MATERIAL SAFETY DATA SHEET

SECTION: 1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY

COMPANY ADDRESS EMERGENCY TELEPHONE NUMBERS:

Manufacturer address:
GRAVITI PHARMACEUTICALS PVT. LTD
Plot No. 621/E, 621/EE, Isnapur village
Patancheru Mandal, Sangareddy (District)
Telangana- 502302
Emergency Telephone number: +91 9885017112

Distributor address
Biocon Pharma Inc
Iselin, NJ 08830-3009 USA

PRODUCT NAME:	**Fenofibrate Tablets USP 54 mg and 160 mg**
CHEMICAL NAME:	Fenofibrate USP
PRODUCT USE:	Fenofibrate tablets are indicated as adjunctive therapy to diet to reduce elevated low-density lipoprotein cholesterol (LDL-C), total cholesterol (Total-C), Triglycerides and apolipoprotein B (Apo B), and to increase high-density lipoprotein cholesterol (HDL-C) in adult patients with primary hypercholesterolemia or mixed dyslipidemia.

SECTION- 2 HAZARDS IDENTIFICATION

Appearance:	Fenofibrate Tablets 54 mg: round shape, yellow colour Fenofibrate Tablets 160 mg: elliptical/oval shape, white colour
Fire and Explosion:	Expected to be non-combustible
Health:	Fenofibrate is contraindicated in: Patients with severe renal impairment, including those receiving dialysis. Patients with active liver disease including those with primary biliary cirrhosis and unexplained persistent liver function abnormalities. Patients with pre-existing gallbladder disease. Nursing mothers. Patients with known hypersensitivity to fenofibrate or Fenofibric acid.

REFERENCE COPY
Sign:.....Date: 07.FEB.20

SECTION-3: COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name	CAS NO.
Fenofibrate USP	49562-28-9
Lactose Monohydrate USP-NF (Super Tab 11 SD)	64044-51-5
Microcrystalline cellulose USP-NF (Avicel PH 101)	9004-34-6
Povidone USP-NF (Kollidon 30)	9003-39-8
Sodium Lauryl Sulfate (Kolliphor SLS fine)	151-21-3
Crospovidone USP-NF (Type A- kollidon CL -F)	9003-39-8
Colloidal silicon dioxide USP-NF (Aerosil 200 Pharma)	7631-86-9
Sodium Stearyl Fumarate	4070-80-8

SECTION-4: FIRST AID MEASURES

Eye Contact: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

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.

Ingestion: If conscious, give water to drink and induce vomiting. Do not attempt 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.

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

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

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 evolved from fires involving this product and associated packaging self-contained breathing apparatus and full protective equipment are recommended for firefighters
Hazardous Combustion Products:	Hazardous combustion or decomposition products the product is expected when the product is exposed to fire.

SECTION-6: ACCIDENTAL RELEASE MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited however; the following guidance may be used as needed.

Health and Safety Precautions:	Avoid all eye and skin contact and do not breathe vapour and mist.
Protective equipment:	Use appropriate personal protection equipment (PPE)
Measures for Cleaning / Collecting:	For small quantities associated with normal therapeutic use, collecting spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labelled sealed container for proper disposal.
Measures for Environmental Precautions:	For large spills, take precautions to prevent entry into waterways sewers, or surface drainage system
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately.

SECTION-7: HANDLING AND STORAGE

General Handling:	
Patients/consumers:	Patients should adhere to the instructions provided within the product information. Insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. 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.

Hygiene measures:	This SDS is for a pharmaceutical agent - Handling of accordance with good industrial hygiene and safety procedures. this product final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.
Storage Conditions:	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Protect from moisture. Keep out of reach of children

SECTION-8: EXPOSURES AND CONTROLS

Exposure Controls

Appropriate engineering controls:	Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits
Personal protective equipment:	Not generally required. The use of personal protective equipment may be necessary as conditions warrant.
Hand protection:	Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.
Eye protection:	In laboratory, medical or industrial settings, or operations in which airborne particulates may be generated, safety glasses with side shields are recommended.
Skin and body protection:	In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible

SECTION-9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Tablets
Odour: No data available
Molecular Formula: No data available
Solubility: No data available
Molecular Formula: No data available
Solubility: No data available
Solvent Solubility: No data available
Water Solubility: No data available
PH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available

Colour
Fenofibrate Tablet 54 mg: yellow
Fenofibrate Tablet 160 mg: white
Odour Threshold: No data available

SECTION-10: STABILITY AND REACTIVITY

Reactivity:	Hazardous reactions will not occur under normal conditions.
Chemical stability:	Stable under normal conditions
Possibility of hazardous reactions:	Hazardous polymerization will not occur
Conditions to avoid:	Direct sunlight. Extremely high or low temperatures.
Incompatible materials:	Strong oxidizers. Strong bases. Strong acids
Hazardous decomposition products:	Decomposition will not occur under normal conditions

SECTION-11: TOXICOLOGICAL INFORMATION

Acute toxicity: Not classified
LD50 and LC50 data: Not available
Skin corrosion/irritation: Not classified
Serious eye damage/irritation: Not classified
Respiratory or skin sensitization: Not classified
Germ cell mutagenicity: Not classified
Teratogenicity: Not available
Carcinogenicity: Not classified
Specific target organ toxicity (single exposure): Not classified
Specific target organ toxicity (repeated exposure): Not classified
Reproductive toxicity: Not classified
Aspiration hazard: Not classified
Information on toxicological effects - ingredient(s)

SECTION-12: ECOLOGICAL INFORMATION

No relevant studies identified.

SECTION-13: DISPOSAL CONSIDERATIONS

Waste disposal recommendations:	Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not dispose of waste into sewer.

Additional information: Contaminated sharps should be discarded immediately or as soon as possible in Containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labelled. Contact your local health department for referral to a Safe Syringe Disposal Program.

SECTION-14: TRANSPOSRATION INFORMATION

IATA/ICAO - Not Regulated

IMDG - Not Regulated

DOT – Not Regulated

SECTION-15: REGULATORY INFORMATION

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

SECTION-16: OTHER INFORMATION

Graviti Pharmaceuticals Pvt Ltd believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

22-01-2020

Prepared & Reviewed by:

Graviti Pharmaceuticals Pvt. Ltd. Hyderabad

22-01-2020

Approved by:

REFERENCE COPY
Sign: Date: 05 Feb-20