:

- ***Eye Protection*:** Safety glasses
- ***Protective Gloves***: Compatible chemical-resistant gloves
- ***Other Protective Clothing*:** Lab coat
- ***Respiratory Equipment (Specify Type):*** NIOSH approved respirator, as conditions warrant.
- ***Work/ Hygienic:*** Do not take internally. Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower. Wash thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:

Olanzapine Tablets, USP 2.5 mg

White to off-white, round, biconvex, coated tablet, debossed with “C4” on one side and plain on other side.

Olanzapine Tablets, USP 5 mg

White to off-white, round, biconvex, coated tablet, debossed with “C5” on one side and plain on other side.

Olanzapine Tablets, USP 7.5 mg

White to off-white, round, biconvex, coated tablet, debossed with “C6” on one side and plain on other side.

Olanzapine Tablets, USP 10 mg

White to off-white, round, biconvex, coated tablet, debossed with “C7” on one side and plain on other side.

Olanzapine Tablets, USP 15 mg

White to off-white, elliptical, biconvex, coated tablet, debossed with “C8” on one side and plain on other side.

Olanzapine Tablets, USP 20 mg

White to off-white, elliptical, biconvex, coated tablet, debossed with “C19” on one side and plain on other side.

Physical States	Solid
Melting Point	No Data Available
Boiling Point	No Data Available
Flash Point	No Data Available
Evaporation Rate	No Data Available
Explosive Limits	Not Applicable
Vapor Density	Not Available.
Specific Gravity	No Data Available
Solubility in Water	Not Available.
Autoignition Point	Not Available
Molecular formula:	C17H20N4S
Molecular weight:	312.4 g/mol

10. STABILITY AND REACTIVITY

Reactivity: Not water reactive.

Chemical Stability: Material is stable at normal conditions.

Conditions to avoid: No data available.

Incompatibility Materials: Strong oxidizing agents.

Hazardous Decomposition Product(s): Carbon oxide, carbon monoxide, nitrogen oxides, sulfur oxides

11. TOXICOLOGY INFORMATION

Toxicological Effects: Olanzapine - Toxicity Data: Oral LDLO (man): 7067 ug/kg; Oral TDLO (woman): 400 ug/kg; Subcutaneous TDLO (rat): 625 ug/kg; Intraperitoneal TDLO rat 5 mg/kg;

Chronic Toxicological: Olanzapine - Investigated as a drug. Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information. Olanzapine RTECS Number: XJ9007750.

12. ECOLOGICAL INFORMATION

Toxicity: Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.

Persistence and Degradability: No data available.

Bioaccumulative Potential: No data available.

Mobility in Soil: No data available.

Results of PBT and vPvB assessment: No data available.

Other adverse effects: No data available.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with local, state, and federal regulations.

14. TRANSPORT INFORMATION

14.1 LAND TRANSPORT (US DOT):

DOT Proper Shipping Name: Not dangerous goods

DOT Hazard Class:

UN/NA Number:

14.2 LAND TRANSPORT (EUROPEAN ADR/RID):

ADR/RID Shipping Name: Not dangerous goods

UN Number:

Hazard Class:

14.3 AIR TRANSPORT (ICAO/IATA):

ICAO/IATA Shipping Name: Not dangerous Goods

Additional Transport information: Transport in accordance with local, state, and federal regulations.

15. REGULATORY INFORMATION

Generic Medicine. Approved by USFDA on February 24, 2023 and the ANDA Number is 210022.

16. OTHER INFORMATION

The above information is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.