

**MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY
AIR QUALITY DIVISION**

October 14, 2024

PERMIT TO INSTALL
118-24

ISSUED TO
Pharmacia & Upjohn Company, LLC, a subsidiary of Pfizer Inc

LOCATED AT
7000 Portage Road
Kalamazoo, Michigan 49001

IN THE COUNTY OF
Kalamazoo

STATE REGISTRATION NUMBER
B3610

The Air Quality Division has approved this Permit to Install, pursuant to the delegation of authority from the Michigan Department of Environment, Great Lakes, and Energy. This permit is hereby issued in accordance with and subject to Section 5505(1) of Article II, Chapter I, Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended. Pursuant to Air Pollution Control Rule 336.1201(1), this permit constitutes the permittee's authority to install the identified emission unit(s) in accordance with all administrative rules of the Department and the attached conditions. Operation of the emission unit(s) identified in this Permit to Install is allowed pursuant to Rule 336.1201(6).

DATE OF RECEIPT OF ALL INFORMATION REQUIRED BY RULE 203: September 25, 2024	
DATE PERMIT TO INSTALL APPROVED: October 14, 2024	SIGNATURE:
DATE PERMIT VOIDED:	SIGNATURE:
DATE PERMIT REVOKED:	SIGNATURE:

PERMIT TO INSTALL

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COMMON ACRONYMS

AQD	Air Quality Division
BACT	Best Available Control Technology
CAA	Clean Air Act
CAM	Compliance Assurance Monitoring
CEMS	Continuous Emission Monitoring System
CFR	Code of Federal Regulations
COMS	Continuous Opacity Monitoring System
Department/department/EGLE	Michigan Department of Environment, Great Lakes, and Energy
EU	Emission Unit
FG	Flexible Group
GACS	Gallons of Applied Coating Solids
GC	General Condition
GHGs	Greenhouse Gases
HVLP	High Volume Low Pressure*
ID	Identification
IRSL	Initial Risk Screening Level
ITSL	Initial Threshold Screening Level
LAER	Lowest Achievable Emission Rate
MACT	Maximum Achievable Control Technology
MAERS	Michigan Air Emissions Reporting System
MAP	Malfunction Abatement Plan
MSDS	Material Safety Data Sheet
NA	Not Applicable
NAAQS	National Ambient Air Quality Standards
NESHAP	National Emission Standard for Hazardous Air Pollutants
NSPS	New Source Performance Standards
NSR	New Source Review
PS	Performance Specification
PSD	Prevention of Significant Deterioration
PTE	Permanent Total Enclosure
PTI	Permit to Install
RACT	Reasonable Available Control Technology
ROP	Renewable Operating Permit
SC	Special Condition
SCR	Selective Catalytic Reduction
SNCR	Selective Non-Catalytic Reduction
SRN	State Registration Number
TBD	To Be Determined
TEQ	Toxicity Equivalence Quotient
USEPA/EPA	United States Environmental Protection Agency
VE	Visible Emissions

*For HVLP applicators, the pressure measured at the gun air cap shall not exceed 10 psig.

POLLUTANT / MEASUREMENT ABBREVIATIONS

acfm	Actual cubic feet per minute
BTU	British Thermal Unit
°C	Degrees Celsius
CO	Carbon Monoxide
CO ₂ e	Carbon Dioxide Equivalent
dscf	Dry standard cubic foot
dscm	Dry standard cubic meter
°F	Degrees Fahrenheit
gr	Grains
HAP	Hazardous Air Pollutant
Hg	Mercury
hr	Hour
HP	Horsepower
H ₂ S	Hydrogen Sulfide
kW	Kilowatt
lb	Pound
m	Meter
mg	Milligram
mm	Millimeter
MM	Million
MW	Megawatts
NMOC	Non-Methane Organic Compounds
NO _x	Oxides of Nitrogen
ng	Nanogram
PM	Particulate Matter
PM ₁₀	Particulate Matter equal to or less than 10 microns in diameter
PM _{2.5}	Particulate Matter equal to or less than 2.5 microns in diameter
pph	Pounds per hour
ppm	Parts per million
ppmv	Parts per million by volume
ppmw	Parts per million by weight
psia	Pounds per square inch absolute
psig	Pounds per square inch gauge
scf	Standard cubic feet
sec	Seconds
SO ₂	Sulfur Dioxide
TAC	Toxic Air Contaminant
Temp	Temperature
THC	Total Hydrocarbons
tpy	Tons per year
µg	Microgram
µm	Micrometer or Micron
VOC	Volatile Organic Compounds
yr	Year

