# Form OP-UA34 - Instructions Pharmaceutical Manufacturing Facility Attributes Texas Commission on Environmental Quality

The unit attributes (OP-UA) forms are used to provide a description and data pertaining to all emission units, emission points, processes and control devices with potentially applicable requirements associated with a particular regulated entity (RN) number and application. The information will be provided in an excel format. Each OP-UA form will include sheets for General Information, a Table of Contents, OP-SUM, OP-REQ2, and the unit attribute tables. The individual unit summary (OP-SUM) information and the negative applicable/superseded requirement determinations (OP-REQ2) will be provided on each individual OP-UA form for the applicable units identified in the unit attribute tables.

#### **General Information Sheet**

The General Information sheet holds the permit information. The following permit application information is requested for the site:

#### Date:

Enter the date the application is being submitted by the applicant to TCEQ (MM/DD/YYYY). Any subsequent submittals must show the date of revision.

#### **Customer Reference No. (CN):**

Enter the customer reference number (CNXXXXXXXXX). This number is issued by TCEQ as part of the central registry process. If a customer reference number has not yet been issued, leave this space blank. Do not enter permit numbers, project numbers, account numbers, etc., in this space.

# Regulated Entity No. (RN):

Enter the regulated entity reference number for the site (RNXXXXXXXX). This number is issued by TCEQ as part of the central registry process. If a regulated entity reference number has not yet been issued, leave this space blank. Do not enter permit numbers, project numbers, account numbers, etc., in this space.

#### **Permit No.:**

Enter the permit number assigned by TCEQ. Leave the permit number blank if a permit number has not been assigned.

#### **Permit Area Name:**

Enter the name of the application area (maximum 50 characters). This should be the same name provided on Form OP-1 (Site Information Summary).

# **Permit Type:**

Choose the type of permit for which this application is being submitted from the dropdown menu (SOP, GOP, TOP). Information on the different permit types can be found on TCEQ's website at: <a href="https://www.tceq.texas.gov/permitting/air/titlev/permit">www.tceq.texas.gov/permitting/air/titlev/permit types.html</a>.

#### **Project Type:**

Choose the project type for which this application is being submitted from the dropdown menu (Initial, Revision, Renewal).

#### **Submission Type:**

Choose the submission type for which this form is being submitted from the dropdown menu (New Application, Existing Application Update).

#### **Project Number:**

Enter the project number assigned by TCEO. Leave the project number blank if a project number has not been assigned.

Title V Form Release Date, Form Number, APD ID Number, and Version Revised Date are present and cannot be altered.

#### **Table of Contents Sheet**

The Table of Contents lists all the sheets in the UA Form. If information is submitted on the OP-SUM, OP-REQ2 or the Unit Attribute tables, the "Data Submitted" column will display a "Yes". If no information is submitted, the "Data Submitted" column will remain blank. The Table of Contents information is auto populated. Applicants will not need to submit any information in the Table of Contents.

#### **Instructions for OP-SUM Sheet**

#### General:

All processes with one or more potentially applicable requirements addressed in this form must be identified on the OP-SUM sheet. The term "process" refers to a collection of units or devices that have a physical relationship, or source cap, where a regulatory requirement is potentially applicable to the process as a whole.

The purpose of this sheet is to list individual processes addressed in the Federal Operating Permit (FOP) application and to provide identifying information and preconstruction authorizations. This form is also used to designate members of groups.

The corresponding preconstruction authorization for process must also be listed on this form. For processes which were authorized to construct or modify under Permits by Rule (PBR), list all applicable PBR information, including registration numbers. If a process is authorized under more than one preconstruction authorization, then list all applicable preconstruction authorizations, including any Prevention of Significant Deterioration (PSD) and/or nonattainment permit(s).

