



CORDEN PHARMA COLORADO, INC.

ENVIRONMENTAL PROGRAMS STATUS REPORT

May 31, 2017

Pollution Prevention Certifications and Memberships:



COLORADO INDUSTRIAL
ENERGY CHALLENGE
Improving Efficiency, Reducing Costs and Emissions



Colorado
Environmental
Partnership



ISO 14001

Introduction

Status Report History and Purpose

The annual Environmental Programs Status Report (Status Report), which was first issued in 1998, is part of the voluntary pollution prevention program at Corden Pharma Colorado. The Status Report serves as an update to the City of Boulder and Boulder County on the current status and results of Corden Pharma Colorado's pollution prevention activities. The Status Report also meets the requirements of City of Boulder municipal code 10-7.7-8(a)(1). The goal is to provide our stakeholders and the general public with an understanding of Corden Pharma Colorado's environmental footprint. The Status Report also demonstrates Corden Pharma Colorado's commitment to continuous improvement in our operations, both benefitting the patients who depend on the medicines Corden Pharma Colorado produces and also protecting the environment. As always, a copy of the latest Environmental Programs Status Report is available for general public review on our website, www.cordenpharma.com/facilities/colorado.

Status Report Summary

In 2016, Corden Pharma Colorado decreased the production of bulk pharmaceuticals and pharmaceutical intermediates by 52 percent from 2015. As a result, there were positive trends in several environmental figures which directly correlate to production rates. However, because of the different environmental impacts of each process, some environmental figures reflect negative trends due to changes in the mix of products produced.

In 2015 and 2016, an area of focus was on implementing projects to substantially reduce the overall global energy impact of the Corden Pharma Colorado manufacturing processes, although the Corden Pharma Colorado Boulder facility does not always benefit from direct energy savings. These energy savings are realized by business partners and are not reflected in energy consumption figures in this report, as overall direct energy usage increased by 1 percent. Total bulk liquid sent offsite fell by 27 percent, however due to a surge in new development processes, the percentage sent offsite for the beneficial purposes of recycling or energy recovery fell from 99 percent to 71 percent. Additional changes from 2015 to 2016 include a 5 percent increase in the amount of material recycled onsite per unit of production, a 2 percent decrease in water use, and a 38 percent decrease in volatile organic compound emissions. Details can be found in the Summary Tables, beginning on page 13.

Status Report Outline

The remainder of this Status Report includes the following sections:

- **2016 Activity Background**
- **Environmental Compliance and Regulatory Status Changes**
- **Pollution Prevention Goals and Objectives**
- **2016 Summary Tables**

2016 Activity Background

This section of the Environmental Programs Status Report details the production and technical development activities at Corden Pharma Colorado and the voluntary environmental performance programs in which the company participates.

Production Activities Summary

Corden Pharma Colorado is a member of the Corden Pharma Group. The Corden Pharma Group includes a network of international companies that manufacture bulk intermediates, active ingredients, and final prescription and over-the-counter medicines.

The current focus of Corden Pharma Colorado's activities is the contract production of therapeutic peptides, highly active compounds, complex small molecules, and oligonucleotides. Corden Pharma Colorado sends the compounds it produces to other manufacturing sites for formulation into finished pharmaceutical products. As a multi-purpose facility that can handle small and large scale production, the medicinal compounds that Corden Pharma Colorado manufactures frequently change in response to market demand and the development of new therapeutic innovations.

The primary compounds that Corden Pharma Colorado produced in 2016 are active pharmaceutical ingredients or intermediates for the following medicines:

- Enfuvirtide (Fuzeon®)

Enfuvirtide was the first of a class of therapies called "fusion inhibitors" that block the AIDS virus from infecting healthy cells.

- Ganciclovir (Cytovene® or Cymevene®) and Valganciclovir (Cymeval® or Valcyte®)

Ganciclovir and Valganciclovir are drugs for the treatment of CMV retinitis in patients with compromised immune systems, including AIDS patients and organ transplant recipients.

