

NORTH CAROLINA DIVISION OF AIR QUALITY (NC DAQ)

Air Permit Review

Permit Issue Date: XX/XX/2005

Region: Raleigh Regional Office
County: Wilson
NC Facility ID: 9800185
Inspector's Name: Will Wike
Date of Last Inspection: 11/16/2004
Compliance Code: 3/In Compliance - Inspection

Facility Data			Permit Applicability (this application only)	
Applicant (Facility's Name): Eon Pharma, LLC CDS ID No.: 3719500185 Facility Address: Eon Pharma, LLC 4700 Eon Drive Wilson, NC 27893 SIC: 2834 / Pharmaceutical Preparations NAICS: 325412 / Pharmaceutical Preparation Manufacturing Facility Classification: Before: Title V After: Title V Fee Classification: Before: Title V After: Title V			SIP: 2D .0515, .0516, .0521 and .0958 NSPS: NESHAP: PSD: PSD Avoidance: 2Q .0317 (for VOCs) NC Toxics: 2D .1100 112(r): Other: MACT Avoidance: 2Q .0317 (for HAPs)	
Contact Data			Application Data	
Facility Contact	Authorized Contact	Technical Contact	Application Number: 9800185.05B Date Received: 04/15/2005 Application Type: Modification Application Schedule: TV-SigMod-2Q.0516 Existing Permit Data Existing Permit Number: 08082/T13 Existing Permit Issue Date: 04/22/2005 Existing Permit Expiration Date: 09/30/2006	
William Conover Director of Engineering (252) 234-2204 4700 Eon Drive Wilson, NC 27893	Michael Doelling Facility Manager (252) 234-2222 4700 Eon Drive Wilson, NC 27893	William Conover Director of Engineering (252) 234-2204 4700 Eon Drive Wilson, NC 27893		
Review Engineer: Jeff Twisdale Review Engineer's Signature: _____ Date: _____		Comments / Recommendations: Issue 08082/T14 Permit Issue Date: XX/XX/2005 Permit Expiration Date: 09/30/2006		

1. Introduction

This application is a request to add a catalytic oxidizer and a packed column scrubber to the Title V Operating Permit. The Division of Air Quality (DAQ) received the application on March 10, 2005 and deemed the application complete on April 15, 2005. The application has been duly signed by the principal executive officer, and includes appropriate application forms, processing fee of \$834, etc. The local zoning consistency determination request was required since new construction coincides with this application.

The application will be processed per 15A NCAC 2Q .0516 "Significant Permit Modification." Because the previous modification to the permit did contravene or conflict with any existing permit condition, the processing route for that application was per 2Q .0501(d), as allowed under 2Q .0516(c). Also, as advised by DAQ and agreed by the company (through their consultant, Trigon Engineering Consultants, Inc.), the previous modification was processed through a "two-step" route, which is allowed under 2Q .0501(d)(2). The construction permit was issued pursuant to the provisions of 2Q .0300. While awaiting issuance of the construction permit, the Permittee submitted an application to modify the current permit (08082T13) and obtain a Title V operation permit prior to commencing operation and to satisfy the requirements of 2Q .0500.

2. Facility Description

Eon Pharma, LLC (EON) operates a generic pharmaceutical manufacturing facility on Eon Drive in Wilson, Wilson County, NC. The facility contracts with different companies to make their products. The facility is operating under the air permit 08082T13. This permit was issued on April 22, 2005 and is currently scheduled to expire on September 30, 2006.

The permitted equipment includes the following: three natural gas-fired boilers, one fluid dryer process (four fluid bed dryers), one coating process (five coating pans), four drying tray ovens, one matrix patch line, and two diesel-fired emergency generators/peak shaving units.

The facility is a Title V major source, currently for volatile organic compounds (VOC) only. After this revision, the facility will remain a major source under Title V for VOCs.

3. Application Chronology

For complete details on the processing events for this application, please refer to the "Comprehensive Application Report for 9800185.05B."

4. Permit Modification/Changes

This modification to an existing Title V permit will be handled as a 2Q .0516 significant modification with the submittal of a Title V permit application and receipt of a Title V operation permit being required before commencement of operation of the new sources / control devices pursuant to 2Q .0501(d) and 2Q .0516(c).