# **Groups:**

- A "group" is a collection of units/processes or devices that have identical applicability (or non-applicability) determinations and may, or may not, have a physical relationship.
- Group members may have different 30 TAC Chapter 116 or 30 TAC Chapter 106 preconstruction authorizations.
- Groups may be used on UA forms only if all unit attributes are identical.
- All groups must be mutually exclusive. Processes cannot be listed in more than one group on a given UA form.
- Grouping is optional.
- Groups are assigned an ID No. by the applicant, which must begin with the prefix "GRP" followed by a maximum of eleven characters (GRPXXXXXXX).

#### **Processes:**

- A "process" is a quasi-unit representing a collection of units or devices that have a physical relationship and for which a regulatory requirement applies to the process as a whole.
- Individual units in a process do not need to be identified unless they have potentially applicable requirements unto themselves. Those individual units should be listed on the appropriate OP-UA form.

# **Specific:**

#### Table 1

#### **Unit Action Indicator (Unit AI):**

Select "A" from the dropdown menu if the process indicated is an addition to the permit. Select "D" from the dropdown menu if the existing process indicated is being deleted from the permit. If the process is not being added/deleted from the permit, leave blank.

#### **Revision No.:**

Complete this section only for a permit revision or renewal. Enter the revision number identified on Form OP-2, Table 2. This number will link the specified change to the appropriate permit revision. If no changes are made to a process in the permit, leave blank.

# **Process ID No.:**

Each process must be assigned an identification number. (Maximum 14 characters)

• Processes are assigned an ID No. by the applicant, which must begin with the prefix "PRO" followed by a maximum of eleven characters (PROXXXXXXX).

# **Group ID No.:**

If applicable, enter the unique identification number for the group which includes this process (GRPXXXXXXX) ("GRP" followed by a maximum of 11 characters) If the process is not a member of a group, leave this column blank. (See general instructions, above, for information regarding requirements for grouping processes in FOP applications.)

# **Process Name/Description:**

Each process must be given a name or description that distinguishes it from other processes as much as practicable. The Name/Description should clearly indicate the type of process. (Maximum 50 characters)

- Enter a text name or description for the process from STARS whenever possible.
- If no STARS name currently exists, a new name that is consistent with the existing naming convention must be provided by the applicant.

**Example:** The following example is intended as guidance on completion of columns on OP-SUM. It should be assumed that all criteria for inclusion in the application are met. Criteria for grouping are also assumed to be satisfied.

Process ID No.	Group ID No.	Name/Description
PRO-COAT1	GRPCOATING	Surface Coating Line 1
PRO-COAT2	GRPCOATING	Surface Coating Line 2
PRO-COAT3		Surface Coating Line 3

# **CAM (For reference only):**

Indicate if the process is subject to 40 CFR Part 64 by selecting "Y" from the dropdown menu in the "CAM" column next to the process. Please refer to 40 CFR Part 64 to determine applicability. Certification by the Responsible Official (RO) pursuant to 30 TAC § 122.165 does not extend to the information which is designated on forms as "For reference only."

#### **Preconstruction Authorizations (PCA):**

At least one PCA must be indicated for each process; however, a process may have multiple authorizations. *All preconstruction authorizations listed on this form must also be identified on Form OP-REQ1*. When a process has multiple authorizations, each PCA must be listed in a separate row.

The following examples are intended as guidance on completion of columns for the preconstruction authorizations. The examples are followed by specific instructions for each column.

Example 1: Adding multiple PCA Categories

Unit AI	Revision No.	Unit ID No.	Group ID No.	Unit Name/Description	CA M	PCA AI	Preconstruction Authorization (PCA) Category	Authorization/ Registration Number	Permit By Rule (PBR) Number	PBR Effective Date
A		Flare1		Diamine Flare	Y	A	NSR Permit	1234		
A		Flare1		Diamine Flare	Y	A	PSD	PSDTX1234		
A		Flare1		Diamine Flare	Y	A	PBR	23456, 34567	106.261	11/01/2003
A		Flare1		Diamine Flare	Y	A	PBR	23456, 34567	106.262	11/01/2003