GENERAL CONDITIONS

1. The process or process equipment covered by this permit shall not be reconstructed, relocated, or modified, unless a Permit to Install authorizing such action is issued by the Department, except to the extent such action is exempt from the Permit to Install requirements by any applicable rule. **(R 336.1201(1))**
2. If the installation, construction, reconstruction, relocation, or modification of the equipment for which this permit has been approved has not commenced within 18 months, or has been interrupted for 18 months, this permit shall become void unless otherwise authorized by the Department. Furthermore, the permittee or the designated authorized agent shall notify the Department via the Supervisor, Permit Section, Air Quality Division, Michigan Department of Environment, Great Lakes, and Energy, P.O. Box 30260, Lansing, Michigan 48909-7760, if it is decided not to pursue the installation, construction, reconstruction, relocation, or modification of the equipment allowed by this Permit to Install. **(R 336.1201(4))**
3. If this Permit to Install is issued for a process or process equipment located at a stationary source that is not subject to the Renewable Operating Permit program requirements pursuant to Rule 210 (R 336.1210), operation of the process or process equipment is allowed by this permit if the equipment performs in accordance with the terms and conditions of this Permit to Install. **(R 336.1201(6)(b))**
4. The Department may, after notice and opportunity for a hearing, revoke this Permit to Install if evidence indicates the process or process equipment is not performing in accordance with the terms and conditions of this permit or is violating the Department's rules or the Clean Air Act. **(R 336.1201(8), Section 5510 of Act 451, PA 1994)**
5. The terms and conditions of this Permit to Install shall apply to any person or legal entity that now or hereafter owns or operates the process or process equipment at the location authorized by this Permit to Install. If the new owner or operator submits a written request to the Department pursuant to Rule 219 and the Department approves the request, this permit will be amended to reflect the change of ownership or operational control. The request must include all of the information required by subrules (1)(a), (b), and (c) of Rule 219 and shall be sent to the District Supervisor, Air Quality Division, Michigan Department of Environment, Great Lakes, and Energy. **(R 336.1219)**
6. Operation of this equipment shall not result in the emission of an air contaminant which causes injurious effects to human health or safety, animal life, plant life of significant economic value, or property, or which causes unreasonable interference with the comfortable enjoyment of life and property. **(R 336.1901)**
7. The permittee shall provide notice of an abnormal condition, start-up, shutdown, or malfunction that results in emissions of a hazardous or toxic air pollutant which continue for more than one hour in excess of any applicable standard or limitation, or emissions of any air contaminant continuing for more than two hours in excess of an applicable standard or limitation, as required in Rule 912, to the Department. The notice shall be provided not later than two business days after start-up, shutdown, or discovery of the abnormal condition or malfunction. Written reports, if required, must be filed with the Department within 10 days after the start-up or shutdown occurred, within 10 days after the abnormal conditions or malfunction has been corrected, or within 30 days of discovery of the abnormal condition or malfunction, whichever is first. The written reports shall include all of the information required in Rule 912(5). **(R 336.1912)**
8. Approval of this permit does not exempt the permittee from complying with any future applicable requirements which may be promulgated under Part 55 of 1994 PA 451, as amended or the Federal Clean Air Act.
9. Approval of this permit does not obviate the necessity of obtaining such permits or approvals from other units of government as required by law.
10. Operation of this equipment may be subject to other requirements of Part 55 of 1994 PA 451, as amended and the rules promulgated thereunder.

11. Except as provided in subrules (2) and (3) or unless the special conditions of the Permit to Install include an alternate opacity limit established pursuant to subrule (4) of Rule 301, the permittee shall not cause or permit to be discharged into the outer air from a process or process equipment a visible emission of density greater than the most stringent of the following. The grading of visible emissions shall be determined in accordance with Rule 303 (R 336.1303). **(R 336.1301)**
 - a) A six-minute average of 20 percent opacity, except for one six-minute average per hour of not more than 27 percent opacity.
 - b) A visible emission limit specified by an applicable federal new source performance standard.
 - c) A visible emission limit specified as a condition of this Permit to Install.
12. Collected air contaminants shall be removed as necessary to maintain the equipment at the required operating efficiency. The collection and disposal of air contaminants shall be performed in a manner so as to minimize the introduction of contaminants to the outer air. Transport of collected air contaminants in Priority I and II areas requires the use of material handling methods specified in Rule 370(2). **(R 336.1370)**
13. The Department may require the permittee to conduct acceptable performance tests, at the permittee's expense, in accordance with Rule 1001 and Rule 1003, under any of the conditions listed in Rule 1001. **(R 336.2001)**

EMISSION UNIT SPECIAL CONDITIONS

EMISSION UNIT SUMMARY TABLE

The descriptions provided below are for informational purposes and do not constitute enforceable conditions.