A catalytic oxidizer (ID No. CatOx-1) and a packed column scrubber (ID No. WS-1) will be added as control devices for the fluid bed dryers (ID Nos. ES-FBD-3 and ES-FBD-4). A detailed analysis of the process is given below in paragraph (a) of this section. The same regulations (2D .0515, .0521, .0958, 2D .1100, and 2Q .0317 (2D .0530 and .1111 avoidance) and their associated specific conditions will continue to apply to the fluid bed dryers with some revision to the 2D .1100 and 2Q .0317 (2D .0530 and .1111 avoidance) conditions. Continued compliance with the above regulations and associated specific conditions is expected.

a. Two existing Fluid Bed Dryers (ID Nos. ES-FBD-3 and ES-FBD-4) and associated new Catalytic Oxidizer (ID No. CatOx-1) and new Packed Column Scrubber (ID No. WS-1)

The fluid bed dryers are existing sources that are used in the manufacture of granulated pharmaceutical products. There are a total of four fluid bed dryers currently permitted. After this modification, two of the fluid bed dryers (ID Nos. ES-FBD-3 and ES-FBD-4) will process batches containing solvent-based formulations containing hazardous air pollutants (HAPs) (methanol and methylene chloride) or aqueous material while the other two existing fluid bed dryers (ID Nos. ES-FBD-1 and ES-FBD-2) will process batches containing only aqueous material. If one fluid bed dryer is processing solvent-based formulations containing HAPs, the other fluid bed dryer will be processing aqueous material or not operating. The oxidizer/scrubber control system will be sized to control either one fluid bed dryer or the other fluid bed dryer, but not both at the same time.

In summary, the new control system (catalytic oxidizer and packed column scrubber) will reduce VOC (methanol and ethanol) and methylene chloride (a state toxic air pollutant (TAP) and a federal HAP) emissions from the existing fluid dryer process (specifically fluid bed dryers (ID Nos. ES-FBD-3 and ES-FBD-4). However, the destruction of methylene chloride by the catalytic oxidizer will result in an increase of hydrogen chloride that may pass through the packed column scrubber. Insignificant increases in criteria pollutants from the firing of natural gas in the catalytic oxidizer will result. Also, insignificant increases in particulate matter may result from the increased production (actual number of annual batches being processed) while still maintaining facility HAP emissions below the respective thresholds for the 40 CFR 63 (MACT) Subpart GGG.

Emissions of particulate matter, VOC, TAPs and HAPs are expected from the fluid dryer process. The emissions are based on 117 batches per year, and throughputs of 1,628 lbs/batch (methanol), 1,739 lbs/batch (methylene chloride), 880 lbs/batch (pharmaceutical powders), and 560 lbs/batch (nonhazardous solvents).

Control Devices

Emissions from the fluid bed dryers will be controlled by a new catalytic oxidizer and a new packed column scrubber installed in series on an existing bagfilter and an existing HEPA filter that operate in series. The existing bagfilters and HEPA filters have been previously evaluated for particulate matter less than 10 microns in diameter (PM-10) control, and their control efficiencies are 99.9% and 99.97%, respectively. Insignificant PM-10 increases are expected. Therefore, particulate matter control will not be specifically addressed since compliance has been easily demonstrated in the past using the bagfilters and HEPA filters for control.

The catalytic oxidizer will control VOC (ethanol and methanol) and HAP (methanol and methylene chloride) emissions and will utilize a precious metal catalyst (platinum) with an expected life of five years. In order to monitor catalyst life, the vendor recommends that the test cores from the catalyst bed should be analyzed annually to ensure proper performance. The natural gas-fired catalytic oxidizer burner (0.6 million Btu per hour heat input) will increase the temperature of the emission stream to 900 degrees Fahrenheit (F) immediately preceding the inlet of the catalyst bed. The normal temperature rise across the catalyst bed is expected to be 50 F resulting in an outlet temperature of 1000 F. The application states that the overall control efficiency of the catalytic oxidizer is 95% considering 100% capture efficiency and 95% destruction efficiency. The catalytic oxidizer appears to be adequately designed, and an initial performance test will ensure that the proper efficiencies and operating parameters are being utilized to demonstrate compliance.