Unit AI	Revision No.	Unit ID No.	Group ID No.	Unit Name/Description	CAM	PCA AI	Preconstruction Authorization (PCA) Category	Authorization/ Registration Number	Permit By Rule (PBR) Number	PBR Effective Date
		T-3	GRPTANKS	Tank 3		A	Standard Permit	12345		
		T-3	GRPTANKS	T 1.2		D	PBR		106.432	09/04/2000

#### **Preconstruction Authorization Action Indicator (PCA AI):**

Select "A" from the dropdown menu if a preconstruction authorization is being added for the process. Select "D" from the dropdown menu if a preconstruction authorization is being deleted from the process. If a preconstruction authorization is not being added/deleted from the process, leave blank.

# **Preconstruction Authorization (PCA) Category:**

Select from the dropdown menu the category of the PCA being added or deleted.

- PBR Permit by Rule claimed or registered under 30 TAC Chapter 106
- Standard Permit 30 TAC Chapter 116 and non-rule Air Quality Standard Permits
- NSR Permit 30 TAC Chapter 116 preconstruction authorizations
- PSD Prevention of Significant Deterioration Permits
- Nonattainment Nonattainment Permits
- GHG Greenhouse Gas Permits
- 112(G) [HAP] Hazardous Air Pollutant Permits
- MSW or IHW Municipal Solid Waste or Industrial Hazardous Waste Permits
- Exemption De Minimis Facilities or Sources authorized by 30 TAC Chapter 116, § 116.119

# **Authorization/Registration Number:**

List all TCEQ permit numbers for 30 TAC Chapter 116 preconstruction authorizations, Title I preconstruction authorizations (PSD and nonattainment permits) and 30 TAC Chapter 106 (PBR) registration numbers, under which the process is operating.

- **30 TAC Chapter 116 Permits:** Enter the TCEQ permit number, for example, 12345. This includes special permits and standard permit registrations.
- **Prevention of Significant Deterioration (PSD) Permit:** Enter the PSD permit number (PSDTXXXX), for example, PSDTX123. If the PSD permit has been modified, include the "M" suffix (PSDTXXXXMXX), for example, PSDTX123M5. *Title I authorizations should only be listed for processes addressed by the PSD or nonattainment permits*.
- **Nonattainment Permit:** Enter each nonattainment permit number (NXXX), for example, N123. If the nonattainment permit has been modified, include the "M" suffix (NXXXMXX), for example, N123M5. *Title I authorizations should only be listed for processes addressed by the PSD or nonattainment permits*.
- **Permit by Rule (previously Standard Exemption):** Enter the PBR Registration No. for each PBR registered under 30 TAC Chapter 106 and each standard exemption previously registered under 30 TAC Chapter 116.
- Exemption: Enter 116.119 for a de minimis facility or source, which has other potentially applicable or applicable requirements (these are authorized by 30 TAC Chapter 116, § 116.119). De minimis facilities or sources should not be included if there are no other potentially applicable or applicable requirements.

### Permit by Rule (PBR) Number:

For each PBR claimed or registered under 30 TAC Chapter 106, and each standard exemption claimed or registered previously under 30 TAC Chapter 116, enter the number in the appropriate format shown below.

Note: All processes authorized by PBR must also be identified on Form OP-PBRSUP.

Format	PBR/standard exemption claimed or registered date
106.XXX	Authorized on or after March 14, 1997 (except 106.181 is on or after December 27, 1996)
XXX	Authorized prior to March 14, 1997

XXX = 30 TAC Chapter 116 standard exemption number or 30 TAC Chapter 106 PBR number.

#### **PBR Effective Date:**

For each PBR claimed or registered under 30 TAC Chapter 106 and each standard exemption claimed or registered, enter the effective date of the rule. MM/DD/YYYY = Effective date of the Standard Exemption or PBR in effect at the time claimed or granted. Information on version dates is available at:

Information on Chapter 116 version dates is available at:

www.tceq.texas.gov/permitting/air/permitbyrule/historical rules/oldselist/se index.html.

