HETERO LABS LIMITED
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SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification	
Material	**Levofloxacin Tablets, 250 mg, 500 mg and 750 mg**
Manufacturer	**Hetero Labs Limited Unit V** Hetero Labs Limited Unit V, APIIC Formulation SEZ, Survey.No 439, 440, 441 & 458, Polepally Village, Jadcherla (Mandal), Mahaboob Nagar (District). Pin-509301 Telangana, India
Distributor	**Camber Pharmaceuticals, Inc.**, Piscatway, NJ 08854

Section 2: Hazard(s) Identification

Section 2, Hazard(s) identification	
Fire and Explosion	Expected to be non-combustible.
Health	Levofloxacin tablets are contraindicated in persons with known hypersensitivity to levofloxacin, or other quinolone antibacterials.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition / Information on Ingredients

Section 3, Composition/information on ingredients	
Ingredients	Levofloxacin Hemihydrate
CAS	138199-71-0

Section 4: First-Aid Measures

Section 4, First-aid measures	
Ingestion	If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.
Inhalation	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
Skin Contact	Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.

Eye Contact	Flush eyes with plenty of water. Get medical attention.
NOTES TO HEALTH PROFESSIONALS	
Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.
OVERDOSAGE	In the event of an acute overdosage, the stomach should be emptied. The patient should be observed and appropriate hydration maintained. Levofloxacin is not efficiently removed by hemodialysis or peritoneal dialysis. Levofloxacin exhibits a low potential for acute toxicity. Mice, rats, dogs and monkeys exhibited the following clinical signs after receiving a single high dose of levofloxacin: ataxia, ptosis, decreased locomotor activity, dyspnea, prostration, tremors, and convulsions. Doses in excess of 1500 mg/kg orally and 250 mg/kg IV produced significant mortality in rodents.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures	
Fire and Explosion Hazards	Assume that this product is capable of sustaining combustion.
Extinguishing Media	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
Special Fire fighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for fire-fighters.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

Section 6: Accidental Release Measures

Section 6, Accidental release measures	
Personal Precautions	Wear protective clothing and equipment consistent with the

	degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labeled container for recovery or disposal.

Section 7: Handling and Storage

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Handling	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
Storage	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Section 8: Exposure Controls / Personal Protection

Section 8, Exposure controls/personal protection

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

Section 9: Physical and Chemical Properties

Section 9, Physical and chemical properties

Physical Form

Levofloxacin tablets are supplied as 250 mg, 500 mg, and 750 mg coated tablets.

Levofloxacin tablets, 250 mg

Levofloxacin tablets, 250 mg are pink coloured, capsule shaped, biconvex, film coated tablets debossed with '25' on one side and 'I' on the other side.

Bottles of 50 Tablets (NDC 31722-721-50)
Blister card 10's (NDC 31722-721-31)
Blister pack of 10 x 10's (NDC 31722-721-32)

Levofloxacin tablets, 500 mg

Levofloxacin tablets, 500 mg are orange coloured, capsule shaped, biconvex, film coated tablets debossed with '26' on one side and 'I' on the other side.

Bottles of 50 Tablets (NDC 31722-722-50)
Blister card 10's (NDC 31722-722-31)
Blister pack of 10 x 10's (NDC 31722-722-32)

Levofloxacin tablets, 750 mg

Levofloxacin tablets, 750 mg are white coloured, capsule shaped, biconvex, film coated tablets debossed with '18' on one side and 'I' on the other side.

Bottles of 20 Tablets (NDC 31722-723-20)

Blister card 10's (NDC 31722-723-31)

Blister pack of 10 x 10's (NDC 31722-723-32)

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Section 11, Toxicological Information

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a lifetime bioassay in rats, levofloxacin exhibited no carcinogenic potential following daily dietary administration for 2 years; the highest dose (100 mg/kg/day) was 1.4 times the highest recommended human dose (750 mg) based upon relative body surface area.

Levofloxacin did not shorten the time to tumor development of UVinduced skin tumors in hairless albino (Skh-1) mice at any levofloxacin dose level and was therefore not photo-carcinogenic under conditions of this study. Dermal levofloxacin concentrations in the hairless mice ranged from 25 to 42 mcg/g at the highest levofloxacin dose level (300 mg/kg/day) used in the photo-carcinogenicity study. By comparison, dermal levofloxacin concentrations in human subjects receiving 750 mg of levofloxacin averaged approximately 11.8 mcg/g at Cmax.

Levofloxacin was not mutagenic in the following assays: Ames bacterial mutation assay (S. typhimurium and E. coli), CHO/HGPRT forward mutation assay, mouse micronucleus test, mouse dominant lethal test, rat unscheduled DNA synthesis assay, and the mouse sister chromatid exchange assay. It was positive in the in vitro chromosomal aberration (CHL cell line) and sister chromatid exchange (CHL/IU cell line) assays.

Levofloxacin caused no impairment of fertility or reproductive

	performance in rats at oral doses as high as 360 mg/kg/day, corresponding to 4.2 times the highest recommended human dose based upon relative body surface area and intravenous doses as high as 100 mg/kg/ day, corresponding to 1.2 times the highest recommended human dose based upon relative body surface area.

Section 12: Ecological Information

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

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Waste Disposal	Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

Section 14: Transport Information

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

Section 15: Regulatory Information

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This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

Section 16: Other Information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. 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.

Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS.