SAFETY DATA SHEETS

This SDS packet was issued with item:

078939790

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

078934167 078934168 078935961 078935963 078935964 078937440 078937543 078939786 078939787 078939788 078939789 078939791

SAFETY DATA SHEET

ALKEM

Gabapentin Capsules USP

1. IDENTIFICATION

Material	**Gabapentin Capsules USP 100 mg, 300 mg and 400 mg**
Recommended Use	Rx Pharmaceutical for human use
Manufacturer	Alkem Laboratories Ltd. Mumbai - 400013, INDIA.
Distributor	Ascend Laboratories, LLC Parsippany, NJ 07054
Contact Phone Number	**001-201-476-1977**

2. HAZARD(S) IDENTIFICATION

GHS – Classification	Not Classified as hazardous
Label Elements	
Signal Word:	Not classified
Hazard Statements:	Not classified in accordance with international standards for workplace safety
Other Hazards	An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).
Note	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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Active Ingredient	**CAS No.**	**Quantity**
Gabapentin	60142-96-3	100 mg/Capsules, 300 mg/Capsules, and 400 mg/Capsules

Inactive Ingredient	**CAS No.**	**Inactive Ingredient**	**CAS No.**
Starch	9005258	Sodium Lauryl Sulfate	151213

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Talc	14807966	Titanium Dioxide	13463677
Lactose	63423	Ferric Oxide Yellow	51274001
Gelatin	9000708	Ferric Oxide Red	1309371

4. FIRST-AID MEASURE

Eye Contact Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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.

Inhalation Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician None

5. FIRE-FIGHTING MEASURE

Suitable Extinguishing Media Carbon dioxide, dry chemical or water.

Special Hazards from Arising from the Substance or Mixture

Hazardous Combustion Products Formation of toxic gases is possible during heating or fire

Fire/Explosion Hazards Fine particles (such as dust and mists) may fuel fires/explosions

Advice for Fire-Fighters During all firefighting activities, wear appropriate protective

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equipment, including self-contained breathing apparatus

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Protective Equipment and Emergency Procedure	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Method and Material for Containment 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. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precaution for Safe Handling	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 (see Section 8). 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 emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Storage Conditions	Store at 20° to 25°C (68° to 77°F); [see USP Controlled Room Temperature].
Specific End Use	Pharmaceutical drug product

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Appropriate Engineering Controls	General room ventilation is adequate unless the process generates dust, mist or fumes. Engineering controls should be used as the primary means to control exposures. 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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Hands	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent).
Respiratory Protection	Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent).

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State	Solid
Form	Capsules

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Sr. No.	Strength	Description	Packs	NDC No.
1	100 mg	White to off white crystalline powder filled in size "4" white hard gelatin capsule imprinted "216" on body with blue ink.	Bottles of 100	67877-222-01
			Bottles of 500	67877-222-05
			Bottles of 1000	67877-222-10
			One Carton of 100 (10 x 10 Unit-dose capsules)	67877-222-38
2	300 mg	White to off white crystalline powder filled in size “1" yellow colour hard gelatin capsule imprinted "215" on body with blue ink.	Bottles of 100	67877-223-01
			Bottles of 500	67877-223-05
			Bottles of 1000	67877-223-10
			One Carton of 100 (10 x 10 Unit-dose capsules)	67877-223-38
3	400 mg	White to off white crystalline powder filled in size "0" Orange colour hard gelatin capsule imprinted "214" on bod y with blue ink.	Bottles of 100	67877-224-01
			Bottles of 500	67877-224-05
			Bottles of 1000	67877-224-10
			One Carton of 100 (10 x 10 Unit-dose capsules)	67877-224-38

Explosive Properties Not explosive

Oxidizing Properties The substance or mixture is not classified as oxidizing

10. STABILITY AND REACTIVITY

Reactivity No data available.

Chemical Stability Stable at normal conditions of use.