The packed column scrubber will control HAP (hydrogen chloride) emissions generated as a result of the catalytic oxidizer control of methylene chloride. The packed column scrubber equipped with a high efficiency mist eliminator will utilize polypropylene (two inch Tri-Pack) packing and a caustic (sodium hydroxide) scrubbing medium. The minimum liquid injection rate is 50 gallons per minute while the pressure drop across the scrubber typically ranges from 4 to 5 inches of water. The pH of the scrubber effluent is normally between 8 and 9. The application states that the overall control efficiency of the packed column scrubber is 98% considering 100% capture efficiency and 98% destruction efficiency. The packed column scrubber appears to be adequately designed, and an initial performance test will ensure that the proper efficiencies and operating parameters are being utilized to demonstrate compliance.

The fluid bed dryers are subject to the requirements of 2D .0515, .0521 .0958 and .1100, and 2Q .0317. Only the catalytic oxidizer installed on the fluid bed dryers will be subject to 2D .0516 due to natural gas combustion.

15A NCAC 2D .0515: Particulates from Miscellaneous Industrial Processes

This regulation limits the allowable emissions of particulates, using the process rate of an industrial process. Based on the process rate of 4,807 lbs/batch and numbers of batch of 0.13 batch/hr, the allowable emission rate for the source would be 1.88 lb/hr. The Permittee has estimated the worst-case potential emissions of particulate matter at 1.5×10^{-7} lb/hr. Therefore, continued compliance is expected.

15A NCAC 2D .0516: Sulfur Dioxide Emissions from Combustion Sources

This regulation limits the allowable emissions of sulfur dioxide formed by the combustion of sulfur in fuels. The catalytic oxidizer (0.6 million Btu per hour heat input) burns natural gas to increase the bed temperature to an optimal level. Since the catalytic oxidizer burns only natural gas (an inherently low sulfur fuel), compliance is expected. Also, no monitoring, record keeping or reporting is required for compliance.

15A NCAC 2D .0521: Control of Visible Emissions

These emission sources are subject to 20% opacity limit. Compliance has been verified during past compliance inspections, and no additional visible emissions are expected from the potential increase in annual production.

15A NCAC 2D .0958: Work Practices for Sources of Volatile Organic Compounds

This facility is already subject to 2D .0958. Compliance will be demonstrated through work practice standards. The facility has been shown to be in compliance with 2D .0958 in previous compliance inspections. Continued compliance is expected with this requirement.

15A NCAC 2D .1100: Control of Toxic Air Pollutants

Please refer to Section 6.

15A NCAC 2Q .0317: Avoidance Conditions

In accordance with 2Q .0317(a)(1), in the existing permit, the Permittee has taken a PSD avoidance limit to restrict the potential to emit for VOC emissions below 250 tons/yr. This emission limit accounts for VOC emissions from all permitted sources. The fluid bed dryers will continue to operate under the same PSD avoidance condition with the allowance of catalytic oxidizer control (95%) to be used in the VOC calculations.

