Annora

SAFETY DATA SHEET

Section 1: Identification	
Material	Spironolactone Tablets 25 mg, 50 mg, and 100 mg
Recommended use	Pharmaceutical product for the treatment of high blood pressure (hypertension).
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Precautionary statements	P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have been read and understood P260 - Do not breathe dust/fume/gas/mist/vapors/spray P281 - Use personal protective equipment as required P308 + P313 - IF exposed or concerned: Get medical attention/advice P314 - Get medical attention/advice if you feel unwell P405 - Store locked up P501 - Dispose of contents/container in accordance with all local and national regulations
Other hazards **Australian Hazard Classification (NOHSC):**	No data available Hazardous Substance. Non-Dangerous Goods.
Section 3: Composition/Information on Ingredients	
Ingredients	**CAS**
Corn starch	9005-25-8
Magnesium stearate	557-04-0
Dibasic Calcium phosphate anhydrous	7757-93-9
Lactose monohydrate	10039-26-6
Spironolactone	52-01-7
Colloidal silicon dioxide	7631-86-9

Povidone	9003-39-8
Sodium lauryl sulfate	151-21-3
Opadry white	NA

Section 4: First-Aid Measures

Description of First Aid Measures

First-aid Measures After Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
First-aid Measures After Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
First-aid Measures After Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
First-aid Measures After Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Section 5: Fire-Fighting Measures

Extinguishing Media

Suitable Extinguishing Media:	Extinguish fires with CO2, extinguishing powder, foam, or water.

Special hazards arising from the substance or mixture

Hazardous Combustion Products:	Emits oxides of sulfur under combustion.
Fire / Explosion Hazards:	Not applicable
Precautionary Measures Fire:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

General Measures:	Personnel involved in clean-up should wear appropriate

	personal protective equipment. Minimize exposure.
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Methods for Cleaning Up:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
Section 7: Handling and Storage	
Precautions for Safe Handling	
Additional Hazards When Processed	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment. Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process missions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Conditions for Safe Storage, Including any Incompatibilities	
Storage Temperature:	Store as directed by product packaging.
Specific End Use(s)	Pharmaceutical drug product
Section 8: Exposure Controls/Personal Protection	
Exposure Controls	
Appropriate 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.
Personal Protective Equipment	
Hand Protection	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eye Protection	Wear safety glasses or goggles if eye contact is possible.
Skin and Body Protection	Impervious protective clothing is recommended if skin

	contact with drug product is possible and for bulk processing operations.
Respiratory Protection	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.
Section 9: Physical and Chemical Properties	
Physical Form	Tablets
Appearance	Spironolactone tablets USP, 25 mg are white to off white colored, round shaped, biconvex film-coated, debossed with V1 on one side and 73 on the other side. Bottle of 30's NDC 31722-094-30 Bottle of 100's NDC 31722-094-01 Bottle of 1000's NDC 31722-094-10 Bottle of 500's NDC 31722-094-05 Spironolactone tablets USP, 50 mg are white to off white colored, oval shaped, film-coated, scored on both edges, debossed with V1 on one side and 7 bisected 4 on other side. Bottle of 30's NDC 31722-095-30 Bottle of 100's NDC 31722-095-01 Bottle of 1000's NDC 31722-095-10 Bottle of 500's NDC 31722-095-05 Spironolactone tablets USP, 100 mg are white to off white colored, round shaped, film-coated, scored on both edges, debossed with V1 on one side and 75 bisected plain other side. Bottle of 30's NDC 31722-096-30 Bottle of 100's NDC 31722-096-01 Bottle of 1000's NDC 31722-096-10 Bottle of 500's NDC 31722-096-05 Store at 20º to 25ºC (68º to 77ºF). [See USP Controlled Room Temperature]. Protect from light. Dispense in tight, light-resistant, child-resistant containers.
Section 10: Stability and Reactivity	
Reactivity:	No data available.
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	No data available.
Oxidizing Properties:	No data available

Conditions to Avoid:	None known
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available.
Section 11: Toxicological Information	
Acute Toxicity: **(Species, Route, End Point, Dose)**	**Spironolactone** Rat Oral LD 50 4121 mg/kg Mouse Oral LD 50 >1000mg/kg Rabbit Oral LD 50 >1000mg/kg Rat Intraperitoneal LD 50 786mg/kg **Povidone** Rat Oral LD50 100 g/kg **Magnesium stearate** Rat Oral LD50 > 2000 mg/kg Rat Inhalation LC50 > 2000 mg/m3 **Hydroxypropyl methylcellulose** Rat Oral LD50 > 10,000 mg/kg
Irritation / Sensitization: **(Study Type, Species, Severity)**	**Spironolactone** Skin Sensitization - GPMT Guinea Pig No effect **Polyethylene glycol** Eye Irritation Rabbit Mild Skin Irritation Rabbit Mild
Repeated Dose Toxicity: **(Duration, Species, Route, Dose, End Point, Target Organ)**	**Spironolactone** 13 Week(s) Rat Oral 50 mg/kg LOAEL Blood 78 Week(s) Rat Oral 50 mg/kg/day LOAEL Liver, Male reproductive system
Reproduction & Developmental Toxicity: **(Study Type, Species, Route, Dose, End Point, Effect(s))**	**Spironolactone** Reproductive & Fertility Rat Oral 15 mg/kg/day NOAEL Fetotoxicity Reproductive & Fertility Rat Intraperitoneal 100 mg/kg/day LOAEL Fertility Embryo / Fetal Development Mouse Intraperitoneal 100 mg/kg/day LOAEL Maternal Toxicity

	Embryo / Fetal Development Rat Oral 50 mg/kg/day LOAEL Fetotoxicity Embryo / Fetal Development Rabbit Oral 20 mg/kg/day LOAEL Fetotoxicity
Genetic Toxicity: **(Study Type, Cell Type/Organism, Result)**	**Spironolactone** Bacterial Mutagenicity (Ames) Salmonella , E. coli Negative Mammalian Cell Mutagenicity Negative without activation
Carcinogenicity: **(Duration, Species, Route, Dose, End Point, Effect(s))**	**Spironolactone** 104 Week(s) Rat Oral 10 mg/kg/day LOAEL Benign tumors 52 Week(s) Non-human Primate Oral 20 mg/kg/day LOAEL Reproductive System
Section 12: Ecological Information	
Toxicity	No data available.
Persistence and degradability	No data available.
Bio-accumulative Potential: **Partition Coefficient:** **(Method, pH, Endpoint, Value)** **Mobility in Soil:**	 **Spironolactone** Predicted 7.4 Log D 3.12 No data available
	No data available.
Section 13: Disposal Considerations	
Waste Treatment Methods:	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: Transport Information	
In Accordance with DOT	Not dangerous goods
In Accordance with IATA	Not dangerous goods
In Accordance with IMDG	Not dangerous goods
Section 15: Regulatory Information	
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3
EU EINECS/ELINCS List	Not Listed

Section 16: Other Information

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Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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.

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