CATEGORY: **PHARMACEUTICAL PROCESS**

BACT Size: Minor Source BACT **PHARM MANUFACTURING OPERATIONS**

BACT Determination Number: 131	**BACT Determination Date:** **3/20/2018**

Equipment Information

Permit Number: N/A -- Generic BACT Determination
Equipment Description: PHARM MANUFACTURING OPERATIONS
Unit Size/Rating/Capacity: BATCH PROCESSING
Equipment Location:

BACT Determination Information

ROCs	**Standard:**	
	Technology Description:	Refrigerated condensers, afterburners, or carbon adsorbers operated 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 ≥

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777 12th Street, Third Floor

SACRAMENTO METROPOLITAN AIR QUALITY MANAGEMENT DISTRICT

Sacramento, CA 95814

BEST AVAILABLE CONTROL TECHNOLOGY DETERMINATION

DETERMINATION NO.: 131

DATE: March 20, 2018

ENGINEER: Jeff Weiss

Category/General Equip Description: Pharmaceutical Manufacturing Operations

Equipment Specific Description: Pharmaceutical Manufacturing Batch Processes (Non-Fugitive)

Equipment Size/Rating: Area Source

Previous BACT Det. No.: #85

This BACT determination will update Determination #85 for Pharmaceutical Manufacturing Operations which was made on November 5, 2015. In addition, this determination is being updated to include T-BACT for HAP emissions.

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.

DISTRICT/AGENCY: US EPA

RACT/BACT/LAER

Source: https://cfpub.epa.gov/rblc/index.cfm?action=Results.PermitSearchResultsht

Pharmaceutical Production (Process Type: 69.011)

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

RBLC#	Process Description	Control
MI-276	Pharmaceuticals	Determination is for equipment at a major source.

RULE Requirements
Source: 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 which, when used, are usually above the criteria concentration limits. However, SMAQMD Rule 443, Rule 464, and pharmaceutical BACT Determination 85 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. This rule is for equipment in an entirely different production scope.

DISTRICT/AGENCY: 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.

DISTRICT/AGENCY: SACRAMENTO METROPOLITAN AQMD

BACT
Listed under BACT Determination #85 – 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 for those cases if uncontrolled emissions are no more than 330 lb/day and are controlled to less than 33 lb/day.

RULE Requirements

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 shall be vented to a carbon adsorber or other approved air pollution control device.
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 shall vent to a device with a capture/control efficiency of 90% by weight.

DISTRICT/AGENCY: SOUTH COAST AQMD

BACT
Source: SCAQMD BACT Guidelines for Non-Major Polluting Facilities, page 91

Pharmaceutical Manufacturing - Afterburner (≥ 0.3 second retention time at ≥ 1400 ºF), Refrigerated Condensers, or Carbon Adsorbers (Emissions limit was not specified because a limit that applies to all equipment within the category is not possible. Please refer to discussion in Section B below).

RULE Requirements

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.
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.

DISTRICT/AGENCY: SAN DIEGO COUNTY APCD

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

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

RULE Requirements
Source: San Diego Rules

No rule has been established for this category of operation.

DISTRICT/AGENCY: YOLO-SOLANO AQMD

BACT
Source: Frank DeMaris, YSAQMD

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

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

RULE REQUIREMENTS
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 shall 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 shall not exceed 10 lb/day unless they are reduced by 85% by weight.

DISTRICT/AGENCY: BAY AREA AQMD

BACT
Source: Bay Area BACT Clearinghouse

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

RULE REQUIREMENTS
Regulation 8: Organic Compounds - 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 shall not emit more than 33 lb/day unless emissions have been reduced by 90% by weight.
Sterilizer	Emissions shall not exceed 33 lb/day unless reduced by 75% by weight.
In-Process Tanks	Tanks must be covered
Air Dryers	Emissions shall not exceed 33 lb/day unless reduced by 90% by weight.

DISTRICT/AGENCY: 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: San Joaquin Valley Rules

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 for those cases if uncontrolled emissions are no more than 330 lb/day and are controlled to less than 33 lb/day. (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.</td></tr>
<tr><td>Separation Operations</td><td>Centrifuges, rotary vacuum filters, or other devices with an exposed liquid surface shall be vented to a carbon adsorber or other approved air pollution control device.</td></tr>
<tr><td>In-Process Tanks</td><td>Tanks must be covered. If emissions are greater than 15 lb/day, a capture/control efficiency of 85%/90% is required.</td></tr>
<tr><td>Dryers</td><td>Equipment emitting > 10 lb/day shall vent to a device with a capture/control efficiency of 90% by weight.</td></tr>
</table>
(SMAQMD, BAAQMD, YSAQMD, SCAQMD)
3. Use of condensing scrubber & 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. Because both the first and the second technology listed above have been achieved yet involve somewhat different control parameters, the control parameters have been combined into a single technology.

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 (Process Type: 69.011)

RBLC#	Process Description	Technologically Feasible Alternative
MI-0276	Pharmaceutical Production	Thermal oxidizer with destruction efficiency of 99%. (Reported to have 99.99% guarantee)
IN-203	Bulk Chemical Mfr.	Afterburner at 98% efficiency
IN-0200	Narasin Finishing Operation	Carbon adsorber at 98% efficiency
IN-0144	Narasin Fermentation	
IN-0098	Monensin Process	Carbon adsorber at 95% efficiency

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) (12/16), Page 40.) San Diego County APCD reinforces this point by labeling technology which has been achieved-in-practice as being only technologically feasible when used blindly at a control efficiency of 90%. 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 of products from multiple clients. In essence, 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 largely involved in large scale production. Ampac Fine Chemicals, on the other hand, is largely an R&D facility. Notwithstanding the aforementioned, please note the following analysis.

Afterburners: An afterburner is not cost-effective as BACT because Ampac's three smaller pilot buildings require BACT yet only generate a small fraction of emissions compared to Plant 1 and its surrounding areas: On the other hand, routing these emissions to a central afterburner is not feasible for the pilot plants since they're located far from the main plant. Furthermore, the VOC concentration in the typical emission stream is dilute and natural gas would be required to supplement the afterburner. It also should be noted that 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 level of night activity depends on scheduling and the demands of any given ACC project. Therefore, pipeline natural gas would be needed in the afterburner to allow night operation. 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. The District's Cost Effectiveness (CE) threshold is 17,500 $/ton. The major source that utilizes the afterburner at 98% efficiency (IN-0203) reported a much higher CE of 29,007 $/ton. This CE is twice the District threshold. The CE for Ampac would likely be even higher 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 at 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 emissions which are more than 7 times lower than MI-0276 is not expected to make this alternative cost-effective. Therefore, afterburners are not technologically feasible.

Carbon Adsorbers: The source utilizing the carbon adsorber at 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 cost-effectiveness would likely yield an even higher number since Ampac's total non-fugitive emissions are only 25% of those emissions given above. Therefore, carbon adsorbers are not technologically feasible.

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 90% control. However, as reflected in the BACT clearinghouses, it's not cost effective to achieve a control of 90% for some process streams because of their chemical and physical characteristics. BACT can not be less stringent than District rules which are considered to be achieved-in-practice.

Therefore, since process stream variability makes a control of over 90% to be not cost-effective and since this variability is especially acute at Ampac Fine Chemicals, 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, 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%.

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. Scrubbers

The analysis for the technologically feasible alternatives are 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 °F 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.

REVIEWED BY: _____ **DATE:** 3-20-18

APPROVED BY: _____ **DATE:** 3/20/18