SMAQMD BACT CLEARINGHOUSE

CATEGORY Type: **PHARMACEUTICAL PROCESS**

BACT Category: BATCH PROCESSING

BACT Determination Number: 261	**BACT Determination Date:** 6/25/2021

Equipment Information

Permit Number: N/A -- Generic BACT Determination

Equipment Description: PHARMACEUTICAL MANUFACTURING PROCESS (AMPAC)

Unit Size/Rating/Capacity: Minor Source BACT

Equipment Location:

EXPIRED

BACT Determination Information

District Contact: Jeff Weiss Phone No.: (279) 207-1155 email: jweiss@airquality.org

ROCs	**Standard:**	
	Technology Description:	Refrigerated condensers, afterburners, or carbon adsorbers per comments (below)
	Basis:	Achieved in Practice
NOx	**Standard:**	
	Technology Description:	
	Basis:	
SOx	**Standard:**	
	Technology Description:	
	Basis:	
PM10	**Standard:**	
	Technology Description:	
	Basis:	
PM2.5	**Standard:**	
	Technology Description:	
	Basis:	
CO	**Standard:**	
	Technology Description:	
	Basis:	
LEAD	**Standard:**	
	Technology Description:	
	Basis:	

Comments: Afterburners, Refrigerated Condensers, or Carbon Adsorbers with a capture/control efficiency of ≥ 90%. For those chemical streams which preclude a control of 90% because of their chemical or physical characteristics, a ≥ 0.3 second retention time at ≥ 1400 ºF for afterburners and an exit gas temperature of -25 °C for condensers will also satisfy BACT if emissions from reactors, distillation columns, crystallizer, evaporators, and centrifuges are less than 15 lb/day and emissions from dryers are less than 10 lb/day. A scrubber may also be used if it achieves a capture/control efficiency of ≥

777 12th Street, Third Floor

SACRAMENTO METROPOLITAN AIR QUALITY MANAGEMENT DISTRICT

Sacramento, CA 95814

BEST AVAILABLE CONTROL TECHNOLOGY DETERMINATION

EXPIRED

DETERMINATION NO.: 261

DATE: December 1, 2020

ENGINEER: Jeff Weiss

Category/General Equip Description: Pharmaceutical Manufacturing Operations

Equipment Specific Description: Pharmaceutical Manufacturing Batch Processes (Non-Fugitive) – Area Source - at Ampac Fine Chemicals

Equipment Size/Rating: Minor Source

Previous BACT Det. No.: #131

This BACT determination will update Determination #131 for Pharmaceutical Manufacturing Operations which was made on March 20, 2018. This equipment category is being evaluated for pharmaceutical manufacturing equipment at Ampac Fine Chemicals that involve reactors, separators, dryers or other similar types of equipment involved in the reacting, heating, cooling, filtering, and drying of chemical compounds. A review of the EPA, CARB, SCAQMD, SJVAPCD, BAAQMD, SDAPCD, and YSAQMD BACT clearinghouses was performed according to the District's BACT Guidelines (10/16). Any applicable rules or regulations from the aforementioned air pollution control agencies were also reviewed that apply to this type of operation. The review of these sources revealed that there has not been a change in the rules, regulations, and BACT determinations that were previously evaluated under BACT Determination No. 131 with one exception.

A review of the San Diego APCD rules revealed that Rule 67.15 had been missed in the evaluation for BACT Determination No. 131. The parts of this rule that are achieved-in-practice are not more stringent than SMAQMD Rule 464 and BACT Determination No. 131; therefore, the prior oversight of this rule does not affect the prior selection of BACT. However, there is a section of this rule that requires further discussion that is discussed in the San Diego "Rule Requirements" section (below).

Because there are not any consequential changes since the last BACT determination, the following BACT/T-BACT analysis is the same as the prior BACT analysis with the following exceptions: San Diego APCD Regulation IV, Rule 67.15 was added to the analysis; SMAQMD BACT No. 131 replaces BACT No. 85; and agency links and contacts were updated.

BACT/T-BACT ANALYSIS

A: ACHIEVED-IN-PRACTICE (Rule 202, §205.1a)

The following control technologies are currently employed as BACT for pharmaceutical manufacturing processes by the following air pollution control districts and state and federal agencies.