Similarly, in accordance with 2Q .0317(a)(5), in order to avoid complying with "pharmaceutical production" MACT regulation, the Permittee has taken a MACT avoidance limit in the existing permit, to restrict the potential to emit for HAP emissions below 10/25 tons/yr on a facility-wide basis. The MACT avoidance limit will be revised to include monitoring, record keeping and reporting requirements for the new control devices (catalytic oxidizer and packed column scrubber). The initial performance test should ensure compliance with the MACT Avoidance limit. The operating parameters placed in the current permit are based on the manufacturer's suggested operating parameters. The manufacturer suggested a minimum inlet temperature immediately preceding the catalyst bed of 900 degrees Fahrenheit and a minimum temperature difference across the catalyst bed of 50 degrees Fahrenheit. The facility will be required to continuously monitor and record daily the minimum inlet temperature and temperature difference across the catalyst bed when the oxidizer is operational. If the catalytic oxidizer is operated below the minimum inlet temperature and temperature difference across the catalyst bed required in the permit, the facility will be in noncompliance with 15A NCAC 2D .1111, and the HAP emissions will be based on no controls during that time. The manufacturer suggested a minimum pressure drop across the scrubber of 4 inches of water and a minimum pH of 8 for the scrubber effluent. The facility will be required to continuously monitor and record daily the minimum pressure drop across the scrubber and pH of the scrubber effluent when the scrubber is operational. If the scrubber is operated below minimum pressure drop and pH required in the permit, the facility will be in noncompliance with 15A NCAC 2D .1111, and the HAP emissions will be based on no controls during that time. The facility will also be required to test the existing fluid bed dryers (ID Nos. ES-FBD-3 or ES-FBD-4) that will be controlled by a catalytic oxidizer (ID No. CatOx-1) and a packed column scrubber (ID No. WS-1) within 180 days of routing HAP emissions to the control equipment. Even with a potential increase in annual production, continued compliance with the MACT avoidance limit is expected with proper operation of the control equipment.

b. Fluid Bed Dryer (ID No. ES-FBD-4)

EON will start operation of the fluid bed dryer (ID No. ES-FBD-4) shortly after the installation of the control equipment mentioned above. The fluid bed dryer will commence operation in summer 2005 after construction was allowed through a 2Q .0501(c)(2) modification under air permit 08082T11 that was issued August 10, 2004. Since the process will be operating in the near future, the notation for construction (**) of this source will be removed. The same applicable regulations and their associated specific conditions will continue to apply (see above) with some revision to the 2D .1100 and 2Q .0317 (2D .0530 and .1111 avoidance) conditions. Continued compliance with the above regulations and associated specific conditions is expected.

5. NSPS, NESHAPS, PSD, Attainment Status, 112(r), and CAM

NSPS

The fluid bed dryers are not subject to any NSPS regulations.

NESHAP/MACT

The fluid bed dryers are not subject to any MACT regulations at this time. As indicated above, the facility has taken a MACT avoidance limit in the existing permit to avoid the "pharmaceutical production" MACT regulation (40 CFR 63 Subpart GGG). As indicated above, all existing and new equipment will continue to operate under this MACT avoidance limit that has been revised to include monitoring, record keeping and reporting requirements for the new control devices (catalytic oxidizer and packed column scrubber).

PSD

The County of Wilson is in attainment of all criteria pollutants. The facility is a "250 tons" category source and is currently considered to be a minor stationary source under the PSD regulations for all criteria pollutants. As indicated above, the facility has taken a limit to restrict the potential to emit for VOC emissions below 250 tons per year threshold on a facility-wide basis. The permit includes the necessary monitoring/record keeping/reporting requirements for all existing and new emission sources: boilers, fluid bed dryers, coating pans, drying tray ovens, matrix patch line, and emergency generators.

The minor source baseline dates for PM-10, sulfur dioxide, and nitrogen oxides have been triggered for Wilson County. This modification does not result in any increase in emissions of PM-10, sulfur dioxide, and nitrogen oxides. Emissions tracking for these pollutants will not be required for PSD Class II increment purposes.

112(r)

This facility is not subject to Section 112(r) of the Clean Air Act requirements because it does not store any of the regulated substances in quantities above the thresholds in this rule.

CAM

The analysis on applicability to any CAM requirement is required at this time since this application is being processed as a significant modification of the Title V Operation Permit pursuant to 2Q .0516. However, each fluid bed dryer (ID No. ES-FBD-3 or ES-FBD-4) is not considered to be a large pollutant specific emission unit (PSEU) because potential after control emissions are less than respective Title V thresholds (100 tpy of VOCs, and 10 tpy of individual HAP and 25 tpy of combined HAPs). Therefore, CAM does not apply at this time.

