

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

March 10, 2021

**PERMIT TO INSTALL  
135-20**

**ISSUED TO**

Pharmacia & Upjohn Company, LLC – a Subsidiary of Pfizer, Inc.

**LOCATED AT**

7000 Portage Road Port-91-106  
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: <b>February 22, 2021</b>	
DATE PERMIT TO INSTALL APPROVED: <b>March 10, 2021</b>	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 <sub>2</sub> 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 <sub>2</sub> S	Hydrogen Sulfide
kW	Kilowatt
lb	Pound
m	Meter
mg	Milligram
mm	Millimeter
MM	Million
MW	Megawatts
NMOC	Non-Methane Organic Compounds
NO <sub>x</sub>	Oxides of Nitrogen
ng	Nanogram
PM	Particulate Matter
PM10	Particulate Matter equal to or less than 10 microns in diameter
PM2.5	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 <sub>2</sub>	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 condition 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
EUB41PROCESS1B	The PROCESS1B area of Building 41. The 1B emission unit includes a dispensing module along with two formulation modules. The two formulation modules are the liquid nano particle (LNP) and Tangential Flow Filter (TFF) modules. The dispensing module includes equipment for weighing solid and liquid materials, which are then charged inside the formulation modules into processing vessels. Processing activities include vessel to vessel transfers. After processing, these vessels are cleaned in place (CIP) with an integrated CIP system. The TFF skids filters are also cleaned in a separate room. Filter integrity testing is also included as part of the emission unit. After final bulk formulation is complete the vessel is transferred to an existing filling line.	PTI date	FGB41PROCESS1B1C
EUB41PROCESS1C	The PROCESS1C area of Building 41. The 1C emission unit includes a dispensing module along with two formulation modules. The two formulation modules are the liquid nano particle (LNP) and Tangential Flow Filter (TFF) modules. The dispensing module includes equipment for weighing solid and liquid materials, which are then charged inside the formulation modules into processing vessels. Processing activities include vessel to vessel transfers. After processing, these vessels are cleaned in place (CIP) with an integrated CIP system. The TFF skids filters are also cleaned in a separate room. Filter integrity testing is also included as part of the emission unit. After final bulk formulation is complete the vessel is transferred to an existing filling line.	PTI date	FGB41PROCESS1B1C
EUB41MANCLN	All manual cleaning activities in Building 41 associated with drug product operations other than use of hand-held aerosol cans.	PTI date	NA

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.

**EUB41MANCLN  
 EMISSION UNIT CONDITIONS**

**DESCRIPTION**

All manual cleaning activities in Building 41 associated with drug product operations other than use of hand-held aerosol cans.

**Flexible Group ID:** NA

**POLLUTION CONTROL EQUIPMENT**

NA

**I. EMISSION LIMIT(S)**

<b>Pollutant</b>	<b>Limit</b>	<b>Time Period / Operating Scenario</b>	<b>Equipment</b>	<b>Monitoring / Testing Method</b>	<b>Underlying Applicable Requirements</b>
1. VOC	17.5 tpy	12-month rolling time period as determined at the end of each calendar month	EUB41MANCLN	SC VI.2	R 3361702(a)

**II. MATERIAL LIMIT(S)**

<b>Material</b>	<b>Limit</b>	<b>Time Period / Operating Scenario</b>	<b>Equipment</b>	<b>Monitoring / Testing Method</b>	<b>Underlying Applicable Requirements</b>
1. Hydrogen peroxide (H <sub>2</sub> O <sub>2</sub> , CAS Number 7722-84-1)	2.0 lbs per day (as 100% H <sub>2</sub> O <sub>2</sub> ) <sup>1</sup>	Calendar month	EUB41MANCLN	SC VI.3	R 336.1225
2. Triethanol-amine (CAS Number 102-71-6)	8.34 lbs per 8-hour shift <sup>1</sup>	Each 8-hour shift	EUB41MANCLN	SC VI.4	R 336.1225

**III. PROCESS/OPERATIONAL RESTRICTION(S)**

1. The permittee shall capture all waste materials from EUB41MANCLN activities 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))**
2. The permittee shall handle all materials for EUB41MANCLN 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 calculations and records in a format acceptable to the AQD District Supervisor by the last day of the calendar month, for the previous calendar month, unless otherwise specified in any monitoring/recordkeeping special condition. **(R 336.1224, R 336.1225, R 336.1702(a))**
2. The permittee shall calculate the VOC emission rates from EUB41MANCLN for each calendar month and for the 12-month rolling time period ending that month using a method acceptable to the AQD District Supervisor. The permittee shall keep all records on file at the facility and make them available to the Department upon request. **(R 336.1702(a))**
3. The permittee shall keep the following information on a daily basis for EUB41MANCLN:
  - a) Milliliters of each H<sub>2</sub>O<sub>2</sub> (CAS Number 7722-84-1) containing cleaning material used.
  - b) Where applicable, milliliters of each H<sub>2</sub>O<sub>2</sub> (CAS Number 7722-84-1) containing cleaning material reclaimed.
  - c) The H<sub>2</sub>O<sub>2</sub> (CAS Number 7722-84-1) content in pounds per milliliter of each cleaning material used.
  - d) H<sub>2</sub>O<sub>2</sub> (CAS Number 7722-84-1) mass emission calculations determining the daily emission rate in pounds per day.