US EPA

RACT/BACT/LAER

Source: https://cfpub.epa.gov/rblc/index.cfm?Action=search.BasicSearch

Pharmaceutical Production (EPA Process Type 69.011)

RBLC# (A)	Process Description	Control
IN-204	Glatt Fluid Bed Dryer	Determination doesn't apply to equip. category.
IN-203	Bulk Chemical Mfr.	Determination is for equipment at a major source.
IN-200	Narasin Finishing Op.	Determination is for equipment at a major source.
IN-146	BPM Support Ops.	Determination doesn't apply to equip. category.
IN-144	Narasin Fermentation	Determination is for equipment at a major source.
IN-098	Monensin Process	Determination is for equipment at a major source.
MI-312	Reactors, et al.	Use of condensing scrubber and condenser which cools exhaust to -15°C.
MI-276	Pharmaceuticals	Determination is for equipment at a major source.

(A) RBLC# refers to the RACT/BACT/LAER identification number.

RULE Requirements

Sources: https://www.epa.gov/caa-permitting/new-source-performance-standards-region-7
https://www.epa.gov/stationary-sources-air-pollution/national-emission-standards-hazardous-air-pollutants-neshap-9

40 CFR 63, Subpart VVVVVV – National Emission Standards for Hazardous Air Pollutants for Chemical Manufacturing Area Sources regulates area sources that have the target HAPs of 1,3-butadiene, 1,3-dichloropropene, acetaldehyde, chloroform, ethylene dichloride, hexachlorobenzene, methylene chloride, quinoline, arsenic compounds, cadmium compounds, chromium compounds, lead compounds, manganese compounds, nickel compounds, or hydrazine in concentrations greater than 0.1% for carcinogens or greater than 1.0% for noncarcinogens. Ampac uses acetaldehyde (VOC) and methylene chloride (non-VOC) in some of their chemical processes. When used, these chemicals are usually above the criteria concentration limits given in the regulation. However, SMAQMD Rules 443 and 464 and pharmaceutical BACT Determination 131 are at least as stringent as the control requirements given in this regulation.

40 CFR 63, Subpart GGG – National Emission Standards for Hazardous Air Pollutants for Source Categories: Pharmaceuticals Production regulates pharmaceutical facilities that are major sources of HAPs. A major source of HAPs is a source that emits at least 10 tons/year

of a single HAP or an aggregate total of 25 tons/year of multiple HAPs. This BACT determination is for equipment at area sources which is covered by another NESHAP, Subpart VVVVVV. Subpart GGG, on the other hand, is for equipment with an entirely different production scope.

CARB

BACT
Source: http://www.arb.ca.gov/bact/bactnew/rptpara.htm

No BACT standards were posted for pharmaceutical manufacturing processes.

RULE REQUIREMENTS
Source: https://www.arb.ca.gov/toxics/atcm/atcm.htm

No ATCMs were posted for pharmaceutical manufacturing processes.

SACRAMENTO METORPOLITAN AQMD

BACT
Listed under BACT Determination #131 – Pharmaceutical Manufacturing Afterburners, refrigerated condensers, or carbon adsorbers with a capture/control efficiency of ≥ 90%. For those chemical streams which preclude a control of 90% because of their chemical or physical characteristics, a ≥ 0.3 second retention time at ≥ 1400 ºF for afterburners and an exit gas temperature of -25 °C for condensers will also satisfy BACT if emissions from reactors, distillation columns, crystallizer, evaporators, and centrifuges are less than 15 lb/day and emissions from dryers are less than 10 lb/day. A scrubber may also be used if it achieves a capture/control efficiency of ≥ 90%.

RULE REQUIREMENTS

Source: Rule 464 – Organic Chemical Manufacturing Operations

Equipment Type	Required VOC Standards
Reactors, Distillation Columns, Crystallizers and centrifuges	Emissions of more than 15 lb/day must have a capture/control efficiency of 90% by weight. Emissions of more than 10 lb/day but not more than 15 lb/day must either have a capture/control efficiency of 90% by weight or utilize a condenser with an outlet gas temperature that doesn't exceed the following: 25°C for 0.5 psi to 1.0 psi, 10°C for 1.0 psi to 1.5 psi, 0°C for 1.5 psi to 2.9 psi, -15°C for 2.9 psi to 5.8 psi, -25°C for over 5.8 psi.
Separation operations	Centrifuges, rotary vacuum filters, or other devices with an exposed liquid surface must be vented to a carbon adsorber or other approved air pollution control device.