- Saquinavir (Invirase®) and Nelfinavir (Viracept®)

Saquinavir and Nelfinavir are protease inhibitors that act to impede an enzyme that is vital in the later stages of HIV reproduction.

- Highly Active Pharmaceutical Products

Corden Pharma Colorado's facilities also include small scale manufacturing laboratories for the production of highly active compounds, drugs that are effective in very small doses. Some of the highly active compounds that Corden Pharma Colorado produced in 2016 are active ingredients for the endometriosis treatment, Nafarelin (Synarel®), and the osteoporosis treatment, Calcitriol (Rocaltrol®).

Technical Development Activities

Corden Pharma Colorado's technical development department designs manufacturing processes for intermediates and APIs that produce high purity medicinal compounds, while optimizing cost, reliability and safety. These same development activities also have environmental benefits:

- Improving the inherent safety of our manufacturing processes often entails the discovery and development of chemical synthesis routes that minimize or eliminate the use of environmentally undesirable materials.
- The improved synthesis routes that Corden Pharma Colorado scientists design also can help avoid high pressure and high temperature process conditions, with both safety benefits and energy savings.
- Starting with the simplest materials as building blocks for our products and improving the efficiency of our manufacturing processes minimizes the demand for raw materials.
- Maximizing the ability of our existing equipment to manufacture pharmaceutical products minimizes the need to construct and operate new facilities.

Corden Pharma Colorado's technical development facilities include both laboratories for process research and pilot scale production facilities for manufacturing drug compounds in the quantities necessary for approval by regulatory agencies, to supply the clinical trials for new drugs, and to demonstrate new manufacturing processes.

Voluntary Environmental Performance Programs

Corden Pharma Colorado participates in a variety of federal, state, local, and industry-wide initiatives that set challenging pollution prevention standards. The following are examples of the pollution prevention programs in which Corden Pharma Colorado currently participates:

City of Boulder Pollution Prevention Program

Corden Pharma Colorado has been a voluntary participant in the City of Boulder's Pollution Prevention Program since its inception. Participation in the Pollution Prevention Program began with the development of a "Pollution Prevention Master Plan and Statement of Commitments" and the setting of specific pollution reduction goals. Corden Pharma Colorado tracks the success of its environmental initiatives as a founding participant in the Pollution Prevention Program through this annual report to the City of Boulder, now titled "Environmental Programs Status Report."

Partners for A Clean Environment

Corden Pharma Colorado was originally certified under Boulder County's Partners for A Clean Environment (PACE) program in 2001. PACE businesses must meet a stringent list of criteria, demonstrating a sincere commitment to a company-wide pollution prevention program and the implementation of projects that have a quantifiable benefit to the environment.

Colorado Environmental Leadership Recognition

The State of Colorado's Environmental Leadership certification recognizes companies that voluntarily perform above and beyond existing mandated environmental regulations. Environmental Leaders like Corden Pharma Colorado must have a comprehensive and operational environmental management system and a pollution prevention plan that commits the company to a program of continuous environmental improvement. In its letter announcing the Environmental Leadership certification, the Colorado Department of Public Health and Environment thanked Corden Pharma Colorado for the "effort and dedication" it brings to environmental issues. Under the Environmental Leadership program, Corden Pharma Colorado has participated in statewide pollution prevention workshops and mentoring programs. Since 2003, Corden Pharma Colorado has held the highest environmental honor that the State of Colorado bestows, the title of "Gold Level" Environmental Leader.

ISO 14001 Certification

Corden Pharma Colorado was certified under the ISO 14001 standard in 2006 and has maintained the certification since that time. Corden Pharma Colorado earned its ISO 14001 certification through a comprehensive independent audit of the company's environmental, health, safety, and security management system.

Colorado Environmental Partnership

The Colorado Environmental Partnership (CEP) is a membership organization consisting of representatives from the business community, government agencies, and public interest groups. The CEP hosts forums that provide opportunities for members and subject matter experts to discuss topics of mutual interest, share experiences, and recognize environmental achievements. The Colorado Environmental Partnership also collaborates with organizations that share its goals in hosting public events for business audiences on a range of topics related to environmental performance and sustainability.

