



COMMONWEALTH OF PENNSYLVANIA  
DEPARTMENT OF ENVIRONMENTAL PROTECTION  
BUREAU OF AIR QUALITY

## GENERAL PLAN APPROVAL APPLICATION INSTRUCTIONS

### General Plan Approval BAQ-GPA-24:

### PHARMACEUTICAL AND SPECIALTY CHEMICAL MANUFACTURING

#### General Instructions

1. Use of this General Plan Approval (GPA) is limited to Title V permitted facilities that produce or handle pharmaceutical or specialty chemical products and which have a previously established Plantwide Applicability Limit (PAL) for VOC emissions or facilities that are covered under § 25 Pa. Code Section 127.448. Pharmaceutical and Specialty Chemical Processes, for the purpose of this GPA, are limited to those emitting processes classified under SIC Codes 2833 through 2844 and 2879.
2. This Pharm/Chem General Plan Approval is not intended for use as an operating permit by the owner or operator of a "Title V facility" as defined in 25 Pa. Code Section 121.1, but rather is intended to be used as an interim operating permit until changes allowed per this permit are incorporated into an existing Title V Permit. The allowed changes under this GPA shall be incorporated into the facility's Title V Permit via an Administrative Amendment.
3. An applicant for BAQ-GPA-24 must fulfill the requirements regarding the filing of compliance review forms as required under 25 Pa. Code, Section 127.412.
4. Authorization to use BAQ-GPA-24 for construction/modification of sources is granted for a term of eighteen (18) months. Upon submission of the Notice of Intent to Operate, operation of the modified source is authorized by this GPA for up to 180 days. The application fee is one thousand dollars (\$1000). An application for extension of the plan approval and the extension request fee (\$300) must be submitted thirty (30) days prior to expiration of the General Plan Approval (i.e. prior to the expiration of the 180 days granted for intent to operate).
5. The application and fees shall be submitted to the appropriate DEP Regional Office.
6. This Pharm/Chem General Plan Approval may not be transferred to another person, except as provided in 25 Pa. Code §127.32 (relating to transfer of plan approvals).
7. The facility owner or operator must keep copies of the General Plan Approvals and applications and other applicable records onsite at the facility and shall make the records available to the Department upon request.

## Detailed Application Instructions

### A. Application Usage Information

Indicate whether the application is for a new General Plan Approval (check “New authorization”) or for an extension of an existing general plan approval (check the box for “Extension”).

### B. Owner Information

Enter the owner information as given in your facility’s Title V Permit.

### C. Operator Information

Enter the operator information only if different from the owner information.

### D. Contact Information

Enter the contact information for the person to be contacted regarding questions about this plan approval application.

### E. Facility Information

Enter facility information. Information should be the same as that given in the facility’s Title V Permit.

### F. Title V Operating Permit Information

Enter the facility’s Title V Permit Information. Information should be the same as that given in the facility’s Title V Permit.

### G. Description of Source, Equipment, VOC & HAP Changes

1. Describe, in the space provided or in attachments, the process changes (sources, equipment and/or relevant chemical changes) being made as part of this general plan approval.
2. Attach a flow diagram of the process. Indicate (on diagram) all raw materials being charged to the process equipment and the points where emissions are being controlled. Describe fully the systems provided to monitor and to record process operating conditions, which may affect the emission of air contaminants (i.e., temperature, pressure).
3. Complete a source information table for each new or modified equipment item included in this General Plan Approval Application. Include information on any VOC and/or HAP emission changes. There are only five entry tables provided. Copy and attach additional sheets as necessary.
4. Source/Equipment Information Entry
  - Enter the Source or *Equipment ID* for the equipment as it will be known at the facility.
  - In the spaces provided, enter *Equipment Type* (i.e., tank, centrifuge, filter dryer, distillation column, etc), *Manufacturer & Model*, *Capacity (gallons)*, *Expected*

*Operating Schedule (Hours/Year)*, and *Emission Controls* (with the exception of new vent condensers being permitted through this general plan approval, these controls will be pre-existing at your facility and will already have a TVOP Source ID & Name that can be provided here). All items listed in the “Emission Controls” section should be listed again in Section H or I of the application. Also, Section I should be used to describe any new vent condenser.

