SAFETY DATA SHEETS

This SDS packet was issued with item:

078950830

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078930299

Safety Data Sheet
TRAZODONE HYDROCHLORIDE TABLETS
Strength: 50 mg, 100 mg, 150 mg , 300 mg and 150 mg
Pack Size: 30's, 90's 100's, 500's and 1000's Tablets per bottle and Carton of 100 Tablets (10 x 10 unit Dose)

Revision No.: 00

EMERGENCY OVERVIEW
Each Trazodone Hydrochloride Tablets intended for oral administration contains Trazodone Hydrochloride and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

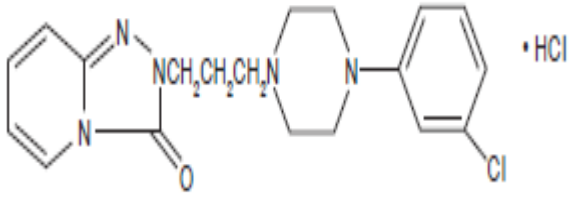
Section 1. Identification

Identification of the product

Product Name: 2-[3-[4-(3-chlorophenyl)-1-piperazinyl]propyl]- 1,2,4-triazolo[4, 3-a]pyridin-3(2H)-one hydrochloride.

Formula: $C_{19}H_{22}ClN_5O \bullet HCl$

Chemical Name:



Manufacturer / supplier identification

Company:	**Cadila Healthcare Ltd., Matoda, India**
Address:	Cadila Healthcare Limited, Plot No- 1A/1 & 2, Pharmez Special Economic Zone, Sarkhej- Bavla N.H. No. 8A, Near Village Matoda, Tal. Sanand, Dist. Ahmedabad-382 213, India
Contact for information:	Tel: +91-79-26868100 Fax: +91-79-26868533
Emergency Telephone No.	Tel: +91-79-26868101
Recommended use / Therapeutic Category	Trazodone hydrochloride tablets are indicated for the treatment of major depressive disorder (MDD) in adults.
Restriction on Use / Contraindications:	Trazodone hydrochloride tablets are contraindicated in: • Patients taking, or within 14 days of stopping, monoamine oxidase inhibitors (MAOIs), including MAOIs such as linezolid or intravenous methylene blue, because of an increased risk of serotonin syndrome

Section 2. Hazard(s) Identification

Dose and Administration	**Dose Selection** An initial dose of 150 mg/day in divided doses is suggested. The dosage should be initiated at a low-dose and increased gradually, noting the clinical response and any evidence of intolerance. Occurrence of drowsiness may require the administration of a major portion of the daily dose at bedtime or a reduction of dosage. The dose may be increased by 50 mg/day every 3 to 4 days. The maximum dose for outpatients usually should not exceed 400 mg/day in divided doses. Inpatients (i.e., more severely depressed patients) may be given up to but not in excess of 600 mg/day in divided doses. Once an adequate response has been achieved, dosage may be gradually reduced, with subsequent adjustment depending on therapeutic response. **Important Administration Instructions** Trazodone hydrochloride tablets can be swallowed whole or administered as a half tablet by breaking the tablet along the score line. Trazodone hydrochloride tablets should be taken shortly after a meal or light snack.
Adverse Effects	The following serious adverse reactions are described elsewhere in the labelling: Suicidal Thoughts and Behaviour in Children, Adolescents and Young Adults • Serotonin Syndrome • Cardiac Arrythmias • Orthostatic Hypotension and Syncope • Increased Risk of Bleeding • Priapism • Activation of Mania or Hypomania • Discontinuation Syndrome • Potential for Cognitive and Motor Impairment • Angle-Closure Glaucoma • Hyponatremia

Over Dose Effect	Death from overdose has occurred in patients ingesting trazodone and other CNS depressant drugs concurrently (alcohol; alcohol and chloral hydrate and diazepam; amobarbital; chlordiazepoxide; or meprobamate). The most severe reactions reported to have occurred with overdose of trazodone alone have been priapism, respiratory arrest, seizures, and ECG changes, including QT prolongation. The reactions reported most frequently have been drowsiness and vomiting. Overdosage may cause an increase in incidence or severity of any of the reported adverse reactions. There is no specific antidote for trazodone hydrochloride overdose.
Contraindications	Trazodone hydrochloride tablets are contraindicated in: • Patients taking, or within 14 days of stopping, monoamine oxidase inhibitors
Pregnancy Comments	Teratogenic Effects Trazadone hydrochloride has been shown to cause increased fetal resorption and other adverse effects on the fetus in the rat when given at dose levels approximately 6 to 9 times the maximum recommended human dose (MRHD) of 400 mg/day on mg/m2 in adolescents. There was also an increase in congenital anomalies in the rabbit at approximately 6 to 17 times the MRHD on mg/m2 basis in adolescents. There are no adequate and well-controlled studies in pregnant women. Trazodone hydrochloride should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Animal Data No teratogenic effects were observed when trazodone was given to pregnant rats and rabbits during the period of organogenesis at oral doses up to 450 mg/kg/day. This dose is 9 and 17 times, in rats and rabbits, respectively, the maximum recommended human dose (MRHD) of 400 mg/day on mg/m2 basis in adolescents. Increased fetal resorption and other adverse effects on the fetus in rats at 6 to 9 times the MRHD and increase in congenital anomalies in rabbits at 6 to 17 times the MRHD on mg/m2 basis in adolescents were observed.
Pregnancy Category	C

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Section 3. Composition / information on ingredients		
Component	**Exposure Limit**	**CAS No.**
Principle Component:		
Trazadone HCL	Not Found	25332-39-2
Inactive Ingredients:		
Microcrystalline Cellulose	Not Found	9004-34-6
Pregelatinized Starch 1500	Not Found	Not Available
Sodium Lauryl Sulphate	Not Found	151-21-3
Sodium Starch Glycolate	Not Found	9063-38-1
Colloidal Silicon Dioxide	Not Found	7631-86-9
Magnesium stearate	Not Found	557-04-0

Section 4. First -aid measures

General

- **After inhalation:**
  Move to fresh air in case of accidental inhalation. assure fresh air breathing.
- **After skin contact:**
  Rinse skin with water/shower
- **After eye contact:**
  Rinse with water while holding the eyes wide open. Contact lenses should be removed.
- **After swallowing:**
  Rinse mouth out with water
- **Information for doctor:**
- **Most important symptoms and effects, acute and delayed-** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed-** No further relevant information available.

