Texas Commission on Environmental Quality

Form OP-UA34 - Instructions
Pharmaceutical Manufacturing Facility Attributes

General:

This form is used to provide a description and data pertaining to all pharmaceutical manufacturing facilities with potentially applicable requirements associated with a particular regulated entity number and application. Each table number, along with the possibility of a corresponding letter (i.e., Table 1a, Table 1b), corresponds to a certain state or federal rule. If the rule on the table is not potentially applicable to a pharmaceutical manufacturing facility, then it should be left blank and need not be submitted with the application. If the codes entered by the applicant show negative applicability to the rule or sections of that rule represented on the table, then the applicant does not have to complete the remainder of the table(s) that correspond to the rule. Further instruction as to which questions should be answered and which questions should not be answered are located in the "Specific" section of the instruction text. The following is included in this form.

Table 1a - 1c: Title 30 Texas Administrative Code Chapter 115 (30 TAC Chapter 115)
Subchapter F, Division 2: Pharmaceutical Manufacturing Facilities

The Texas Commission on Environmental Quality (TCEQ) regulated entity number (RNXXXXXXX) and the application area name (from Form OP-1) must appear in the header of each page for purpose of identification for the initial submittal. The date of the initial form submittal must also be included and should be consistent throughout the application (*MM/DD/YYYY*). **Leave the permit number blank for the initial form submittal.** If this form is included as part of the permit revision process, enter the permit number assigned by the TCEQ, the area name (from Form OP-1), the date of the revision submittal, and the regulated entity number.

Unit attribute questions that do not require a response from all applicants are preceded by qualification criteria in the instructions. If the unit does not meet the qualification criteria, a response to the question is not required. **Anytime a response is not required based on the qualification criteria, leave the space on the form blank.**

Notwithstanding any qualification criteria in the form instructions or information provided in other TCEQ guidance, the applicant may leave an attribute question blank (or indicate "N/A" for "Not Applicable") if the attribute is not needed for the applicable requirement determinations of a regulation for a unit.

In some situations, the applicant has the option of selecting alternate requirements, limitations, and/or practices for a unit. Note that these alternate requirements, limitations, and/or practices must have the required approval from the TCEQ Executive Director and/or the U.S. Environmental Protection Agency (EPA) Administrator before the federal operating permit application is submitted.

The Texas Commission on Environmental Quality (TCEQ) **requires** that a Core Data Form be submitted on all incoming registrations unless **all** of the following are met: the Regulated Entity and Customer Reference Numbers have been issued by the TCEQ and no core data information has changed. The Central Registry, a common record area of the TCEQ, maintains information about TCEQ customers and regulated activities, such as company names, addresses, and telephone numbers. This information is commonly referred to as "core data." The Central Registry provides the regulated community with a central access point within the agency to check core data and make changes when necessary. When core data about a facility is moved to the Central Registry, two new identification numbers are assigned: the *Customer Reference (CN)* number and the *Regulated Entity (RN)* number. The Core Data Form is required if facility records are not yet part of the Central Registry or if core data for a facility has changed. If this is the initial registration, permit, or license for a facility site, then the Core Data Form must be completed and submitted with application or registration forms. If amending, modifying, or otherwise updating an existing record for a facility site, the Core Data Form is not required, unless any core data information has changed. To review additional information regarding the Central Registry, go to the TCEQ website at www.tceq.texas.gov/permitting/central_registry/index.html.

Specific:

Table 1a: Title 30 Texas Administrative Code Chapter 115 (30 TAC Chapter 115) Subchapter F, Division 2: Pharmaceutical Manufacturing Facilities

Complete only for synthesized pharmaceutical manufacturing facilities located in Brazoria, Chambers, Collin, Dallas, Denton, Ellis, El Paso, Fort Bend, Galveston, Gregg, Hardin, Harris, Jefferson, Johnson, Kaufman, Liberty, Montgomery, Nueces, Orange, Parker, Rockwall, Tarrant, Waller, or Victoria County.

Process ID No.:
Enter the identification number (ID No.) for the pharmaceutical manufacturing process (facility) (maximum 10 characters) as listed on Form OP-SUM (Individual Unit Summary).

SOP Index No.:
Site operating permit (SOP) applicants should indicate the SOP index number for the process (maximum 15 characters consisting of numeric, alphanumeric characters, and/or dashes prefixed by a code for the applicable regulation [i.e., 60KB-*XXXX*]). For additional information relating to SOP index numbers, please go to the TCEQ website at www.tceq.texas.gov/assets/public/permitting/air/Guidance/Title_V/additional_fop_guidance.pdf.

Alternate Control Requirement (ACR):
Enter "YES" if using an alternate method for demonstrating and documenting continuous compliance with applicable control requirements or exemption criteria and demonstrating substantially equivalent reduction efficiencies, which have been approved by the TCEQ Executive Director. Otherwise, enter "NO."