Colorado Industrial Energy Challenge

In June of 2010, Corden Pharma Colorado became a Charter Member of the Colorado Industrial Energy Challenge (CIEC) program. CIEC is a voluntary program sponsored by the Colorado Energy Office (CEO) and the U.S. Department of Energy (DOE). The program challenges industrial firms to set energy efficiency goals and to demonstrate progress towards achieving their goals. Corden Pharma Colorado was awarded an “Excellence in Energy Efficiency” award in 2012, and again in 2017, for its energy reduction efforts.

Volunteer Work with Boulder County Parks and Open Space

Corden Pharma Colorado has been supporting Boulder County Open Space since 2009. Each year, Corden Pharma Colorado employee volunteers, along with their friends and families, have spent a day or two working to maintain and improve various open spaces. Employees have built fences, repaired trails, collected native seeds, fixed bridges, restored burned slash pile areas, removed infected trees, and worked on whatever else might be needed. In 2016 Corden cleaned up tree branches at Heil Ranch and created wood piles in support of the Boulder County Parks and Open Space efforts to control fires. In the summer of 2017, Corden Pharma Colorado will support another activity, and then likely again in the fall.

Environmental Compliance or Regulatory Status Changes

There was no change in Corden Pharma Colorado's compliance or regulatory status in 2016.

Pollution Prevention Goals and Objectives

Corden Pharma Colorado is committed to pursuing pollution prevention goals associated with our energy reduction, process waste minimization, and other pollution prevention efforts. This section details the progress Corden Pharma Colorado made in 2016 towards these three goal categories, including specific program achievements and plans for further action in 2017 and 2018.

Energy Reduction Goals

Due to recent increases in energy demand driven by process improvements and growth of the business, energy reduction has been a challenge. From 2015 to 2016, the company increased onsite energy consumption by 1 percent. However, energy consumption at Corden Pharma Colorado has decreased 24 percent since 2005 when the company's original energy goals were set.

Corden Pharma Colorado continues to identify, evaluate, and implement energy reduction measures. A number of initiatives have been completed over the last ten years that were highly effective. As explained below, two objectives (1b and 1c) substantially reduce the overall global energy impact of the Corden Pharma Colorado manufacturing processes, although Corden Pharma Colorado does not benefit from direct energy savings. These energy savings are realized by business partners and therefore are not reflected in onsite energy consumption figures. To display the positive impact of the project, this report provides a second energy graph in the "2016 Summary Tables" section.

The following objectives are underway to continue to support energy reduction both on and off site:

Objective 1a: Implement a new standard for lighting in manufacturing buildings, where LED lights will be used in new installations. This will result in lower energy consumption.

Achievement: Corden Pharma Colorado has implemented the new lighting standard and has installed several dozen LED lights for specific applications to collect data on performance and functionality. Technology continues to evolve rapidly, especially for fixtures in electrically classified areas, and will continue to be evaluated and installed.

Objective 1b: Improve the production efficiency of the existing pressure swing adsorption (PSA) nitrogen beds. These units supply nitrogen for manufacturing equipment, primarily for flammability control. If PSA nitrogen is not available, it is necessary to make-up the difference by vaporizing cryogenic nitrogen purchased from an outside supplier.

Achievement: Project fully implemented in 2016, resulting in a 32 percent increase in PSA production with no increase in power demand

at the Corden Pharma Colorado facility. This results in less cryogenic nitrogen being purchased and therefore an overall lower global energy requirement for the nitrogen generation processes on-site, although direct energy savings are not located at the facility.