Overdose Treatment	Death from overdose has occurred in patients ingesting trazodone and other CNS depressant drugs concurrently (alcohol; alcohol and chloral hydrate and diazepam; amobarbital; chlordiazepoxide; or meprobamate). The most severe reactions reported to have occurred with overdose of trazodone alone have been priapism, respiratory arrest, seizures, and ECG changes, including QT prolongation. The reactions reported most frequently have been drowsiness and vomiting. Overdosage may cause an increase in incidence or severity of any of the reported adverse reactions. There is no specific antidote for trazodone hydrochloride overdose. In managing overdosage, consider the possibility of multiple drug involvement. For current information on the management of poisoning or overdose, contact a poison control centre
Section 5. Fire -fighting measures	
	Extinguishing media · **Suitable extinguishing agents:** Use extinguishing media appropriate for surrounding fire. Extinguishing blanket. Carbon dioxide. Dry powder **Special hazards arising from the substance or mixture** Stable under normal conditions. · **Advice for firefighters** Small amounts: Use normal individual fire protective equipment. Large amounts: Not · **Protective equipment:** Hand protection : Gloves Skin and body protection : Lab coat Respiratory protection : Quarter mask (DIN EN 140)
Specific hazards arising from the chemical	No additional information available
Special protective equipment and precautions for firefighters	Use normal individual fire protective equipment
General fire hazards	No unusual fire or explosion hazards noted

Section 6. Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection.
Environmental precautions:	No additional information available
Methods and material for containment and cleaning up:	Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Poorly soluble in water. Clean with the help of detergents.
Section 7. Handling and Storage	
Storage:	Store at 20 to 25°C (68 to 77°F) Dispense in a tightly closed container with a child-resistant closure (as required). Keep out of the reach of children. **Precautions for safe handling**: Keep it dry & in a cool, well ventilated place away from heat. Store in original container **Information about fire - and explosion protection:** No special measures required.
Section 8. Exposure controls / personal protection	
Respiratory Protection	Quarter mask (DIN EN 140)
Skin protection	For prolonged or repeated skin contact use suitable protective gloves.
Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	General ventilation normally adequate.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations	Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.
Engineering controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Section 9. Physical and chemical properties	
Appearance	Description of **Trazodone Hydrochloride Tablets USP 50 mg**: Whit to Off-white, round shape, biconvex bevelled tablets, bisect on one side and plain on other side. The bisected side of tablet is debossed with "8" on upper side of bisect and "05" on lower side of bisect Description of **Trazodone Hydrochloride Tablets USP 100 mg**: Whit to Off-white, round shape, biconvex bevelled tablets, bisect on one side and plain on other side. The bisected side of tablet is debossed with "8" on upper side of bisect and "06" on lower side of bisect Description of **Trazodone Hydrochloride Tablets USP 150 mg**: Whit to Off-white, oval shape, flat faced bevelled tablets, having one full bisect and two trisect notches on one side and two trisect on other side. The full bisected side of tablet is debossed with "8" on one side of bisect and "07" on other bisect segment. Description of **Trazodone Hydrochloride Tablets USP 300 mg**: Whit to Off-white, oval shape, flat faced bevelled tablets, having one full bisect and two trisect notches on one side and two trisect on other side. The full bisected side of tablet is debossed with "8" on one side of bisect and "08" on other bisect segment.

Solubility	Not available.	**Odour**	Not available.
Boiling point	Not available.	**Melting Point**	Not available.
Evaporation rate	Not available.	**Vapour density**	Not available.
Reactivity in water	Not available.	**Vapour pressure**	Not available.
% Volatile by volume	Not available.	**Specific gravity**	Not available.

Section 10. Stability and Reactivity

Conditions to avoid	Contact with incompatible materials.
Stable	**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Hazardous reactions	No dangerous reaction known under conditions of normal use.
Decomposition products	When heated to decomposition, emits dangerous fumes.
Incompatible materials	Strong Oxidizing agent

Section 11. Toxicological information

General	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Ingestion	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.
Other	Not Available

Symptoms related to the physical, chemical and Toxicological characteristics	Not Available
Information on toxicological effects	
Acute toxicity	No drug or dose related occurrence of carcinogenesis was evident in rats receiving oral doses up to 7.3 times the maximum recommended human dose of 400mg/day on mg/m2 basis
Further information	NA
Section 12. Ecological information	
	Poorly soluble in water. No data available on ecotoxicity.
Section 13. Disposal Consideration	
	Dispose the waste in accordance with all applicable Federal, State and local laws.
Section 14. Transport Information	
	The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG). In accordance with ADR / RID / IMDG / IATA / ADN
Section 15. Regulatory Information	
	Generic Medicine. Under Approval by USFDA & the ANDA Number is 205253
Section 16. Other information	
	None

Date of issue: 31/08/17 **Supersedes edition:** New Edition