Information on Chapter 106 version dates is available at:

www.tceq.texas.gov/permitting/air/permitbyrule/historical rules/old106list/index106.html.

Please note that prior to March 14, 1997, a standard exemption list was incorporated by reference into 30 TAC Chapter 116 and each standard exemption had an assigned number, e.g., 112. Each standard exemption now resides in a section of 30 TAC Chapter 106 (e.g., 30 TAC § 106.148) and now is referred to as a PBR.

(Standard exemptions were readopted under the PBR designation on March 14, 1997.) Information regarding PBRs may be found on the TCEQ website at <a href="https://www.tceq.texas.gov/permitting/air/permitbyrule/air-pbr">https://www.tceq.texas.gov/permitting/air/permitbyrule/air-pbr</a>.

The applicant has the option of claiming a newer and more stringent version of the standard exemption or PBR if the original applicable version of the standard exemption or PBR cannot easily be determined. As an example of a standard exemption authorized before March 14, 1997, Standard Exemption No. 6 had an effective date of August 30, 1988. It was then amended with a new effective date of July 20, 1992. The standard exemption identifier for a compressor engine constructed in 1993 and registered under Standard Exemption No. 6 would be represented as:

Permit By Rule (PBR) Number	PBR Effective Date	
6	07/20/1992	

As an example of a PBR authorized on or after March 14, 1997, Standard Exemption No. 6 had an effective date of June 7, 1996. It was then amended and moved to 30 TAC § 106.512 with an effective date of March 14, 1997. The PBR identifier for a compressor engine constructed in 1998 and registered under 30 TAC § 106.512 would be represented as:

Permit By Rule (PBR) Number	PBR Effective Date
106.512	03/14/1997

# **Instructions for OP-REQ2 Sheet**

# General:

The purpose of this sheet is to document negative applicability from potentially applicable requirements or to document duplicative, redundant, and or contradicting requirements that have been superseded by a more stringent or equivalent requirement for processes when a permit shield is requested. Negative applicability or superseded requirement determinations when a permit shield is NOT requested may be documented on this sheet OR the appropriate unit attribute table.

A negative applicability determination is any regulatory citation that provides the basis whereby every operating condition of a process is not subject to a regulation. For example, Title 40 Code of Federal Regulation § 60.110b(a) [40 CFR § 60.110b(a)] could be the regulatory basis for a negative applicability determination for a VOC storage tank of less than 75 cubic meters; therefore, the storage tank is completely exempt from 40 CFR Part 60, Subpart Kb.

Note: Numerous regulatory citations appear to authorize exemptions to qualifying processes from those regulations. However, closer examination typically reveals that there are still some requirements which must still be met (such as monitoring and/or recordkeeping).

For certain processes subject to certain 40 CFR Part 63 standards, other federal regulations may apply. In many instances one of the overlapping regulations may specify which rule supersedes the other. The regulation may state that the owner or operator only has to comply with a specific subpart after the compliance date or it may state that compliance with the subpart is deemed to be in or constitute compliance with other subparts. Although superseded rules do not qualify as negative applicability determinations, it has been determined that these instances can be documented on the OP-REQ2, if the applicant elects to comply only with the superseding requirement. For example, a surface coating process subject to 40 CFR Part 63, Subpart IIII, may not be required to comply with 40 CFR Part 63, Subpart PPPP due to rule overlap of 40 CFR Part 63, Subpart IIII. In this case, the permit applicant may request a permit shield from 40 CFR Part 63, Subpart PPPP. In this case, the applicant must submit the superseding requirement citation §63.4481(d), and a textual description of the superseding determination, if they elect to comply with only the superseding requirement.

When a process has one or more potential applicable requirements, the applicant must list all the requirements for which negative applicability or superseded requirement determinations can be made. Once the negative applicability or superseded requirement determinations have been made, indicate the citation and reason for the non-applicability or superseded requirement in the appropriate columns. Indicate the determinations for all potentially applicable requirements for each process before listing the next process.