Emission Unit ID	Emission Unit Description (Including Process Equipment & Control Device(s))	Installation Date / Modification Date	Flexible Group ID
EUCR3225-S3	All equipment in or around Building 225, located in API Region III. Includes high-performance liquid chromatography for the PGE2 process (PTI No. 118-24).	01-01-1976/ 06-14-1995/ 03-15-2016/ 02-07-2019/ 09-13-2021/ 01-31-2022/ 03-17-2023/ TBD	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3

Changes to the equipment described in this table are subject to the requirements of R 336.1201, except as allowed by R 336.1278 to R 336.1291.

EUCR3225-S3 EMISSION UNIT CONDITIONS

DESCRIPTION

All equipment in or around Building 225, located in API Region III. Includes high-performance liquid chromatography for the PGE2 process. (PTI No. 118-24).

Flexible Group ID: FGCRALLPART-S3, FGCRALLTOX-S3, FGCFUG-S3, FGPHARMAMACT-S3

POLLUTION CONTROL EQUIPMENT

Particle Scrubbers on SCRB1006, SCRB1007; HEPA Filters on EF1C1HB1, EX27, EX30, EX34; Scrubbers connected to the thermal oxidizer system (TOX). TOX: Two parallel thermal oxidizer, quench, and scrubber trains—one in use and one as a backup.

I. EMISSION LIMIT(S)

Pollutant	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. VOC (total)	75 lbs/month	Calendar month	When emitting from unconnected vent T-K271	SC VI.3	R 336.1702(a)
2. Diisobutyl Aluminum Hydride	0.01 pph ¹	Hourly	T-K271 while emitting from the unconnected bypass vent	SC VI.3	R 336.1225
3. Toluene	2.00 pph ¹	Hourly	T-K271 while emitting from the unconnected bypass vent	SC VI.3	R 336.1225
4. Isobutylene	0.01 pph ¹	Hourly	T-K271 while emitting from the unconnected bypass vent	SC VI.3	R 336.1225
5. Isobutane	0.01 pph ¹	Hourly	T-K271 while emitting from the unconnected bypass vent	SC VI.3	R 336.1225
6. Particulate matter (PM)	188.6 lbs/month ¹	Calendar month	All EUCR3225-S3 vents combined	SC VI.2	R 336.1225
7. PM	Limits in the table below:	Hourly	EUCR3225-S3	SC VI.2	R 336.1225, R 336.1331(c)
8. PM10	188.6 lbs	Calendar month	All EUCR3225-S3 vents combined	SC VI.2	40 CFR 52.21(c) and (d)
9. PM10	Limits in the table below:	Hourly	EUCR3225-S3	SC VI.2	40 CFR 52.21(c) and (d)
10. PM2.5	188.6 lbs	Calendar month	All vents in EUCR3225-S3 combined	SC VI.2	40 CFR 52.21(c) and (d)
11. PM2.5	Limits in the table below:	Hourly	EUCR3225-S3	SC VI.2	40 CFR 52.21(c) and (d)

Pollutant	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
12. VOC (total)	3.91 tpy	12-month rolling time period as determined at the end of each calendar month	High-performance liquid chromatography column loading process exhausted through SCRB1006	SC VI.6	R 336.1702(a)

Emission Limits for PM, PM10, and PM2.5							
Exhaust ID	PM, PM10, and PM2.5			PM only			Maximum Gas Flow Rate (dscfm)
	Lbs Per Hour By Size Category*			Lbs Particulate Per 1000 Lbs Of Dry Exhaust Gas			
	A	B	C	A	B	C	
13. EF1C1HB1	0.14	0.1	0.06	0.01	0.01	0.006	2,400
14. SCRB1006	0.82	0.41	0.21	0.01	0.01	0.006	24,000
15. SCRB1007	0.41	0.21	0.1	0.01	0.01	0.006	12,000
16. EX-27	0.33	0.24	0.14	0.01	0.01	0.006	5,500
17. EX-30	0.12	0.09	0.05	0.01	0.01	0.006	2,000
18. EX-34	0.34	0.24	0.15	0.01	0.01	0.006	5,700

*See Appendix 10-S3 for approved procedures for determination of the particle size category.