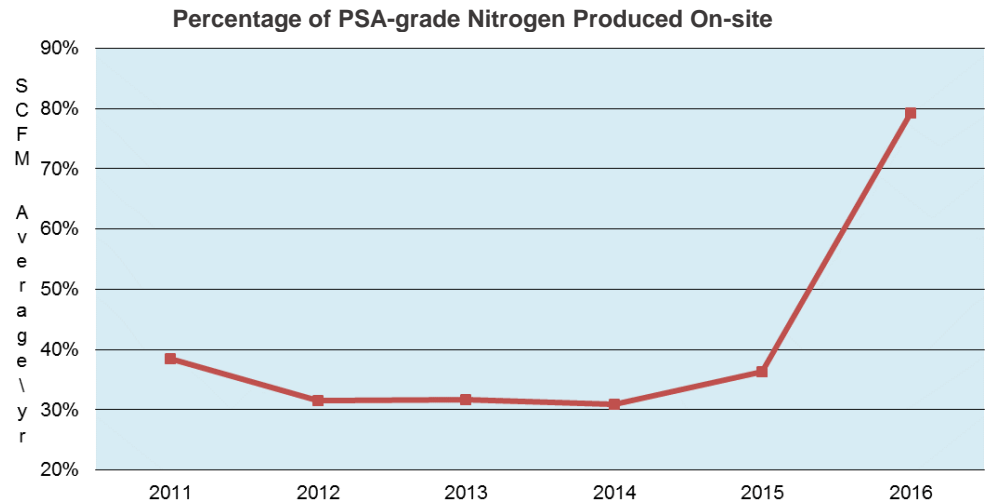
Original Goal Target Savings (annual)	270,000 KWH
2016 Actual Savings	433,000 KWH

Objective 1c: Program a control system to optimize nitrogen loading on the vent collection manifolds. This will reduce demand for cryogenic nitrogen makeup into the PSA header while still maintaining stability of the vent collection system.

Achievement: The control system was implemented in 2016, and the following global energy savings were realized:

Original Goal Target Savings (annual)	475,000 KWH
2016 Actual Savings	1,594,000 KWH

This energy savings is not realized directly at the facility but impacts the overall global energy usage of the process. This also eliminates ~132 tanker shipments annually of cryogenic nitrogen with additional energy savings and reduced industrial traffic as a result. These savings are independent of the PSA project identified above in Objective 1b. The table below displays the results of both Objective 1b and 1c:



Objective 1d: In 2017, to meet production needs, one manufacturing area is being converted to conform to ISO 8 cleanroom standards. In this area, Corden Pharma Colorado will replace an existing HVAC unit. Overall capacity will increase with dual units due to implementation of the ISO 8 cleanroom standards and replacement of swamp cooling with Dx cooling. To mitigate the effect of this capacity increase, the dual

replacement air conditioning units will be controlled by Variable Frequency Drives (VFD) and will utilize multiple service modes to allow up to 40 percent reduced usage during non-active production periods.

Process Waste Minimization Goals

Corden Pharma Colorado strives to reduce the solvent waste and air emissions its pharmaceutical manufacturing processes generate. The company achieves these goals by modifying manufacturing processes to reduce the need for production material, recycling materials for re-use, controlling air emissions, and many other process waste minimization efforts. Over the years, Corden Pharma Colorado has successfully reduced the process waste from many manufacturing steps. The following specific objectives were identified to further advance these efforts in 2016 and 2017.

Objective 2a: Make additional emissions control investments in the North and South Pilot Plants. Specifically, pilot scale equipment will be connected to the emissions control system, providing the flexibility to deploy this equipment for commercial manufacturing purposes while maintaining low emissions levels.

Achievement: Starting in 2011 and continuing into 2016, Corden Pharma Colorado has connected additional pilot scale equipment and processes in the North and South Pilot Plants to the emissions control system (ECS). These changes reduced VOC and HAP emissions from pilot scale manufacturing processes.

Objective 2b: Optimize aqueous waste workup onsite to minimize the amount of hazardous waste sent offsite for direct thermal destruction and maximize the amount treated in the onsite wastewater treatment plant or sent offsite for use as an alternative fuel.

