

**SAFETY DATA SHEET****Section 1: Identification**

<b>Material</b>	<b>Sildenafil citrate for Oral Suspension 10 mg/mL</b>
<b>Other means of identification</b>	None.
<b>Recommended use</b>	Pharmaceutical product used for Treatment of pulmonary arterial hyperten
<b>Manufacturer</b>	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc.</b> , Piscataway, NJ 08854

**Section 2: Hazard(s) Identification**

<b>Hazard Classification:</b>	Not Classified as Hazardous
<b>Additional Hazard Information:</b>	May be harmful if swallowed. May cause eye irritation (based on components) Animal studies indicate that this material may cause adverse effects on the cardiovascular system.
<b>Known Clinical Effects:</b>	Adverse effects most commonly reported in clinical use include difficult digestion (dyspepsia), nose bleed, headache, flushing, insomnia, abnormal redness of skin (erythema), difficulty breathing, muscle pain, fever, gastrointestinal irritation, tingling/itching (paresthesia), transient changes in light perception and color vision, effects on hearing, and effects on vision.

**Section 3: Composition/Information on Ingredients**

<b>API</b>	Sildenafil citrate
<b>CAS</b>	171599-83-0

**Section 4: First-Aid Measures****Description of First Aid Measures**

<b>Ingestion</b>	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.
<b>Skin Contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Eye Contact</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Inhalation</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Section 5: Fire-Fighting Measures**

<b>Extinguishing Media:</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Hazardous Combustion Products:</b>	Formation of toxic gases is possible during heating or fire.
<b>Fire Fighting Procedures:</b>	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
<b>Fire / Explosion Hazards:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.

**Section 6: Accidental Release Measures**

<b>Personal Precautions, Protective Equipment and Emergency Procedures</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Environmental precautions</b>	Place waste in an appropriately labelled, sealed container for

disposal. Care should be taken to avoid environmental release.

**Methods and Materials for Contamination and Cleaning Up**  
**Measures for Cleaning / Collecting:** 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** Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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 emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

**Conditions for safe storage, including any incompatibilities** Store at room temperature, 20°C-25°C (68°F-77°F) [see USP Controlled Room Temperature].

## Section 8: Exposure Controls/Personal Protection

**Control Parameters** Refer to available public information for specific member state **Occupational Exposure Limits**.

**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** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**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.

**Hands** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes** Wear safety glasses or goggles if eye contact is possible.

**Skin** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

## Section 9: Physical and Chemical Properties

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**Physical Form**                      **Powder**  
 White to off white grape flavored powder.

Sildenafil for Oral Suspension		
Package Configuration	Strength	NDC

Powder for oral Suspension-bottle	10 mg/mL (when reconstituted)	31722-136-31
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## Section 10: Stability and Reactivity

<b>Reactivity</b>	No data available
<b>Chemical stability</b>	Stable under normal condition of use.
<b>Possibility of hazardous reactions</b>	None
<b>Oxidizing Properties</b>	No data available
<b>Conditions to avoid</b>	Not known
<b>Incompatible materials</b>	As a precautionary measure, keep away from strong oxidizers.
<b>Hazardous decomposition products</b>	No data available.

## Section 11: Toxicological Information

### Information on Toxicological Effects

**General Information** The information included in this section describes the potential hazards of the individual ingredients.

### Acute Toxicity: (Species, Route, End Point, Dose)

#### Sildenafil citrate

Rat	oral	LDmin.	300-500 mg/kg
Mouse	oral	LDmin.	500-1000 mg/kg
Rat	Dermal	LD50	>2000 mg/kg

## Section 12: Ecological Information

<b>Environmental Overview:</b>	In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater. Harmful effects to aquatic organisms could occur.
<b>Mobility, Persistence and Degradability:</b>	The active ingredient in this formulation is water soluble and is expected to remain primarily in water.
<b>Bioaccumulation and Toxicity:</b>	The active ingredient in this formulation has low potential to bioaccumulate and long-term adverse effects to aquatic organisms are not expected. See aquatic toxicity data, below.

## 13. DISPOSAL CONSIDERATIONS

<b>Disposal Procedures:</b>	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.
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## Section 14: Transport Information

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## Section 15: Regulatory Information

EU Indication of danger: Not classified

OSHA Label: Non-hazardous in accordance with international standards for workplace safety

## Section 16: Other Information, including date of preparation or last revision

**Issue Date: 27-05-2021**

**Version: 00**

### **Further information**

**Revision date: Nil**

**Revision note: Nil**

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.

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