Acrid ID No.:
If an alternate control requirement (ACR) has been approved, enter the corresponding ACR unique identifier for each unit. If the unique identifier is unavailable, then enter the date of the ACR approval letter in the table column. The unique identifier and/or the date of the approval letter are contained in the Compliance File under the appropriate account number. Otherwise, leave this column blank.

▼ **Continue only if "Alternate Control Requirement" is "NO."**

★ Complete "Unit Uncontrolled VOC Emissions" only if the pharmaceutical manufacturing facility is located in Gregg, Nueces, or Victoria County.

Uncontrolled VOC Emissions: Enter "YES" if the facility emits an uncontrolled combined weight of volatile organic compound (VOC) less than 550 pounds (249.5 kilograms) in any continuous 24-hour period. Otherwise, enter "NO." (If not claiming exemption 30 TAC § 115.137(b)(5), enter "NO" or leave this column blank.)

▼ Do not continue if "Uncontrolled VOC Emissions" is "YES."

★ Complete "Combined Weight of Uncontrolled VOC Emissions" only if the pharmaceutical manufacturing facility is located in Brazoria, Chambers, Collin, Dallas, Denton, Ellis, El Paso, Fort Bend, Galveston, Hardin, Harris, Jefferson, Johnson, Kaufman, Liberty, Montgomery, Orange, Parker, Rockwall, Tarrant, or Waller County.

Combined Weight of Uncontrolled VOC Emissions:
Enter "YES" if any unit emits an uncontrolled combined weight of VOC less than 15 pounds (6.8 kilograms) in any continuous 24-hour period. Otherwise, enter "NO." (If not claiming exemption 30 TAC § 115.137(a)(5), enter "NO" or leave this column blank.)

Reactors:
Enter "YES" if the process includes reactors, distillation units, crystallizers, centrifuges or vacuum dryers. Otherwise, enter "NO."

Centrifuge VOC Vapor Pressure Exemption:
Enter "YES" if the process contains centrifuges which process liquids containing VOC with vapor pressure less than 0.5 psia (3.4 kilopascals) at 68°F (20°C). Otherwise, enter "NO." (If not claiming exemption 30 TAC § 115.137(a)(4) or 30 TAC § 115.137(b)(4), enter "NO" or leave this column blank.)

★ Complete "Other Centrifuges" only if "Centrifuge VOC Vapor Pressure Exemption" is "YES."

Other Centrifuges:
Enter "YES" if the process contains centrifuges which process liquids containing VOC with vapor pressure greater than or equal to 0.5 psia (3.4 kilopascals) at 68°F (20°C). Otherwise, enter "NO."

Table 1b: Title 30 Texas Administrative Code Chapter 115 (30 TAC Chapter 115) Subchapter F, Division 2: Pharmaceutical Manufacturing Facilities

Process ID No.:
Enter the identification number (ID No.) for the pharmaceutical manufacturing process (maximum 10 characters) as listed on Form OP-SUM (Individual Unit Summary).

SOP Index No.:
Site operating permit (SOP) applicants should indicate the SOP index number for the process (maximum 15 characters consisting of numeric, alphanumeric characters, and/or dashes prefixed by a code for the applicable regulation [i.e., 60KB-*XXXX*]). For additional information relating to SOP index numbers, please go to the TCEQ website at www.tceq.texas.gov/assets/public/permitting/air/Guidance/Title_V/additional_fop_guidance.pdf.

Air Dryers:
Enter "YES" if the process includes air dryers or production equipment exhaust systems. Otherwise, enter "NO."

Emissions ≤ 33 Lbs/Day:
Enter "YES" if VOC emissions from all air dryers and production equipment exhaust systems are reduced to less than or equal to 33 pounds per day (15 kilograms per day). Otherwise, enter "NO."

Storage Tanks at Loading Facility:
Enter "YES" if the process produces VOC emissions from truck or railcar deliveries to storage tanks at loading facilities. Otherwise, enter "NO."

★ **Complete "Loading Facility Storage Tank Capacity Exemption" and "Loading Facility Storage Tank VOC Vapor Pressure Exemption" only if "Storage Tank at Loading Facility" is "YES."**

Loading Facility Storage Tank Capacity Exemption:
Enter "YES" if the process contains storage tanks at loading facilities with capacities less than or equal to 2,000 gallons (7,571 liters). Otherwise, enter "NO." (If not claiming exemption 30 TAC § 115.137(a)(1) or 30 TAC § 115.137(b)(1), enter "NO" or leave this column blank.)

Loading Facility Storage Tank VOC Vapor Pressure Exemption:
Enter "YES" if the process contains storage tanks at loading facilities that store VOC with vapor pressure less than or equal to 4.1 psia (28 kilopascals) at 68°F (20°C). Otherwise, enter "NO." (If not claiming exemption 30 TAC § 115.137(a)(2) or 30 TAC § 115.137(b)(2), enter "NO" or leave this column blank.)