Achievement: Implemented changes in 2014. As a result, in 2014, 32,000 gallons of aqueous waste that would have previously been shipped offsite for thermal destruction was instead treated in the onsite wastewater treatment plant, and this waste avoidance continued into 2015 and 2016. Additionally, in 2017, more process waste streams were identified for aqueous workup, and the procedure was modified to allow for them to be treated onsite.

Objective 2c: For two process intermediates, implement a change to re-use a spent solvent as a replacement for new solvent.

Achievement: A change was implemented for one intermediate step in early 2017 to re-use methanol filtrate to rinse a vessel instead of using new methanol. A similar change will be implemented on another intermediate step of the process later in 2017.

Other Pollution Prevention Goals

In addition to the energy efficiency and process waste minimization efforts listed above, Corden Pharma Colorado also set the following additional pollution prevention goal:

Objective 3a: Reduce paper usage by electronically managing some business records that the company currently prints on paper.

Achievement: Corden Pharma Colorado has previously converted several document types to electronic files. Corden Pharma Colorado is currently working on a multi-year implementation of an electronic data management system to convert additional records and forms to electronic storage.

Other Pollution Prevention Activities

The following activities represent additional efforts to prevent pollution in 2016 and 2017:

- Corden Pharma Colorado employees participated in the Boulder County Clean Air Consortium Summer Clean Air Challenge.

In addition to the projects and plans mentioned above, all Corden Pharma Colorado process teams continue to identify and evaluate pollution prevention opportunities in their areas of expertise. The Pollution Prevention Team supports and tracks all pollution prevention efforts at Corden Pharma Colorado, with a focus on reducing energy consumption and solvent usage and increasing solvent recovery in production processes.

2016 Summary Tables

2016 Production at Corden Pharma Colorado

In 2016, as measured by mass, Corden Pharma Colorado decreased the production of bulk pharmaceuticals and pharmaceutical intermediates by 52 percent from 2015. At the same time, the company's raw materials usage decreased by 45 percent. The environmental figures below reflect the result of both Corden Pharma Colorado's production changes as well as the company's implementation of pollution prevention measures.

Recycling of Raw Materials – Onsite Recycling

The list below compares process requirements and recycling volumes for chemicals that were recycled onsite. The "process requirement" represents the amount of each material needed during the year. The "amount recycled" reflects the reuse of a compound in a process, rather than disposing of it. The "percentage recycled" is the percentage of the process requirement that was met using recycled material instead of virgin material.

The overall amount of raw materials that Corden Pharma Colorado recycled onsite in 2016 decreased by 50 percent from 2015 but the amount recycled per unit of production increased by 5 percent from 2015. These changes were due to changes in the production mix and the resulting changes in the company's demand for recyclable materials.

Chemical ¹	Process Requirement (lbs)	Amount Recycled (lbs)	Percentage Recycled
Acetonitrile	426,121	297,846	70%
Ethyl Acetate	282,354	64,163	23%
Methanol	648,706	19,841	3%
TOTAL		381,850	

¹ Offsite recycling is not included in this list. See table below, "Bulk Liquid Sent Offsite- Waste and Recycling"

Water Usage

The following table details water use at Corden Pharma Colorado in 2016.

Type of Usage	2012 (gallons)	2013 (gallons)	2014 (gallons)	2015 (gallons)	2016 (gallons)
Process	21,641,521	16,738,822	18,807,328	18,899,536	19,019,464
Commercial	1,655,609	1,609,853	1,637,228	1,747,121	1,655,609
Cooling	6,976,245	10,950,000	9,683,469	8,557,277	7,853,316
Irrigation	1,551,050	1,499,750	1,543,400	1,494,764	1,459,250
Total	31,824,425	30,798,425	31,671,425	30,698,698	29,987,639

Wastewater Pretreatment Plant Discharge

Corden Pharma Colorado sends aqueous wastes from production activities through its onsite pretreatment facility. Wastewater leaving the system is discharged to the City of Boulder treatment facility. The following table lists the major components of the wastewater that Corden Pharma Colorado discharges to the City of Boulder treatment facility:

