ScieGen Pharmaceuticals, Inc.
89 Arkay drive
Hauppauge, New York 11788
Tel: 631-434-2723
Fax: 631-357-3178

SAFETY DATA SHEET

Date: 01/26/2018

Generic Name: Quetiapine extended-release tablets, USP 150 mg, 200 mg, 300 mg and 400 mg.

Brand Equivalent: Seroquel XR® (Quetiapine fumarate) extended-release Tablets, 50 mg, 150 mg, 200 mg, 300 mg and 400 mg

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SECTION 1: IDENTIFICATION	
Product Name	Quetiapine extended-release tablets, USP
Active substance	Quetiapine fumarate
Synonyms	N/A
Formula	$C_{42}H_{50}N_6O_4S_2 \bullet C_4H_4O_4$
Intended Use	Quetiapine extended-release tablets are indicated for the treatment of schizophrenia.
Chemical Name	2-[2-(4-dibenzo [b,f] [1,4]thiazepin-11-yl-1-piperazinyl) ethoxy]-ethanol fumarate (2:1) (salt)
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

2. HAZARDS IDENTIFICATION	
Additional Hazard Information: Short Term: Long Term:	Accidental ingestion may cause effects similar to those seen in clinical use. Repeat-dose studies in animals have shown a potential to cause adverse effects on developing fetus and thyroid
Known Clinical Effects:	Adverse effects associated with therapeutic use include dizziness, sleepiness (somnolence) dry mouth, constipation, difficult digestion (dyspepsia), low blood pressure on standing (orthostatic hypotension), increased heart rate (tachycardia). May cause harm to breastfed babies.
Statement of Hazard	Causes eye irritation. May damage the unborn child. May cause harm to breastfed babies. Toxic to aquatic life with long lasting effects

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EU Classification **EU Indication of danger**	Toxic to Reproduction: Category 2 Dangerous for the Environment
Australian Hazard Classification (NOHSC):	R51/53 - Toxic to aquatic organisms, may c ause long-term adverse effects in the aquatic environment. Hazardous Substance. Non-Dangerous Goods

3. Composition/Information on ingredients		150 mg	200 mg	300 mg	400 mg
Components	**CAS-No**	**Concentration (%w/w)**			
Quetiapine fumarate, USP*	1111-974-69-7	29.441	37.624	42.326	50.727
Lactose monohydrate, NF (80M)	64044-51-5	*			
Microcrystalline Cellulose, NF (Avicel 101)	9004-34-6	*			
Sodium citrate Dihydrate, USP	6132043	*			
Hypromellose, USP (Methocel K4M Premium CR)	9004653	*			
Hypromellose, USP (Methocel K100 Premium LVCR)	9004653	*			
Magnesium Stearate, NF	557-04-0	*			
Hypromellose	9004653	*			
Titanium dioxide	13463677	*			
Polyethylene glycol	25322683	*			
Ferric oxide Red, NF	1309-37-1	*			
Ferric oxide yellow, NF	51274-00-1				

* Proprietary, In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. **Present in trace amounts.

4. FIRST AID MEASURES	
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.
Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
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.

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5. FIRE-FIGHTING MEASURES	
Suitable extinguishing media	Extinguish fires with CO2, extinguishing powder, foam, or Water.
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Fire Fighting Procedures	During all fire fighting activities, wear appropriate protective equipment, including selfcontained breathing apparatus.
Fire / Explosion Hazards:	Fine particles (such as dust and mist) may fuel fires/explosions.

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.

7. HANDLING AND STORAGE	
General Handling	Minimize dust generation and accumulation. 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 Conditions	Store as directed by product packaging.

8. Exposure controls/Personal protection	
Environmental Exposure Controls	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

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	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).
Hands	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations- preferred, Maintain eyewash facilities in the work area.
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.
Respiratory protection	If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
Appearance **Physical State** **Color** **Form** **Molecular Formula**	coated tablets 150 mg and 400 mg-white 200 mg-yellow 300 mg –light yellow Extended release Tablets Mixture
Molecular Weight	Mixture

10. Stability and Reactivity	
Reactivity	No data available
Chemical Stability	Stable under normal conditions
Oxidizing Properties	No data available
Conditions to Avoid	Fine particles (such as dust and mists) may fuel fires/explosions.
Hazardous Decomposition Products	No data available
Incompatible Materials	As a precautionary measure, keep away from strong oxidizers