However, since the facility is installing a catalytic oxidizer and a packed column scrubber and will be required to monitor the operating parameters (e.g. minimum inlet temperature of the catalyst bed, pressure drop across the scrubber), CAM will be addressed at this time. Since the control devices will be operated as necessary to comply with the MACT Avoidance limit and because a continuous compliance determination method (CCDM) based on operating parameters and initial performance testing will be placed in the permit, the facility will be exempt from CAM requirements. The facility will be required to conduct monitoring that satisfies criteria established in the CAM rule to provide reasonable assurance of compliance with applicable requirements by:

- Continuously monitor and record daily the minimum inlet temperature of the catalyst bed and the minimum temperature difference across the catalyst bed for the catalytic oxidizer;
- Continuously monitor and record daily the minimum pressure drop across the scrubber and the minimum pH of the scrubber effluent for the packed column scrubber;
- Periodic internal and external structural integrity inspections including an annual catalyst inspection;
- Monthly inspection of the spray nozzles and the packing material for the packed column scrubber; and
- Initial performance test

The facility will be required to test the existing fluid bed dryers (ID Nos. ES-FBD-3 and ES-FBD-4) that will be controlled by a catalytic oxidizer (ID No. CatOx-1) and a packed column scrubber (ID No. WS-1) within 180 days of routing HAP emissions to the control equipment. The initial performance test should ensure compliance with the MACT Avoidance limit. The operating parameters placed in the current permit are based on the manufacturer's suggested operating parameters. The manufacturer suggested a minimum inlet temperature immediately preceding the catalyst bed of 900 degrees Fahrenheit and a minimum temperature difference across the catalyst bed of 50 degrees Fahrenheit. The facility will be required to continuously monitor and record daily the minimum inlet temperature and temperature difference across the catalyst bed when the oxidizer is operational. If the catalytic oxidizer is operated below the minimum inlet temperature and temperature difference across the catalyst bed required in the permit, the facility will be in noncompliance with 15A NCAC 2D .1111, and the HAP emissions will be based on no controls during that time. The manufacturer suggested a minimum pressure drop across the scrubber of 4 inches of water and a minimum pH of 8 for the scrubber effluent. The facility will be required to continuously monitor and record daily the minimum pressure drop across the scrubber and pH of the scrubber effluent when the scrubber is operational. If the scrubber is operated below minimum pressure drop and pH required in the permit, the facility will be in noncompliance with 15A NCAC 2D .1111, and the HAP emissions will be based on no controls during that time.

6. Facility-wide Air Toxics

The facility has the potential to exceed the toxic pollutant emission rates (TPER) for methylene chloride and hydrogen chloride as a result of this modification (installation of a catalytic oxidizer and a packed column scrubber on two fluid bed dryers). The existing permit emission limits emissions of methylene chloride will be revised to assure compliance with its acceptable ambient level (AAL). Specifically, the permit will restrict the hourly methylene chloride emissions from two (not four) fluid bed dryers (ID Nos. ES-FBD-3 and ES-FBD-4) to total 1.73 lb/hr and from the five coating pans to total 39 lbs/hr, with an operating limit of only one source (one from two fluid bed dryers OR one from five coating pans) can use methylene chloride at any given time. In addition, the annual emissions of methylene chloride will be limited to 4,346 lb/yr for the two fluid bed dryers combined and to 15,654 lb/yr for five coating pans combined. The catalytic oxidizer installed on the two fluid bed dryers will be used to control the methylene chloride emissions. Hydrogen chloride will be emitted from the two fluid bed dryers when utilizing methylene chloride in the process and the catalytic oxidizer as control. The wet scrubber will be used to control the hydrogen chloride emissions. Specifically, the permit will restrict the hourly hydrogen chloride emissions from the two fluid bed dryers (ID Nos. ES-FBD-3 and ES-FBD-4) to total 0.56 lb/hr, with an operating limit of only one of two fluid bed dryers can utilize methylene chloride at any given time. Tom Anderson, a meteorologist with DAQ's Air Quality Analysis Branch (AQAB), has reviewed the atmospheric dispersion modeling results and confirms that compliance will be demonstrated (Ref. Mr. Anderson's memo dated April 15, 2005). Maximum impacts were 71% and 13%, respectively, of the 1-hour and annual AALs for methylene chloride, and 2% of the 1-hour AAL for hydrogen chloride.