Equipment Type	Required VOC Standards
In-Process Tanks	Tanks must be covered. If emissions are greater than 15 lb/day, a capture/control efficiency of 85%/90% is required.
Dryers	Equipment emitting > 10 lb/day must vent to a device with a capture/control efficiency of 90% by weight.

SOUTH COAST AQMD

BACT
Source: SCAQMD BACT Guidelines for Non-Major Polluting Facilities, page 97

Pharmaceutical Manufacturing - Afterburner (≥ 0.3 second retention time at ≥ 1400 ºF), refrigerated condensers, or carbon adsorbers (emissions limit was not specified because SCAQMD states that a limit that applies to all equipment within the category is not possible. Please refer to discussion under the Technologically Feasible and Cost Effective Section below).

RULE REQUIREMENTS

Source: Reg. XI, Rule 1103 – Pharmaceuticals and Cosmetics Manufacturing Operations

Equipment Type	Required VOC Standards
Reactors, Distillation Columns, Crystallizers and Centrifuges	Emissions of more than 15 lb/day must vent to a condenser with an outlet gas temperature that doesn't exceed the following: 25°C for 0.5 psi to 1.0 psi, 10°C for 1.0 psi to 1.5 psi, 0°C for 1.5 psi to 2.9 psi, -15°C for 2.9 psi to 5.8 psi, -25°C for over 5.8 psi.
In-Process Tanks	Covers must be closed except during loading or unloading.
Separation Operations and Air Dryers	Emissions of 330 lb/day or more must be reduced by 90%. Emissions less than 330 lb/day must be reduced to less than 33 lb/day.

SAN DIEGO COUNTY APCD

BACT
Source: https://www.sdapcd.org/content/dam/sdc/apcd/PDF/Misc/APCD_bact.pdf

Low VOC content material if emissions > 10 lb/day.

RULE REQUIREMENTS

Source: Reg. IV, Rule 67.15 -- Pharmaceutical and Cosmetic Manufacturing Operations

Equipment Type	Required VOC Standards
Reactors, Distillation Columns, Crystallizers and Centrifuges	Emissions of more than 15 lb/day from this equipment must vent to a condenser with an outlet gas temperature that doesn't exceed the following: 25°C for 0.5 psi to 1.0 psi, 10°C for 1.0 psi to 1.5 psi, 0°C for 1.5 psi to 2.9 psi, -15°C for 2.9 psi to 5.8 psi, -25°C for over 5.8 psi.
Separation Operations (A)	Equipment with an exposed liquid surface with VOC of 0.5 psia or more at 20°C controlled by at least 90%. (A)
In-Process Tanks	Tanks with VOCs of 0.5 psia or more at 20°C must be closed except during loading, unloading, or maintenance.
Air Dryers	Emissions of 33 lb/day or more must be reduced by at least 90%.

(A) This control method is only technologically feasible and is not achieved-in-practice. Refer to the discussion that immediately follows this table.

Rules and regulations are considered to be achieved-in-practice; however, there are rare situations where this is not the case. During this BACT review, it was observed that San Diego APCD Rule 67.15, Section (d)(2) requires that centrifuges, rotary vacuum filters, and other filters use a control with a minimum collection and control efficiency of 90% by weight. It has been determined that this rule section has not been achieved-in-practice for the following reasons:

This rule section is more stringent than the other district rules that were reviewed. The other district rules either specify a control without a minimum control efficiency or they specify a control with a minimum control efficiency of 90% or less but only after an uncontrolled emission threshold is reached. Further, Section (d)(2) is more stringent than San Diego's BACT determination which lists a blanket 90% control as only technologically feasible (https://www.sdapcd.org/content/dam/sdc/apcd/PDF/Misc/APCD_bact.pdf - Page 3-21).

This is significant because BACT is not supposed to be less stringent than a district's rule/BARCT. Also, it's not likely that the BACT determination is older than the rule since the rule was promulgated 32 years ago in 1988. The section (d)(2) requirement was not

changed in the Rule's 1996 revision. Lastly, Section (d)(2) is more stringent than the posted BACT determinations of other districts for this source category. In short, there's a sharp discordance between Section (d)(2) and the body of achieved-in-practice regulations.

