

T-33

COMMONWEALTH OF PENNSYLVANIA  
DEPARTMENT OF ENVIRONMENTAL PROTECTION  
FIELD OPERATIONS - BUREAU OF AIR QUALITY

**OPERATING PERMIT**

In accordance with provisions of the Air Pollution Control Act, the act of January 8, 1960, P.L. 2119, as amended, and after due consideration of an application received under Chapter 127 of the Rules and Regulations of the Department of Environmental Protection, the Department hereby issues this permit for the operation of the air contamination source(s) described below:

|                   |   |                  |                               |
|-------------------|---|------------------|-------------------------------|
| <b>Permit No.</b> | <u>OP-09-0010</u>                         | <b>Source(s)</b> | <u>Facility VOC, RACT</u>     |
| <b>Owner</b>      | <u>Teva Pharmaceuticals USA</u>           | <b>Air</b>       | <u>FCG [unclear]</u>          |
| <b>Address</b>    | <u>650 Cathill Road</u>                   | <b>Cleaning</b>  | <u>APR 13 1999</u>            |
|                   | <u>Sellersville, PA 18960</u>             | <b>Device</b>    | <u>DET A [unclear]</u>        |
| <b>Attention</b>  | <u>Mr. Steve Altomare</u>                 | <b>Location</b>  | <u>West Rockhill Township</u> |
|                   | <u>Director of Manufacturing Services</u> |                  | <u>Bucks County</u>           |

This permit is subject to the following conditions:

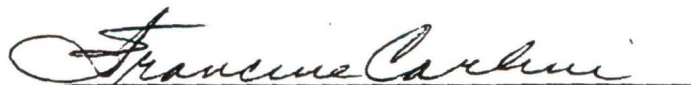
1. That the source(s) and any associated air cleaning devices are to be:
  - a. operated in such a manner as not to cause air pollution;
  - b. in compliance with the specifications and conditions of all applicable Plan Approvals issued;
  - c. operated and maintained in a manner consistent with good operating and maintenance practices.
2. This permit is valid only for the specific equipment, location and owner named above.

(SEE ADDITIONAL CONDITIONS ATTACHED)

Failure to comply with the conditions placed on this permit is a violation of Section 127.444. Violation of this or any other provision of Article III of the Rules and Regulations of the Department of Environmental Protection will result in suspension or revocation of this permit and/or prosecution under Section 9 of the Air Pollution Control Act.

Issued 4/9/1999

Expires 4/9/2004

  
Francine Carlini  
Regional Manager  
Air Quality

cc: Division of Permits, RCSOB  
Administration  
SEFO  
Re (RN99)75-19

OPERATING PERMIT CONDITIONS  
APPLICATION NO. OP-09-0010  
TEVA PHARMACEUTICALS USA

**CONDITIONS (continued):**

3. General Requirements

- a. This Operating Permit incorporates Reasonably Available Control Technology (RACT) determinations as required by Title I provisions of the CAAA, and, 25 Pa. Code Sections 129.91 through 129.95. This Operating Permit is issued to Teva Pharmaceuticals USA, West Rockhill Township, Bucks County.
- b. The company shall not impose conditions upon or otherwise restrict the Department's access to the aforementioned source(s) and shall allow the Department to have access at any time to said source(s) with such measuring and recording equipment, including equipment for recording visual observations, as the Department deems necessary and proper for performing its duties and for the effective enforcement of the Air Pollution Control Act.
- c. If at any time the Department has cause to believe that air contaminant emissions from the aforementioned source(s) may be in excess of the limitations specified in, or established pursuant to, any applicable rule or regulation contained in Article III of the Rules and Regulations of the Department of Environmental Protection, the company shall be required to conduct whatever tests are deemed necessary by the Department to determine the actual emission rate(s). Such testing shall be conducted in accordance with the provisions of Chapter 139 of the Rules and Regulations of the Department of Environmental Protection, where applicable, and in accordance with any restrictions or limitations established by the Department at such time as it notifies the company that testing is required.
- d. The expiration date shown on the Operating Permit is for state purposes. For Federal enforcement purposes the RACT provisions of the Operating Permit shall remain in effect as part of the State Implementation Plan (SIP), until replaced pursuant to 40 CFR 51, and approved by the US Environmental Protection Agency (EPA).

4. Facility Inventory

The sources of VOC emissions at the facility are manufacturing processes utilizing isopropyl alcohol.

5. Emission Limitations

Emissions of VOC from the facility shall not exceed 24.0 tons per year calculated as a 12-month rolling sum.

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**CONDITIONS (continued):**

6. RACT Determination

RACT for the Pony Mixer shall be using the Direct Compression Process.

7. Monitoring, Recordkeeping, and Reporting Procedures:

The company shall maintain records in accordance with the minimum recordkeeping requirements of 25 Pa. Code 129.95. At a minimum, this shall include:

- (a) Records shall provide sufficient data and calculations to clearly demonstrate that the requirements of Condition No. 5 are met.
- (b) Data or information required to determine compliance with Condition No. 5 shall be recorded and maintained in a time frame consistent with the averaging period of the requirements.
- (c) Records shall be retained for at least five years and be made available to the Department on request.

Re 30 (RN99)75-18