	Discharge (in Pounds unless otherwise indicated)					
	1995 (Baseline)	2012	2013	2014	2015	2016
Volume, gal	21,035,000	8,581,463	10,107,002	9,865,603	8,890,417	7,378,314
Total Organic Content (TOC)	115,000	6,586	10,530	9,541	6,906	3,673
Chromium	31	5.1	2.9	3.8	1.6	1.3
Copper	4.3	14.5	31.1	16.4	12.2	16.6
Lead	2.8	2.2	2.9	4.1	3.7	3.1
Nickel	4.1	0.0	2.4	2.9	2.3	1.8
Zinc	73	35.2	40.3	72.1	43.2	55.6

Bulk Liquid Sent Offsite - Waste Disposal and Recycling

The following values represent the amount of material Corden Pharma Colorado sent offsite in bulk quantities for recycling, energy recovery, or incineration. Due to a change in production mix and the different solvents required for each product, from 2015 to 2016, the total bulk liquid sent offsite decreased by 27 percent, but bulk liquid sent offsite per unit of product produced increased by 52 percent. The percentage sent offsite for the beneficial purposes of recycling or energy recovery fell from 99 percent to 71 percent. This is the result of an increase in the production of smaller scale new processes for which solvent recycling programs are not feasible.

Description	2012	2013	2014	2015	2016
Total bulk liquid sent offsite (kg)	2,704,298	2,016,233	5,222,723	2,349,820	1,704,338
% Change from previous year	+22%	-25%	+159%	-55%	-27%
% Sent offsite for recycling	2%	2%	53.7%	1%	0%
% Sent offsite for energy recovery	51%	79%	45.9%	98%	71%

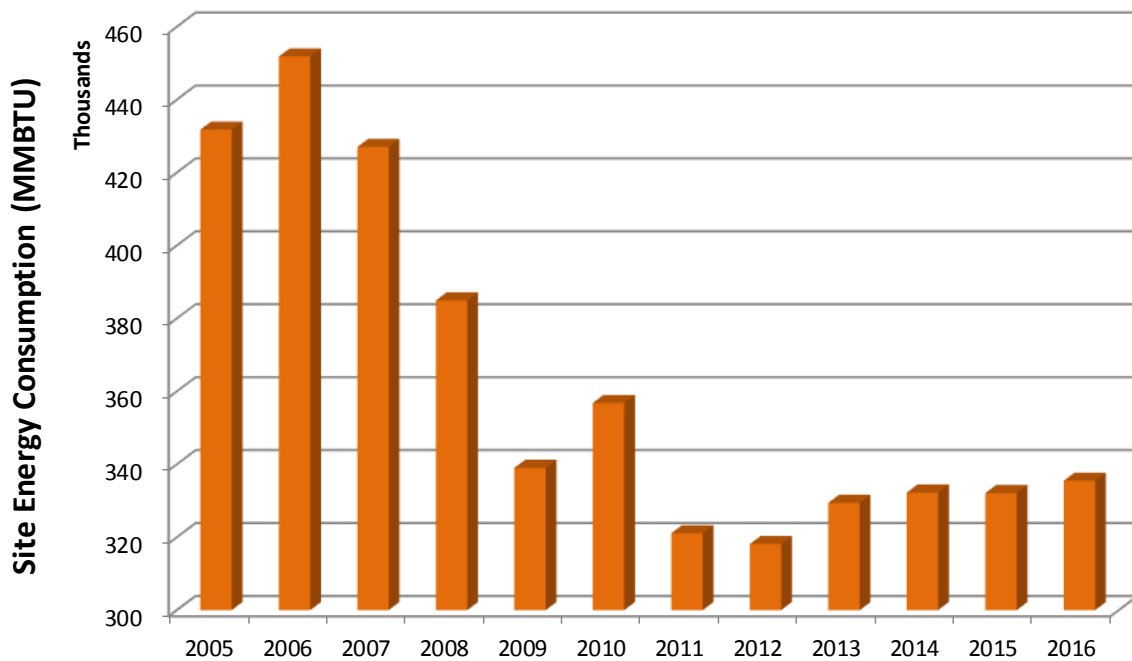
Energy Consumption

The following table presents the standard energy metrics of natural gas and electricity consumption at Corden Pharma Colorado. Additionally, off-site nitrogen consumption converted to energy equivalents, is also presented since it has been a focus area for the company, and since it has a positive impact on global energy consumption. From 2015 to 2016, both electricity usage and natural gas consumption increased, but overall global energy use impact has decreased.