Negative applicability or superseded requirement determinations for potentially applicable requirements, confirmed by TCEQ, may be approved as a permit shield (see instructions outlined in Area Wide Applicability Determinations, Form OP-REQ1, to request a permit shield). If a permit shield is requested, the determinations are always required on the OP-REQ2 sheet. For additional information relating to permit shields, refer to the TCEQ guidance document entitled "Site Operating Permit (SOP) Permit Shield Guidance found on TCEQ's website at: www.tceq.texas.gov/permitting/air/guidance/titlev/tv\_site\_guidance.html.

# **Specific:**

Fill out the OP-REQ2 sheet to provide a negative applicability determination for processes included on this OP-UA form. If the process is not submitted on an OP-UA form, submit the negative applicability determination on the standalone OP-REQ2 form.

#### **Unit Action Indicator (AI):**

Complete this section only for a permit revision or renewal. Select "A" from the dropdown menu if the negative applicability or superseded requirement is an addition to the permit. Select "D" from the dropdown menu if the negative applicability or superseded requirement is being deleted from the permit. For revisions to existing negative applicability or superseded requirements in the permit, use the "D" indicator for the existing permit shield and the "A" indicator for the revised permit shield.

# **Revision No.:**

Complete this section only for a permit revision or renewal. Enter the revision number identified on Form OP-2, Table 2 (only for revision items within the application). This number will link the specific negative applicable requirement determination to the appropriate revision.

#### **Process ID No.:**

Select the identification number (ID No.) (maximum 14 characters) of the process as listed on the OP-SUM sheet.

#### **Potentially Applicable Regulatory Name:**

Select the name of the potentially applicable requirement from the dropdown menu for which negative applicability or superseded requirement is being demonstrated. If the potentially applicable regulatory name is not found in the dropdown menu, enter it manually (maximum 50 characters).

Note: Permit shields cannot be granted for permit authorizations of any kind (i.e. - PSD, NSR permit, Acid Rain, etc.).

# **Negative Applicability or Superseded Requirement Citation:**

Enter the citation of the paragraph of the rule that was used to determine negative applicability or superseded requirements. Provide the citation detail to the level of the paragraph allowing the exemption, exclusion, or non-applicability. If there is more than one citation for determining negative applicability or superseded requirements, select the most appropriate or the clearest (least likely to be misinterpreted). Negative applicability or superseded requirement determinations by the applicant are subject to auditing during the permit application review. The applicant must always indicate the negative applicability or superseded requirement citation on the OP-REQ2. For examples on the level of detail for citations, see table below (maximum 36 characters).

Example Applicable Regulatory Requirements\*

Regulation	Potentially Applicable Regulatory Name (Input Format)	Negative Applicability or Superseded Requirement Citation (Input Format)
30 TAC Chapters 111, 112, 113, 115 and 117	Chapter 111	§ 111.XXX(x)(yy)(zz)
	Chapter 112	§ 112.XXX(x)(yy)(zz)
	Chapter 113	§ 113.XXX(x)(yy)(zz)
	Chapter 115, Storage of VOCs	$\S 115.XXX(x)(yy)(zz)$
	Chapter 117, ICI	$\S 117.XXX(x)(yy)(zz)$
40 CFR Part 60, Subparts, New Source Performance Standards (NSPS)	NSPS XXX	60.XXX(x)(yy)(zz)
40 CFR Part 61, Subparts, National Emission Standards for Hazardous Air Pollutants (NESHAP)	NESHAP XX	61.XX(x)(yy)(zz)
40 CFR Part 63, Subparts, NESHAP by source category, including hazardous organic (HON)	MACT XX	§ 63.XXX(x)(yy)(zz)

<sup>\*</sup> This list is not intended to be exhaustive

# Negative Applicability/Superseded Requirement Reason:

Enter a textual description indicating the reason for the negative applicability or superseded requirement determination. If a permit shield is requested, the textual description provided will be recreated as the *Basis of Determination* for the permit shield in the permit. The description may include rule text, rule preamble, or other text resulting from a historical rule interpretation, EPA applicability determination Index (ADI), or case law. Use multiple lines if necessary (maximum 250 characters).