Possibility of Hazardous Reactions

Polymerization Will not occur

Conditions to Avoid Fine particles (such as dust and mists) may fuel fires/explosions

Incompatible Materials As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

Short Term Dust may cause irritation (based on components). The active ingredient is not acutely toxic.

Known Clinical Adverse effects associated with therapeutic use include dizziness, tiredness,

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Effects swelling, and nausea

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

Gabapentin

Species	Route	End Point	Dose
Mouse	Oral	LD50	> 5000 mg/kg
Rat	Oral	LD50	> 5000mg/kg
Rat	IV	LD50	> 2000mg/kg
Mouse	IV	LD50	1000-2000mg/kg
Rat	Subcutaneous	LD50	> 4000mg/kg

Talc (non-asbestiform)

Species	Route	End Point	Dose
Rat	Oral	LD50	> 1600 mg/kg

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization (Study Type, Species, Severity):

Gabapentin

Study Type	Species	Severity
Eye Irritation	Rabbit	Non-irritating

Repeated Dose Toxicity (Duration, Species, Route, Dose, End Point, Target Organ):

Gabapentin

Duration	Species	Route	Dose	End Point	Target Organ
52 weeks	Rat	Oral	250 mg/kg/day	NOAEL	Liver, Kidney
52 weeks	Monkey	Oral	250 mg/kg/day	NOAEL	Not identified
13 weeks	Mouse	Oral	1000 mg/kg/day	NOAEL	No effect at max dose

Reproduction & Developmental Toxicity (Study Type, Species, Route, Dose, End Point, Effect(s)):

Gabapentin

Study Type	Species	Route	Dose	End Point	Effect(s)
Reproductive & Fertility	Rat	Oral	500 mg/kg/day	NOAEL	Negative
Embryo/Fetal Development	Mouse	Oral	3000 mg/kg/day	NOAEL	No effects at max dose
Embryo/Fetal	Rat	Oral	300	NOAEL	Developmental toxicity,

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Development			mg/kg/day		Not Teratogenic
Peri-/Postnatal Development	Rat	Oral	500 mg/kg/day	NOAEL	Negative

Genetic Toxicity (Study Type, Cell Type/Organism, Result):

Gabapentin

Study Type	Cell Type/Organism,	Result
Bacterial Mutagenicity (Ames)	Salmonella, E. coli	Negative
In Vitro Chromosome Aberration	Hamster Lung Cells	Negative
In Vivo Unscheduled DNA Synthesis	Rat Hepatocyte	Negative
In Vivo Chromosome Aberration	Hamster Bone Marrow	Negative

Carcinogenicity (Duration, Species, Route, Dose, End Point, Effect(s)):

Gabapentin

Duration	Species	Route	Dose	End Point	Effect(s)
2 Year(s)	Mouse	Oral, in feed	2000 mg/kg/day	NOEL	Not carcinogenic
2 Year(s)	Male Rat	Oral, in feed	1000 mg/kg/day	NOEL	Malignant tumors, Pancreas

12. ECOLOGICAL INFORMATION

Environmental Overview The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Toxicity No data available

Persistence and Degradability No data available

Bio-accumulative Potential :

Gabapentin

Partition Coefficient:

Method	pH	Endpoint	Value
Predicted	7.4	Log D	-1.31

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATION

Waste Treatment Methods: 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

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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.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Generic Medicine. Approved by USFDA & the ANDA Number is 090858.

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Gabapentin	
Standard for the Uniform Scheduling for drugs and poisons	Schedule 4
EU EINECS/ELINCS List	262-076-3
Starch	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register	Present
EU EINECS/ELINCS List	232-679-6
Lactose	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS)	Present
REACH - Annex IV - Exemptions from the obligations of Register	Present
EU EINECS/ELINCS List	200-559-2
Talc	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS)	Present
EU EINECS/ELINCS List	238-877-9

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16. OTHER INFORMATION

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections, which pertain to their particular conditions.

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

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.

Date of Preparation: 26/11/2019

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