The permittee shall keep the records using mass balance, or an alternative method and format acceptable to the AQD District Supervisor. The permittee shall keep all records on file and make them available to the Department upon request.<sup>1</sup> **(R 336.1224, R 336.1225)**

4. The permittee shall keep the following information for EUB41MANCLN for each shift EUB41MANCLN operates:
  - a) Gallons of each triethanolamine (CAS Number 102-71-6) containing cleaning material used.
  - b) Where applicable, gallons of each triethanolamine (CAS Number 102-71-6) containing cleaning material reclaimed.
  - c) The triethanolamine (CAS Number 102-71-6) content in pounds per gallon of each cleaning material used.
  - d) Triethanolamine (CAS Number 102-71-6) mass emission calculations determining the emission rate in pounds per shift.

The permittee shall keep the records using mass balance, or an alternative method and format acceptable to the AQD District Supervisor. The permittee shall keep all records on file and make them available to the Department upon request.<sup>1</sup> **(R 336.1225)**

#### **VII. REPORTING**

NA

#### **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:

NA

**IX. OTHER REQUIREMENT(S)**

NA

**Footnotes:**

<sup>1</sup> This condition is state only enforceable and was established pursuant to Rule 201(1)(b).

## FLEXIBLE GROUP SPECIAL CONDITIONS

### FLEXIBLE GROUP SUMMARY TABLE

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

<b>Flexible Group ID</b>	<b>Flexible Group Description</b>	<b>Associated Emission Unit IDs</b>
FGB41PROCESS1B1C	The PROCESS1B and PROCESS1C areas of Building 41.	EUB41PROCESS1B, EUB41PROCESS1C

**FGB41PROCESS1B1C  
 FLEXIBLE GROUP CONDITIONS**

**DESCRIPTION**

The PROCESS1B and PROCESS1C areas of Building 41.

**Emission Unit:** EUB41PROCESS1B, EUB41PROCESS1C

**POLLUTION CONTROL EQUIPMENT**

Each emission unit has a prefilter and HEPA filter in series for dispensing activities

**I. EMISSION LIMIT(S)**

<b>Pollutant</b>	<b>Limit</b>	<b>Time Period / Operating Scenario</b>	<b>Equipment</b>	<b>Monitoring / Testing Method</b>	<b>Underlying Applicable Requirements</b>
1. VOC	18.4 tpy	12-month rolling time period as determined at the end of each calendar month	FGB41PROCESS1B1C	SC VI.2	R 336.1702(a)
2. PM	0.02 pph	Hourly	EUB41PROCESS1B	SC VI.3	R 336.1224, R 336.1331
3. PM	0.02 pph	Hourly	EUB41PROCESS1C	SC VI.3	R 336.1224, R 336.1331

**II. MATERIAL LIMIT(S)**

<b>Material</b>	<b>Limit</b>	<b>Time Period / Operating Scenario</b>	<b>Equipment</b>	<b>Monitoring / Testing Method</b>	<b>Underlying Applicable Requirements</b>
1. Lots produced	186 per month	Calendar month	FGB41PROCESS1B1C	SC VI.4	R 336.1702(a)

**III. PROCESS/OPERATIONAL RESTRICTION(S)**

1. The permittee shall not dispense solid materials in EUB41PROCESS1B or EUB41PROCESS1C unless the associated prefilter and HEPA filter are installed, maintained, and operated in a satisfactory manner acceptable to the AQD District Supervisor. Satisfactory operation of each prefilter and HEPA filter includes following manufacturer's recommendations for maintenance and replacement. **(R 336.1224, R 336.1225, R 336.1301, R 336.1331, R 336.1910)**
2. The permittee shall transfer and charge solid materials to process equipment in EUB41PROCESS1B and EUB41PROCESS1C in a closed fashion, such that the contents of the charging container and of the receiving vessel are only exposed to the air during the times required to open and close the connection between the charging container and the receiving vessel. **(R 336.1224, R 336.1225, R 336.1301, R 336.1331, R 336.1910)**

**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 calculations and records in a format acceptable to the AQD District Supervisor by the last day of the calendar month, for the previous calendar month, unless otherwise specified in any monitoring/recordkeeping special condition. **(R 336.1702(a))**
2. The permittee shall calculate the VOC emission rates from FGB41PROCESS1B1C for each calendar month and for the 12-month rolling time period ending that month using a method acceptable to the AQD District Supervisor. The permittee shall keep all records on file at the facility and make them available to the Department upon request. **(R 336.1702(a))**
3. The permittee shall keep a record of maintenance and replacement activities for each prefilter and HEPA filter train. The permittee shall keep all records on file at the facility and make them available to the Department upon request. **(R 336.1910)**
4. The permittee shall keep a record, in a manner acceptable to the AQD District Supervisor, of the number of lots produced in FGB41PROCESS1B1C during each calendar month. The permittee shall keep all records on file at the facility and make them available to the Department upon request. **(R 336.1702(a))**

**VII. REPORTING**

NA

**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:

<b>Stack &amp; Vent ID</b>	<b>Maximum Exhaust Diameter / Dimensions (inches)</b>	<b>Minimum Height Above Ground (feet)</b>	<b>Underlying Applicable Requirements</b>
1. SVB41PROCESS1B <sup>A</sup>	2	35	R 336.1225, 40 CFR 52.21(c)&(d)
2. SVB41PROCESS1C <sup>A</sup>	2	35	R 336.1225, 40 CFR 52.21(c)&(d)

<sup>A</sup> This vent is allowed to have a gooseneck downward discharge.

**IX. OTHER REQUIREMENT(S)**

NA

**Footnotes:**

<sup>1</sup> This condition is state only enforceable and was established pursuant to Rule 201(1)(b).