Phone calls placed with San Diego County APCD's Engineering Division and its Rule Development Division verified that Section (d)(2) has not been achieved-in-practice. This is partly due to Rule 67.15, Section (d)(1) which is used as an acceptable alternative for centrifuges if a 90% control can not be attained. It was also reported that filters have not yet been regulated by this section. Consequently, SMAQMD has disregarded Rule 67.15, Section (d)(2) for the purposes of this achieved-in-practice review.

YOLO-SOLANO AQMD

BACT
Source: Ben Beattie, YSAQMD

Thermal oxidizer for a pharmaceutical pill coating line venting solvent emissions.

Low VOC content material if emissions > 10 lb/day.

RULE REQUIREMENTS
Source: Rule 2.35 – Pharmaceutical Manufacturing Operations

Equipment Type	Required VOC Standards
Reactors, Distillation Columns, Crystallizers and Centrifuges	Capture/Control of 85% by weight required over 10 lb/day.
Separation Operations	Rotary vacuum filter, other filter, or separation device with an exposed liquid surface must not emit more than 10 lb/day unless emissions have been reduced by 85% by weight.
In-Process Tanks	Covers must be closed except during loading or unloading.
Air Dryers	Emissions must not exceed 10 lb/day unless they are reduced by 85% by weight.

BAY AREA AQMD

BACT
Source: Bay Area BACT Clearinghouse

No BACT standard has been established for this category of operation.

RULE REQUIREMENTS

Source: Reg. VIII, Rule 24 -- Pharmaceutical and Cosmetic Manufacturing Operations

Equipment Type	Required VOC Standards
Reactors, Distillation Columns, Crystallizers and Centrifuges	Emissions of more than 15 lb/day must vent to a condenser with an outlet gas temperature that doesn't exceed the following: 25°C for 0.5 psi to 1.0 psi, 10°C for 1.0 psi to 1.5 psi, 0°C for 1.5 psi to 2.9 psi, -15°C for 2.9 psi to 5.8 psi, -25°C for over 5.8 psi.
Separation Operations	Rotary vacuum filter, other filter, or separation device with an exposed liquid surface must not emit more than 33 lb/day unless emissions have been reduced by 90% by weight.
In-Process Tanks	Tanks must be covered
Air Dryers	Emissions must not exceed 33 lb/day unless reduced by 90% by weight.

SAN JOAQUIN VALLEY APCD

BACT
Source: San Joaquin Valley BACT Clearinghouse

No BACT standard has been established for this category of operation.

RULE REQUIREMENTS
Source: https://www.valleyair.org/rules/1ruleslist.htm#reg4

A rule has not been established.

The following control technologies have been identified and are ranked based on stringency:

<table>
<tr><th colspan="2">SUMMARY OF ACHIEVED-IN-PRACTICE CONTROL TECHNOLOGIES</th></tr>
<tr><td>VOC</td><td>
1. Afterburners, Refrigerated Condensers, or Carbon Adsorbers with a capture/control efficiency of ≥ 90%. For those chemical streams which preclude a control of 90% because of their chemical or physical characteristics, a ≥ 0.3 second retention time at ≥ 1400 ºF for afterburners and an exit gas temperature of -25 °C for condensers will also satisfy BACT if emissions from reactors, distillation columns, crystallizer, evaporators, and centrifuges are less than 15 lb/day and emissions from dryers are less than 10 lb/day. A scrubber may also be used if it achieves a capture/control efficiency of ≥ 90%. (SMAQMD)
2.
<table>
<tr><td>Reactors, Distillation Columns, Crystallizers and Centrifuges</td><td>Emissions of more than 15 lb/day must have a capture/control efficiency of 90% by weight. Emissions of more than 10 lb/day but not more than 15 lb/day must either have a capture/control efficiency of 90% by weight or utilize a condenser with an outlet gas temperature that doesn't exceed the following: 25°C for 0.5 psi to 1.0 psi, 10°C for 1.0 psi to 1.5 psi, 0°C for 1.5 psi to 2.9 psi, -15°C for 2.9 psi to 5.8 psi, -25°C for over 5.8 psi. (SMAQMD)</td></tr>
<tr><td>Separation Operations</td><td>Equipment with an exposed liquid surface must be controlled by at least 90% (SDAPCD)</td></tr>
<tr><td>In-Process Tanks</td><td>Process tanks must be covered. If emissions are greater than 15 lb/day, a capture/control efficiency of 85%/90% is required. (SMAQMD)</td></tr>
<tr><td>Dryers</td><td>Equipment emitting more than 10 lb/day must vent to a device with a capture/control efficiency of 90% by weight. (SMAQMD)</td></tr>
</table>
3. Use of condensing scrubber and condenser which cools exhaust to -15°C. (EPA)
4. Use of low VOC content material. (SDAPCD, YSAQMD)
</td></tr>
<tr><td>HAPs</td><td>T-BACT is the same as achieved-in-practice BACT for VOC.</td></tr>
</table>