- For VOC changes, check the VOC box in the first column. Provide the information requested by the table including *Total Potential Uncontrolled Emissions (pounds/day)*, *Total Potential Controlled Emissions (pounds/day)*, *Total Potential Controlled Emissions (tons/yr)*, and *Calculation/ Estimation Method* for the totalized VOCs.
  - For HAP changes, list each HAP by name in separate rows of the table and check the HAP box in the first column for each row where a name is listed. Provide the requested information for each separate HAP including *Total Potential Uncontrolled Emissions (pounds/day)*, *Total Potential Controlled Emissions (pounds/day)*, *Total Potential Controlled Emissions (tons/yr)*, and *Calculation/ Estimation Method*. Attach additional information tables as necessary if there are more than four HAPS.
5. In the EMISSION CHANGE SUMMARY section sum up the VOC and HAP emission changes due to the equipment changes being made as part of this General Plan Approval.
  6. Sum up the changes to Site VOC emissions from changes being permitted through this GPA including equipment changes as well as changes in chemical processes. This total is the number you will compare to the PAL limit for VOCs for your facility. This number must be less than the PAL to use this General Plan Approval.
  7. Indicate if the process changes identified in this general plan approval will employ stable process hold points for backup emissions control. If the box is checked, attach a list of hold points associated with the process changes and the relevant back up control to be used to reach the hold points. Enter the information for each backup control in the table in Section I.
  8. Describe and quantify any other expected collateral emission increases at the site that are indirectly due to the changes described in this General Plan approval. (i.e., combustion emissions from boilers, heaters, compressors, etc.)

#### H. Primary Operating Scenario Combustion Device & Scrubber Information

1. Enter the data requested for the control devices used to control emissions for the systems being installed or modified as part of this general plan approval:
  - *Enter the Title V Source ID & Source Name* for this control device in the existing Title V permit.
  - Enter *Type* of control device (i.e., combustor, scrubber)
  - *Manufacturer & Model No.*
  - *Capacity* of device in lb/hour
  - *Destruction Removal Efficiency (DRE)* from relevant regulatory performance testing or vendor documentation
2. In the section provided or in attachments, describe how the changes being made in this general plan approval impact each combustion control device and scrubber

listed in the table (i.e., loading or exhaust flow characteristics). Describe why these items do not require further stack testing and explain why the operational limits required in your Title V Permit (e.g. temperature, scrubber flow rate, pH, normality, etc.) are still adequate at the new loading and/or exhaust flow (attach any additional sheets as necessary).

3. Indicate in the line below the table whether the equipment entered into the table will be operated in compliance with all requirements for the equipment in the existing Title V Permit. If applicable, describe any differences in the space provided below.

I. Secondary Operating Scenario Vent Condenser Device Information

1. Enter the data requested for the back-up vent condensers used to control emissions for the systems being installed or modified as part of this general plan approval:
  - *Title V Source ID & Source Name* for this control device in the existing Title V permit. Put a check in the box to indicate if this device is being used only as a backup control.
  - *Type of condenser*
  - *Manufacturer & Model No.*
  - *Vapor Pressure of Material Being Condensed (psi).*
  - *Temperature (°C)* - Check the box indicating the temperature location which will be used to monitor for correct operation of the condenser.
2. Indicate in the line below the table whether the equipment entered into the table will be operated in accordance with all requirements for the equipment in the existing Title V Permit. If NO, describe any differences in the space provided below.
3. Describe how the changes being made in this General Plan Approval impact each condenser listed above. Demonstrate that these impacts meet the temperature requirements of 25 Pa. Code Section 129.68 as related to total vapor load, total flow rate, and compound vapor pressure (attach any design sheets as necessary).

J. Air Concentration Modeling For New Hazardous Air Pollutants (HAPS)

If new HAP emissions are generated as part of the GPA application or there is a change in HAP emission characteristics (e.g. new venting location), it will be necessary to conduct risk modeling of the emissions. Provide a brief summary of the modeling results below. Show that results of the modeled one-hour maximum ambient air concentration for each HAP, resulting from the aggregation of emissions from all sources of release, do not exceed the appropriate endpoint criterion: STEL/40, C/10, 3 x TWA/20, IDLH/20, or LC50/100. Show that the results of the modeled maximum annual air average concentration for each HAP resulting from the aggregation of emissions from all sources of release do not exceed the endpoint criterion of a 1-in-1 million risk and a hazard quotient (HQ) of 1. In addition, show that the results of the modeled maximum annual average air concentration for the hazard index and cumulative risk do not exceed the appropriate end point criterion of 1 and 1-in-1 million cancer risk. Attach a compact disk containing the modeling data to this application.

**NOTE: The Emissions Modeling Protocol must be pre-approved by PADEP for use with GPA-24 prior to submission of the results with the GPA-24 Application.**

K. Attachments

Number and list all attachments submitted with this application in the space provided.

L. Permit Information

Indicate if you are making a request for confidentiality per 25 Pa. Code Section 127.12(d). If yes, include a justification for confidentiality in the attachments to the application. Mark the appropriate pages as "confidential".

M. Applicant's Checklist

Verify that the appropriate enclosures are included with the application by checking the boxes.

N. Affidavit

Provide a signature, date, and printed name of the "responsible official" as defined in 25 Pa. Code Section 121.1 (relating to definitions) certifying this GPA application.