II. MATERIAL LIMIT(S)

Material	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. Material produced in PM-emitting activities	115 lots/month ¹	Calendar month	EUCR3225-S3	SC VI.5	R 336.1225, R 336.1227(2)
2. Lots of product produced in VOC processes.	30 lots/month	Calendar month	EUCR3225-S3	SC VI.7	R 336.1225, R 336.1227(2), R 336.1702(a)
3. Material produced in 1MAV-emitting activities	90 kg/lot ¹	Calendar month	EUCR3225-S3	SC VI.8	R 336.1226(a)
4. Material produced in 2MAV-emitting activities	90 kg/lot ¹	Calendar month	EUCR3225-S3	SC VI.9	R 336.1226(a)

III. PROCESS/OPERATIONAL RESTRICTION(S)

- Except for the T-K271 unconnected bypass vent and the high-performance liquid chromatography column loading process exhausted through SCRB1006, the permittee shall not operate equipment located in EUCR3225-S3 in vacuum service while processing a VOC unless the vacuum pump is connected to the thermal oxidizer control and the thermal oxidizer control is installed, maintained, and operated in a satisfactory manner. **(R 336.1224, R 336.1225, R 336.1702(a), R 336.1910)**
- The permittee shall capture all waste materials from the solvent cleaning of the solids drum charging glove boxes and shall store them in closed containers. The permittee shall dispose of all these materials in an acceptable manner in compliance with all applicable state rules and federal regulations. **(R 336.1224, R 336.1225, R 336.1702(a))**
- The permittee shall capture all waste materials from the solvent cleaning of the lipid storage tanks and shall store them in closed containers. The permittee shall dispose of all these materials in an acceptable manner

in compliance with all applicable state rules and federal regulations. **(R 336.1224, R 336.1225, R 336.1702(a))**

4. The permittee shall handle all materials for EUCR3225-S3 activities containing volatile compounds other than water in a manner to minimize the generation of fugitive emissions. The permittee shall keep containers covered at all times except when operator access is necessary. **(R 336.1224, R 336.1225, R 336.1702(a))**

IV. DESIGN/EQUIPMENT PARAMETER(S)

NA

V. TESTING/SAMPLING

Records shall be maintained on file for a period of five years. **(R 336.1201(3))**

NA

VI. MONITORING/RECORDKEEPING

Records shall be maintained on file for a period of five years. **(R 336.1201(3))**

1. The permittee shall complete all required records in a format acceptable to the AQD District Supervisor and make them available by the last day of the calendar month, for the previous calendar month, unless otherwise specified in any monitoring/recordkeeping special condition. **(R 336.1225, R 336.1702(a), R 336.1331(c), R 336.1910)**
2. The permittee shall calculate and record the actual PM, PM₁₀, and PM_{2.5} emission rates on a monthly basis using a method similar to that described in Appendix 4-S3. **(R 336.1225, R 336.1227(2), R 336.1331(c))**
3. The permittee shall calculate the actual VOC emissions from the T-K271 unconnected bypass vent for each calendar month using the method detailed in Appendix 4-S3. **(R 336.1702(a))**
4. The permittee shall conduct and record the results of a visible emission observation (described in Appendix 3-S3) of the particulate control device exhausts once per calendar month during a period when the particulate control devices are being operated. **(R 336.1331)**
5. The permittee shall monitor and record, in a satisfactory manner, the amount of material, in lots, produced in PM-emitting activities in EUCR3225-S3 on a calendar month basis.¹ **(R 336.1225, R 336.1227(2))**
6. The permittee shall calculate the actual VOC emissions from the high-performance liquid chromatography column loading process exhausted through SCRB1006exhaust hood for each calendar month and the 12-month rolling time period, as determined at the end of each calendar month, in a format acceptable to the AQD District Supervisor. The permittee shall keep all records on file at the facility and shall make them available to the department upon request. **(R 336.1702(a))**
7. The permittee shall monitor and record, in a satisfactory manner, the amount of material, in lots, produced in VOC-emitting activities in EUCR3225-S3 on a calendar month basis.¹ **(R 336.1225, R 336.1227(2))**
8. The permittee shall monitor and record, in a satisfactory manner, the amount of material, in kg/lot, produced in 1MAV-emitting activities in EUCR3225-S3 on a calendar month basis.¹ **(R 336.1226(a))**
9. The permittee shall monitor and record, in a satisfactory manner, the amount of material, in kg/lot, produced in 2MAV-emitting activities in EUCR3225-S3 on a calendar month basis.¹ **(R 336.1226(a))**