7. Statement of Compliance

The facility was last inspected by RRO (Will Wike) on November 16, 2004. The facility appeared to be in compliance with all requirements of the permit during this inspection.

8. Facility Emissions Review

The following table represents the facility-wide emissions considering controls:

Pollutant	Actual Emissions (tons per year)	Potential Emissions (tons per year)
Particulate (TSP)	0.24	3
Particulate (PM-10)	0.24	3
Carbon Monoxide	2.65	21
Nitrogen Oxides	3.28	30
Sulfur Dioxide	0.03	4.4
Volatile Organic Compounds	21.2	< 250
Methanol	5.93	< 10
Methylene Chloride	3.79	< 10
Hydrogen Chloride (single largest HAPs)	0.71	< 10
HAPs (aggregate)	10.4	< 25

9. Stipulation Review

- Revised Section 1 Table to remove notation (***) and footnote for emission source (ID No. ES-FBD-4).
- Revised Section 1 Table to remove notation (***) and footnote for control devices (ID Nos. CatOx-1 and WS-1) installed on the fluid bed dryers (ID Nos. ES-FBD-3 and ES-FBD-4).
- Revised Section 2.1 B Heading/Table to remove notation (***) and footnote for emission source (ID No. ES-FBD-4).
- Revised Section 2.1 B Heading/Table to remove notation (***) and footnote for control devices (ID Nos. CatOx-1 and WS-1) installed on the fluid bed dryers (ID Nos. ES-FBD-3 and ES-FBD-4).
- Revised Section 2.2 B Heading to remove notation (***) & footnote for emission source (ID No. ES-FBD-4).
- Revised Section 2.2 B Heading to remove notation (***) and footnote for control devices (ID Nos. CatOx-1 and WS-1) installed on the fluid bed dryers (ID Nos. ES-FBD-3 and ES-FBD-4).
- Revised Part II Section 1 Table A to remove emission source (ID No. ES-FBD-4) and associated control devices (ID Nos. CD-22 and HEPA-22) from the table and the notation (***) / footnote.
- Removed Part II Section 1 Table B for control devices (ID Nos. CatOx-1 and WS-1) installed on the fluid bed dryers (ID Nos. ES-FBD-3 and ES-FBD-4) including notation (***) / footnote and reference to application (9800185.05A) received April 15, 2005.
- Revised Part II Section 3 Specific Condition 1 to remove 2D .0515, .0958 & .1100 as applicable regulations
- Revised Part II Section 2 Specific Condition 3 to remove the requirement to file an application for emission source (ID No. ES-FBD-4) and associated control devices (ID Nos. CD-22 and HEPA-22).
- Removed Part II Section 2 Specific Condition 4 that does not allow operation of emission sources (ID Nos. ES-FBD-3 and ES-FBD-4) utilizing methylene chloride with the associated control devices (ID Nos. CatOx-1 and WS-1) until a Title V Application is filed, and a Title V Operation Permit is obtained.
- Included the latest version of General Conditions in Part I and Part II.

10. Conclusions, Comments, and Recommendations

- In accordance with 2Q .0304(b) "Consistency Determination," the company had provided a copy of the request for a local zoning consistency determination in this application. DAQ received that letter "stamped received on March 14, 2005" from the City of Wilson on March 18, 2005. Then DAQ received the official local zoning consistency determination from the City of Wilson on April 1, 2005.
- In accordance with 2Q .0112 "Applications Requiring Professional Engineer Seal," Linda M. Lamb of Trigon Engineering sealed the technical portions of the application concerning the control system design. Ms. Lamb is a registered Professional Engineer (PE) in North Carolina (Ref. PE Seal No. 18125).
- The draft permit was sent to RRO and EON on April 26, 2005 for review. No comments were received.
- Per 2Q .0516(f), public participation pursuant to 2Q .0521 and EPA/Affected State review pursuant to 2Q .0522 are required. The DRAFT permit will be sent to public notice with a 30 day comment period. The PROPOSED permit will be sent to EPA for their 45 day review at the same time (parallel processing).
- Recommend issuance of this air permit once public notice and EPA review periods have been completed.