The following control technologies have been identified as the most stringent, achieved-in-practice technologies. The first control technology listed is the most stringent that has been achieved-in-practice.

BEST CONTROL TECHNOLOGIES ACHIEVED		
Pollutant	**Standard**	**Source**
VOC	Afterburners, Refrigerated Condensers, or Carbon Adsorbers with a capture/control efficiency of ≥ 90%. For those chemical streams which preclude a control of 90% because of their chemical or physical characteristics, a ≥ 0.3 second retention time at ≥ 1400 ºF for afterburners and an exit gas temperature of -25 °C for condensers will also satisfy BACT if emissions from reactors, distillation columns, crystallizer, evaporators, and centrifuges are less than 15 lb/day and emissions from dryers are less than 10 lb/day. A scrubber may also be used if it achieves a capture/control efficiency of ≥ 90%.	SMAQMD
HAPs	T-BACT is the same as achieved-in-practice BACT for VOC.	

B. TECHNOLOGICALLY FEASIBLE AND COST EFFECTIVE (Rule 202, §205.1.b.)

1. Technologically Feasible Alternatives for Criteria Pollutants:

Technologically feasible alternatives are any alternative basic equipment, fuel, process, emission control device, or technique, singly or in combination, that is determined to be technologically feasible by the Air Pollution Control Officer. The following are the technologically feasible alternatives identified as capable of reducing emissions beyond the levels determined to be “Achieved-in-Practice” per Rule 202, §205.1.a.

Pharmaceutical Production (EPA Process Type 69.011)

RBLC# (A)	Process Description	Technologically Feasible Alternative
MI-276	Pharmaceutical Production	Thermal oxidizer with destruction efficiency of 99%. (Reported to have 99.99% guarantee)
IN-203	Bulk Chemical Mfr.	Afterburner with a 98% control efficiency
IN-200	Narasin Finishing Operation	Carbon adsorber with a 98% control efficiency
IN-144	Narasin Fermentation	
IN-098	Monensin Process	Carbon adsorber with a 95% control efficiency

(A) RBLC# refers to the RACT/BACT/LAER identification number.

South Coast AQMD has identified BACT as the use of afterburners, refrigerated condensers, or carbon adsorbers; however, South Coast did not specify an emissions limit for these technologies because of the large physical and chemical variability of chemical process streams. This variability precludes the possibility of a fixed control efficiency (ref: http://www.aqmd.gov/docs/default-source/bact/bact-guidelines/part-c---policy-and-procedures-for-non-major-polluting-facilities.pdf?sfvrsn=13 (2/19), Page 40.) San Diego County APCD reinforces this point in their BACT determination by labeling technology with a control

efficiency of 90% as being only technologically feasible: their achieved-in-practice method specifies neither a control efficiency nor a limit. This variability is especially pronounced in Sacramento where a pharmaceutical company (Ampac Fine Chemicals) has a business model that is based on process innovation and improvement among multiple clients. The company's operations are based on variability. In addition, the control criteria identified above are from major sources that operate on a much larger scale and are involved in large scale production. Ampac Fine Chemicals, on the other hand, is largely an R&D facility. In addition to this general information, please note the following analysis for specific air pollution control technologies.

Afterburners: An afterburner is not cost-effective as BACT because Ampac's three smaller pilot buildings require BACT yet generate only a small fraction of emissions compared to the main plant area. As an alternate method, the emissions could be routed to a central afterburner located at the main plant, but this is also not feasible because the pilot plants are not located near the main plant. Furthermore, the VOC concentration in the typical emission stream is often dilute and natural gas would be required to supplement the afterburner. Also, Ampac's night operations are sporadic and may involve as much as half the plant or as little as a few pieces of equipment. The amount of night production is dependent on scheduling and the demands of any given project. Therefore, pipeline natural gas would be needed in the afterburner to allow night operation. During night operations, large amounts of natural gas combustion would add criteria pollutants into the atmosphere without appreciably reducing VOCs.

