

SAFETY DATA SHEET

Section 1: Identification	
Material	Gabapentin Tablets 300 mg and 600 mg
Recommended use	Pharmaceutical product used as anticonvulsant
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	
Statement of Hazard:	Non-hazardous in accordance with international standards for workplace safety.
Additional Hazard Information: Short Term:	Dust may cause irritation (based on components) The active ingredient is not acutely toxic.
Known Clinical Effects:	Adverse effects associated with therapeutic use include dizziness, tiredness, swelling, and nausea.
EU Indication of danger:	Not classified
<p>This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.</p>	
Section 3: Composition/Information on Ingredients	
Active Ingredient	CAS
Gabapentin	60142-96-3
Hypromellose	9004-65-3
Copovidone	25086-89-9
Polyethylene Oxide	25322-68-3
Microcrystalline Cellulose	9004-34-6
Magnesium Stearate	557-04-0
Opadry II white	NA
Section 4: First-Aid Measures	
Eye Contact	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.
Ingestion	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Section 5: Fire-Fighting Measures	
Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Not known .
Fire Fighting Procedures:	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.
Fire / Explosion Hazards:	Not applicable
Section 6: Accidental Release Measures	
Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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	
Handling	If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. 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.

Storage	Store as directed by product packaging.
8. Exposure controls / personal protection	
Analytical Method:	This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
Engineering Controls:	Engineering controls should be used as the primary means to control exposures.
Environmental Exposure Controls:	Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment	
Eye/face Protection	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin and body protection	Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory Protection	Not required for the normal use of this product. 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	Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Section 9: Physical and Chemical Properties																															
Physical State	Solid Tablet																														
Description	<p>Gabapentin tablets are supplied as follows:</p> <p>300 mg tablets: Gabapentin 300 mg tablets are white color, oval-shaped, film coated tablets debossed with “G5” on one side and “V1” on other side.</p> <p>NDC 31722-091-90 Bottle of 90s</p> <p>600 mg tablets: Gabapentin 600 mg tablets are yellow color, oval-shaped, film coated tablets debossed with “G7” on one side and “V1” on other side.</p> <p>NDC 31722-092-90 Bottle of 90s</p> <p>Storage: Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p>																														
Section 10: Stability and Reactivity																															
Chemical Stability:	Stable under normal conditions of use.																														
Conditions to Avoid:	None known																														
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers																														
Section 11: Toxicological Information																															
General Information:	The information included in this section describes the potential hazards of the individual ingredients.																														
Acute Toxicity																															
LD50 Oral	<table border="1"> <thead> <tr> <th style="background-color: #4F81BD; color: white;">Gabapentin</th> <th></th> <th></th> <th></th> <th></th> </tr> </thead> <tbody> <tr> <td></td> <td>Mouse</td> <td>Oral</td> <td>LD50 > 5000</td> <td>mg/kg</td> </tr> <tr> <td></td> <td>Rat</td> <td>Oral</td> <td>LD50 > 5000</td> <td>mg/kg</td> </tr> <tr> <td></td> <td>Rat</td> <td>IV</td> <td>LD50 > 2000</td> <td>mg/kg</td> </tr> <tr> <td></td> <td>Mouse</td> <td>IV</td> <td>LD50 1000-2000</td> <td>mg/kg</td> </tr> <tr> <td></td> <td>Rat</td> <td>Subcutaneous</td> <td>LD50 > 4000</td> <td>mg/kg</td> </tr> </tbody> </table>	Gabapentin						Mouse	Oral	LD50 > 5000	mg/kg		Rat	Oral	LD50 > 5000	mg/kg		Rat	IV	LD50 > 2000	mg/kg		Mouse	IV	LD50 1000-2000	mg/kg		Rat	Subcutaneous	LD50 > 4000	mg/kg
Gabapentin																															
	Mouse	Oral	LD50 > 5000	mg/kg																											
	Rat	Oral	LD50 > 5000	mg/kg																											
	Rat	IV	LD50 > 2000	mg/kg																											
	Mouse	IV	LD50 1000-2000	mg/kg																											
	Rat	Subcutaneous	LD50 > 4000	mg/kg																											
Section 12: Ecological Information																															
Environmental Overview:	The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.																														

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	
DOT	Not regulated
TDG	Not regulated
IATA	Not regulated
IMDG/IMO	Not regulated
Section 15: Regulatory Information	
Gabapentin Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4	
Section 16: Other Information, including date of preparation or last revision	
<p>Issue Date: 02-03-2024</p> <p>Version: 00</p> <p>Further information</p> <p>Revision date: Nil</p> <p>Revision note: Nil</p> <p>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.</p> <p>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.</p>	