11. Toxicological Information	
General Information	Carcinogenicity studies were conducted in C57BL mice and Wistar rats. Quetiapine was administered in the diet to mice at doses of 20, 75, 250, and 750 mg/kg and to rats by gavage at doses of 25, 75, and 250 mg/kg for two years. These doses are equivalent to 0.1, 0.5, 1.5, and 4.5 times the maximum human dose (M RHD) of 800 mg/day based on mg/m2

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	body surface area (mice) or 0.3, 1, and 3 times the MRHD based on mg/m2 body surface area (rats). There were statistically significant increases in thyroid gland follicular adenomas in male mice at doses 1.5 and 4.5 times the MRHD on mg/m2body surface area and in male rats at a dose of 3 times the MRHD on mg/m2body surface area. Mammary gland adenocarcinomas were statistically significantly increased in female rats at all doses tested (0.3, 1, and 3 times the MRHD on mg/m2 body surface area). Thyroid follicular cell adenomas may have resulted from chronic stimulation of the thyroid gland by thyroid stimulating hormone (TSH) resulting from enhanced metabolism and clearance of thyroxine by rodent liver. Changes in TSH, thyroxine, and thyroxine clearance consistent with this echanism were observed in subchronic toxicity studies in rat and mouse and in a 1-year toxicity study in rat; however, the results of these studies were not definitive. The relevance of the increases in thyroid follicular cell adenomas to human risk, through whatever mechanism, is unknown. Antipsychotic drugs have been shown to chronically elevate prolactin levels in rodents. Serum measurements in a 1-year toxicity study showed that quetiapine increased median serum prolactin levels a maximum of 32- and 13-fold in male and female rats, respectively. Increases in mammary neoplasms have been found in rodents after chronic administration of other antipsychotic drugs and are considered to be prolactin-mediated. The relevance of this increased incidence of prolactin-mediated mammary gland tumors in rats to human risk is unknown. The mutagenic potential of quetiapine was tested in the in vitro Ames bacterial gene mutation assay and in the in vitro mammalian gene mutation assay in Chinese Hamster Ovary cells. The clastogenic potential of quetiapine was tested in the in vitro chromosomal aberration assay in cultured human lymphocytes and in the in vivo bone marrow micronucleus assay in rats up to 500 mg/kg which is 6 times the maximum recommended human dose on mg/m2body surface area. Based on weight of evidence quetiapine was not mutagenic or clastogenic in these tests. Quetiapine decreased mating and fertility inmale Sprague-Dawley rats at oral doses of 50 and 150 mg/kg or approximately 1 and 3 times the maximum human dose (MRHD) of 800 mg/day on mg/m2body surface area. Drug-related effects included increases in interval to mate and in the number of matings required for successful impregnation. These effects continued to be observed at 3 times the MRHD even after a two-week period without treatment. The no-effect

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	dose for impaired mating and fertility in male rats was 25 mg/kg, or 0.3 times the MRHD dose on mg/m2body surface area. Quetiapine adversely affected mating and fertility in female Sprague-Dawley rats at an oral dose approximately 1 times the MRHD of 800 mg/day on mg/m2body surface area. Drug-related effects included decreases in matings and in matings resulting in pregnancy, and an increase in the interval to mate. An increase in irregular estrus cycles was observed at doses of 10 and 50 mg/kg, or approximately 0.1 and 1 times the MRHD of 800 mg/day onmg/m2 body surface area. The no-effect dose in female rats was1 mg/kg or 0.01 times the MRHD of 800 mg/day on mg/m2body surface area.
Short Term Known Clinical Effects	Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, drowsiness, muscle weakness, gastrointestinal disturbances, liver effects, and hypersensitivity reactions.
Acute Toxicity (Species, Route, End Point, Dose) Alginic acid	Due to lack of data the classification is not possible
Repeated Dose Toxicity	Due to lack of data the classification is not possible
Reproduction & Development Toxicity	No route specified Dose not specified, Not teratogenic, Negative
Genetic Toxicity	Due to lack of data the classification is not possible
Carcinogenicity	Not listed as a carcinogen by IARC, NTP or US OSHA
Other Toxicity Information	Due to lack of data the classification is not possible

12. Ecological Information	
Toxicity	No data available
Environmental Overview	Environmental properties have not been investigated. Releases to the environment should be avoided.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available
Mobility in soil	Not available
Other adverse effects	Not available

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13. Disposal considerations	
Waste treatment method	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.

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

15. Regulatory Information	
EU Indication of danger	Harmful

16. Other information	
Recommended Restrictions for Use:	Not available
Prepared on	*01/26/2018*
Revision	00
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