Based on EPA data, an afterburner is also not expected to be cost-effective. Two major sources have been identified that use afterburners. The first major source (IN-0203), which utilizes an afterburner at a 98% control efficiency, reported a cost effectiveness of 29,007 $/ton. This cost is almost twice the District cost threshold of 17,500 $/ton. The CE for Ampac would likely be even higher than 29,007 $/ton since Ampac's emissions are at least 4.5 times lower than IN-0203 (e.g. 25 tons/year per afterburner at IN-0203 versus 5.5 tons/year at Ampac).

The other major source (MI-0276) utilizes an afterburner with a control efficiency of 99% or 99.99% which emits 39 tons/year of VOC emissions. While a CE number wasn't reported, a CE for a higher control efficiency than for IN-0203 combined with Ampac's emissions which are more than 7 times lower than MI-0276 is not expected to make this alternative cost-effective. Therefore, for the reasons given, afterburners at these levels of control are not technologically feasible.

Carbon Adsorbers: Carbon adsorbers were identified as technologically feasible at 95% control and 98% control. The source that utilizes the less effective control of 95% (IN-0098) reported a CE of 47,354 $/ton for emissions of 23.7 tons/year and another unit at 49,303 $/ton for emissions of 23.0 tons/year. This is 3 times higher than the District CE threshold. Ampac's cost-effectiveness would likely yield a higher number since Ampac's total non-fugitive emissions are only 25% of those emissions given above. Therefore, carbon adsorbers at this level of control are not technologically feasible for the reasons given.

Refrigerated Condensers: Most pharmaceutical process streams can achieve a control of 90% when using afterburners, condensers, or carbon adsorbers. For APC condensers, a minimum exhaust gas temperature of -25 ºC will typically achieve a control of at least 90%. However, as reflected in the BACT clearinghouses, it is not cost effective to achieve a control of 90% for some process streams because of their individual chemical and physical characteristics.

It should be noted that BACT can not be less stringent than District rules which are considered to be achieved-in-practice. Therefore, BACT will be the use of afterburners, refrigerated condensers, or carbon adsorbers with a capture/control efficiency of ≥ 90%. However, for those chemical streams which preclude a control of 90% because of their chemical or physical characteristics, afterburners operating at a ≥ 0.3 second retention time at ≥ 1400 ºF and condensers operating at an exit gas temperature of -25 °C will also satisfy BACT if emissions from reactors, distillation columns, crystallizer, evaporators, and centrifuges are less than 15 lb/day and emissions from dryers are less than 10 lb/day. A scrubber may also be used if it achieves a capture/control efficiency of ≥ 90%.

2. Technologically Feasible Alternatives for Toxics (T-BACT):

Technologically feasible methods are any basic equipment, fuel, process, emission control device, or technique, singly or in combination, that is determined to be technologically feasible by the Air Pollution Control Officer. The following are the technologically feasible methods identified as capable of reducing emissions beyond the levels determined to be "Achieved-in-Practice" per Rule 202, §205.1.a.

Pollutant	Technologically Feasible Alternative
VOC	1. Afterburner with a capture/destruction efficiency of ≥ 90%. 2. Refrigerated condensers with a capture/control efficiency of ≥ 90%. 3. Carbon adsorber with a capture/control efficiency of ≥ 90%. 4. Wet Scrubbers

The analysis for the technologically feasible alternatives is the same as mentioned for BACT. Please refer to Section B (above) for discussion.

C. SELECTION OF BACT AND T-BACT:

BACT for Pharmaceutical Manufacturing Batch Operations	
Pollutant	**Standard**
VOC	Afterburners, refrigerated condensers, or carbon adsorbers with a capture/control efficiency of ≥ 90%. For those chemical streams which preclude a control of 90% because of their chemical or physical characteristics, a ≥ 0.3 second retention time at ≥ 1400 ºF for afterburners and an exit gas temperature of -25 °C for condensers will also satisfy BACT if emissions from reactors, distillation columns, crystallizer, evaporators, and centrifuges are less than 15 lb/day and emissions from dryers are less than 10 lb/day. A scrubber may also be used if it achieves a capture/control efficiency of ≥ 90%.
Toxics	T-BACT is the same as BACT for VOCs.