In-Process Tanks:
Enter "YES" if the process includes in-process tanks that contain VOC. Otherwise, enter "NO."

Storage Tank VOC Vapor Pressure Exemption:
Enter "YES" if the process contains storage tanks containing VOC with a vapor pressure less than or equal to 1.5 psia (10.3 kilopascals) at 68°F (20°C). Otherwise, enter "NO." (If not claiming exemption 30 TAC § 115.137(a)(3) or30 TAC § 115.137(b)(3), enter "NO" or leave this column blank.)

Other Storage Tanks:
Enter "YES" if the process contains other storage tanks containing VOC with a vapor pressure greater than 1.5 psia (10.3 kilopascals) at 68°F (20°C). Otherwise, enter "NO."

Table 1c Title 30 Texas Administrative Code Chapter 115 (30 TAC Chapter 115) Subchapter F, Division 2: Pharmaceutical Manufacturing Facilities

Process ID No.:
Enter the identification number (ID No.) for the pharmaceutical manufacturing process (maximum 10 characters) as listed on Form OP-SUM (Individual Unit Summary).

SOP Index No.:
Site operating permit (SOP) applicants should indicate the SOP index number for the process (maximum 15 characters consisting of numeric, alphanumeric characters, and/or dashes prefixed by a code for the applicable regulation [i.e., 60KB-*XXXX*]). For additional information relating to SOP index numbers, please go to the TCEQ website at www.tceq.texas.gov/assets/public/permitting/air/Guidance/Title_V/additional_fop_guidance.pdf.

Filters:
Enter "YES" if the process contains rotary vacuum filters or other filters, which have an exposed liquid surface, which processes liquids containing VOC. Otherwise, enter "NO."

Filter VOC Vapor Pressure Exemption:
Enter "YES" if the process contains filters which process liquids containing VOC with vapor pressure less than 0.5 psia (3.4 kilopascals) at 68°F (20°C). Otherwise, enter "NO." (If not claiming exemption 30 TAC § 115.137(a)(4) or 30 TAC § 115.137(b)(4), enter "NO" or leave this column blank.)

Other Filters:
Enter "YES" if the process contains filters, which process liquids containing VOC with vapor pressure greater than or equal to 0.5 psia (3.4 kilopascals) at 68°F (20°C). Otherwise, enter "NO."

Vapor Recovery System:
Enter "YES" if any portion of the facility utilizes a vapor recovery system to comply with an emission specification in 30 TAC § 115.531 or a control requirement in 30 TAC § 115.532. Otherwise, enter "NO."

Control Device Type:
Select one of the following options for the control device type. Enter the code on the form.

Code	Description
INC	Vapor recovery system with a direct-flame incinerator
SOLV	Vapor recovery system with a solvent recovery system other than a carbon adsorption system
CADS	Vapor recovery system with a carbon adsorption system
OTHER	Other control device

Control Device ID No.:
If applicable, enter the identification number (ID No.) for the control device to which emissions are routed. This number should be consistent with the control device identification number (maximum 10 characters) as listed on Form OP-SUM (Individual Unit Summary).

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Federal Operating Permit Program

Table 1a: Title 30 Texas Administrative Code Chapter 115 (30 TAC Chapter 115)
Subchapter F, Division 2: Pharmaceutical Manufacturing Facilities

Date:	Permit No.:	Regulated Entity No.:
Area Name:		Customer Reference No:

Process ID No.	SOP Index No.	Alternate Control Requirement (ACR)	ACR ID No.	Uncontrolled VOC Emissions	Combined Weight Of Uncontrolled VOC Emissions	Reactors	Centrifuge VOC Vapor Pressure Exemption	Other Centrifuges

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Federal Operating Permit Program

Table 1b: Title 30 Texas Administrative Code Chapter 115 (30 TAC Chapter 115)
Subchapter F, Division 2: Pharmaceutical Manufacturing Facilities

Date:	**Permit No.:**	**Regulated Entity No.:**
Area Name:		**Customer Reference No:**

Process ID No.	SOP Index No.	Air Dryers	Emissions ≤ 33 Lbs/Day	Storage Tanks at Loading Facility	Loading Facility Storage Tank Capacity Exemption	Loading Facility Storage Tank VOC Vapor Pressure Exemption	In-Process Tanks	Storage Tank VOC Vapor Pressure Exemption	Other Storage Tanks

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Federal Operating Permit Program

Table 1c: Title 30 Texas Administrative Code Chapter 115 (30 TAC Chapter 115)
Subchapter F, Division 2: Pharmaceutical Manufacturing Facilities

Date:	Permit No.:	Regulated Entity No.:
Area Name:		Customer Reference No:

Process ID No.	SOP Index No.	Filters	Filter VOC Vapor Pressure Exemption	Other Filters	Vapor Recovery System	Control Device Type	Control Device ID No.

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