VII. REPORTING

1. Within 30 days after completion of the installation, construction, reconstruction, relocation, or modification authorized by this Permit to Install, the permittee or the authorized agent pursuant to Rule 204, shall notify the AQD District Supervisor, in writing, of the completion of the activity. Completion of the installation, construction, reconstruction, relocation, or modification is considered to occur not later than commencement

of trial operation of high-performance liquid chromatography for the PGE2 process in EUCR3225-S3.
(R 336.1201(7)(a))

VIII. STACK/VENT RESTRICTION(S)

The exhaust gases from the stacks listed in the table below shall be discharged unobstructed vertically upwards to the ambient air unless otherwise noted:

Stack & Vent ID	Maximum Exhaust Diameter / Dimensions (inches)	Minimum Height Above Ground (feet)	Underlying Applicable Requirements
1. SVC225EF1C1HB1	14	55	R 336.1225, 40 CFR 52.21(c) and (d)
2. SVC225EX27	29	68	R 336.1225, 40 CFR 52.21(c) and (d)
3. SVC225EX30	17	54	R 336.1225, 40 CFR 52.21(c) and (d)
4. SVC225EX34	25	53	R 336.1225, 40 CFR 52.21(c) and (d)
5. SVC225SCRB1006	35	79	R 336.1225, 40 CFR 52.21(c) and (d)
6. SVC225SCRB1007	25	80	R 336.1225, 40 CFR 52.21(c) and (d)
7. SVC225TK271	4	61	R 336.1225, 40 CFR 52.21(c) and (d)

IX. OTHER REQUIREMENT(S)

1. The permittee shall comply with all applicable provisions of the National Emission Standards for Hazardous Air Pollutants, as specified in 40 CFR Part 63, Subpart A and Subpart GGG for Pharmaceuticals Production by the initial compliance date. **(40 CFR Part 63, Subparts A and GGG)**

Footnotes:

- ¹ This condition is state only enforceable and was established pursuant to Rule 201(1)(b).

APPENDIX 3-S3. Monitoring Requirements

The following monitoring procedures, methods, or specifications are the details to the monitoring requirements identified and referenced in EUCR3225-S3. Alternative monitoring procedures, methods, or specifications must be approved by the AQD District Supervisor. All other provisions of Appendix 4-S3 of ROP# MI-ROP-B3610-2021, revised May 12, 2022, remain applicable.

A “visible emissions observation” refers to a survey to be performed for the purpose of determining if there is the presence of visible emissions or if there are no visible emissions, other than uncombined water vapor. Visible emission observation shall be taken at least once per month, for a 1-minute duration, during daylight hours. This can be performed by either a certified or non-certified reader. A log of the required observations shall contain the following information: date, time, observer, status of visible emissions (Yes/No).

APPENDIX 4-S3. Recordkeeping

The permittee shall use the following approved formats and procedures for the recordkeeping requirements referenced in EUCR3225-S3 for the T-K271 unconnected bypass vent. Alternative formats must be approved by the AQD District Supervisor. An alternative format has been approved. All other provisions of Appendix 4-S3 of ROP# MI-ROP-B3610-2021a, revised May 12, 2022, remain applicable.

MONTHLY RECORDKEEPING FORMAT- REGION III UNCONNECTED VOC EQUIPMENT PROCESSES			
Process Building	VOC Maximum (lbs/lot)	Actual Number of lots/month	Estimated VOC Emissions (lbs/month)
225	2.5		

The permittee shall use the following approved formats and procedures for the recordkeeping requirements referenced in EUCR3225-S3. Alternative formats must be approved by the AQD District Supervisor. An alternative format has been approved. All other provisions of Appendix 4-S3 of ROP# MI-ROP-B3610-2021a, revised May 12, 2022, remain applicable.

MONTHLY RECORDKEEPING FORMAT- REGION III TSP PROCESSES			
Process Building	Particulate Maximum (lbs/lot)	Actual Number of lots/month	Estimated Particulate Emissions (lbs/month)
225	1.64		

APPENDIX 10-S3. Particle Size Categories

The permittee shall use the following approved procedures for determination of the particle size category and appropriate control equipment for the requirements referenced in Table EUCR3225-S3.

- Category A Mean particle size by weight <100 microns
- Category B Mean particle size by weight >100 microns but <200 microns
- Category C Mean particle size by weight >200 microns

Control Device	Particle Size/ Control Class
Rotoclone	A, B, C
Exhaust Fan	B, C
Scrubber	A, B, C
Baghouse	A, B, C
Dust Collector	A, B, C