APPROVED BY: *Brian F Krebs* **DATE:** 06-25-2021

BACT Determination #261

Appendix A

BACT Determinations

EPA and Local Air Districts

Determinations from the EPA BACT/RACT/LAER Clearinghouse

EPA Process Type 69.011 for VOC

RBLC	Permit Date	Process Description	Control Technology	Basis
IN-204	10-2-14	Glatt Fluid Bed Dryer	Thermal Oxidizer, 98% Control	Case by Case
IN-203	8-29-14	Bulk Chemical Mfr.	Thermal Oxidizer, 98% Control	PSD BACT
IN-200	7-24-14	Narasin Finishing Op.	Carbon Adsorber, 98% Control	Case by Case
IN-146	10-6-09	BPM Support Ops.	(A)	(A)
IN-144	10-1-09	Narasin Fermentation	100 ton/year	PSD BACT
IN-098	1-16-01	Monensin Process	Carbon Adsorber, 23.7 ton/yr	PSD BACT
MI-312	1-12-01	Reactors, et al.	Condenser/Scrub, 7.7 lb/hr, -15 °C	Case by Case
MI-276	10-31-00	Pharmaceuticals	Thermal Oxidizer, 0.84 lb/hr	Case by Case

(A) Determination does not apply to equipment category.

SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT
Best Available Control Technology (BACT) Guidelines for Non-Major Polluting Facilities*

10-20-2000 Rev. 0
7-9-2004 Rev. 1

Equipment or Process: Pharmaceutical Manufacturing

	Criteria Pollutants					
Rating/Size	**VOC**	**NOx**	**SOx**	**CO**	**PM_{10}**	**Inorganic**
Operations Involving Solvents	Afterburner (≥0.3 second Retention Time at ≥1,400°F), Refrigerated Condenser, or Carbon Adsorber (07-11-97)					
Solids Handling					Baghouse (07-11-97)	
Solids Storage Tanks					Baghouse or Vent Filter (07-11-97)	

Note: This equipment may also be subject to SCAQMD Rule 1103 and 40 CFR 63 Subpart GGG – National Emission Standards Pharmaceuticals Production. (7-9-2004)

* Means those facilities that are not major polluting facilities as defined by Rule 1302 - Definitions

NEW SOURCE REVIEW REQUIREMENTS FOR BEST AVAILABLE CONTROL TECHNOLOGY (BACT)

GUIDANCE DOCUMENT

June 2011

San Diego County
Air Pollution Control District
10124 Old Grove Road
San Diego CA 92131
Ph: (858) 586-2600

PHARMACEUTICAL MANUFACTURING
Fee Schedule 54A

The BACT Control Options which have been determined to be technologically feasible (T/F - demonstrated but not necessarily proven in field application) or have achieved the BACT emission rate limits in practice (A/P - demonstrated in use for the specific equipment category) are listed below. The BACT Control Options are listed in descending order of control stringency. If the top-listed T/F control option is proposed, no further analysis is required. If the first T/F control option is not chosen, then the applicant must review and determine the cost-effectiveness of each T/F control option in the order listed. The first control option determined to be cost-effective must be installed to meet the BACT requirement. A control option is considered cost-effective if the annualized cost of implementing that control option is equal to or less than the reference cost-effectiveness value for the same pollutant shown in Table 2-4. If none of the T/F control options are determined to be cost-effective, the applicant must propose the A/P control option, propose an alternative technology that meets the BACT emission rate limit or perform a full Top-down BACT Analysis as described in Section 4. The applicant is responsible for ensuring that the installed equipment meets the specified BACT Emission Rate Limit. (See Section 2 for further guidance.)

	VOC	NOx	SOx	PM
BACT Control Option	Collection System Vented to Carbon Adsorber or Afterburner (T/F) **BACT Emission Rate Limit -** emissions controlled to overall capture/ destruction efficiency ≥ 90% by weight	(N/A)	(N/A)	Baghouse or Vent Filters. (A/P)
BACT Control Option	Low VOC content materials (A/P)	(N/A)	(N/A)	Baghouse or Vent Filters. (A/P)

The applicant may choose to limit the Potential to Emit (PTE) from the equipment to less than 10 pounds per day for each pollutant in lieu of meeting the stated BACT requirement.