#### **OP-UA34 Form Unit Attribute Tables- Instructions**

#### 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 - 1d: 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 Tables 1a - 1d 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 14 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/permitting/air/guidance/titlev/tv fop guidance.html.

#### **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."

#### ACR 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, Nucces, 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."

# **★** Complete "Centrifuge VOC Vapor Pressure Exemption" and "Other Centrifuges" only if "Reactors" is "YES."

# **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.)

#### **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."

#### Vapor Recovery System:

Select one of the following options if the reactors, distillation units, crystallizers, centrifuges or vacuum dryers utilize a vapor recovery system to comply with an emission specification in 30 TAC § 115.531 or a control requirement in 30 TAC § 115.532. If a vapor recovery system is not utilized, enter "NONE."

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
NONE	A vapor recovery system is not utilized to comply with an emission specification or control
	requirement

#### **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 14 characters) as listed on Form OP-SUM (Individual Unit Summary).

# 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 14 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/permitting/air/guidance/titlev/tv fop guidance.html.

#### **Air Drvers:**

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

#### Emissions $\leq$ 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."

# Vapor Recovery System:

Select one of the following options if the air dryers utilize a vapor recovery system to comply with an emission specification in 30 TAC § 115.531 or a control requirement in 30 TAC § 115.532. If a vapor recovery system is not utilized, enter "NONE."

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
NONE	A vapor recovery system is not utilized to comply with an emission specification or control
	requirement

#### **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 14 characters) as listed on Form OP-SUM (Individual Unit Summary).

# **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."

# **Vapor Recovery System:**

Select one of the following options if the storage tanks at a loading facility utilize a vapor recovery system to comply with an emission specification in 30 TAC § 115.531 or a control requirement in 30 TAC § 115.532. If a vapor recovery system is not utilized, enter "NONE."

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
NONE	A vapor recovery system is not utilized to comply with an emission specification or control
	requirement

#### **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 14 characters) as listed on Form OP-SUM (Individual Unit Summary).

# 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 14 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/permitting/air/guidance/titlev/tv fop guidance.html.

**★** 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 68F (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."

#### **Vapor Recovery System:**

Select one of the following options if the in-process tanks utilize a vapor recovery system to comply with an emission specification in 30 TAC § 115.531 or a control requirement in 30 TAC § 115.532. If a vapor recovery system is not utilized, enter "NONE."

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
NONE	A vapor recovery system is not utilized to comply with an emission specification or control
	requirement

#### **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 14 characters) as listed on Form OP-SUM (Individual Unit Summary).

# **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) or 30 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."

# ★ Complete "Vapor Recovery System" only if "Other Storage Tanks" is "YES."

#### **Vapor Recovery System:**

Select one of the following options 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) that utilize a vapor recovery system to comply with an emission specification in 30 TAC § 115.531 or a control requirement in 30 TAC § 115.532. If a vapor recovery system is not utilized, enter "NONE."

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
NONE	A vapor recovery system is not utilized to comply with an emission specification or control
	requirement

#### **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 14 characters) as listed on Form OP-SUM (Individual Unit Summary).

# Table 1d: 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 14 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/permitting/air/guidance/titlev/tv fop guidance.html.

#### 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."

# **★** Complete "Vapor Recovery System" only if "Other Filters" is "YES.

# Vapor Recovery System:

Select one of the following options if the filter 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. If a vapor recovery system is not utilized, enter "NONE."

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
NONE	A vapor recovery system is not utilized to comply with an emission specification or control
	requirement

#### **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 14 characters) as listed on Form OP-SUM (Individual Unit Summary).