Energy Type	2012	2013	2014	2015	2016
Natural Gas (therms)	1,089,240	1,247,374	1,199,737	1,128,570	1,135,760
Electricity (KWH)	20,846,541	20,443,647	21,226,316	21,922,788	22,469,916
Off-site Nitrogen (KWH equivalent)	4,597,349	4,128,613	4,752,131	4,009,166	2,377,549

Energy reduction has been a priority at Corden Pharma Colorado for many years. A number of initiatives have been completed over the last ten years that were highly effective as shown in the following graph:

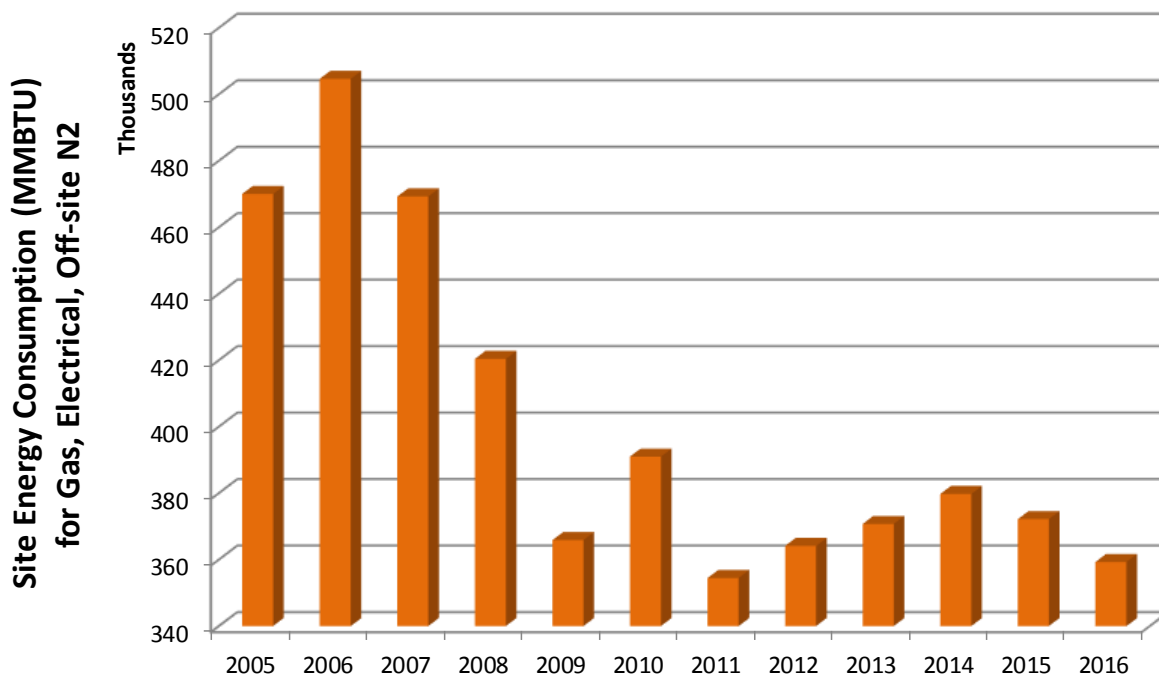
Combined Onsite Energy Use (Electricity & Natural Gas)



NOTE: Electricity unit conversions made using Colorado Industrial Energy Challenge methodology, accounting for typical coal plant thermal efficiency.

Additionally, when the graph is updated to include the energy used offsite to produce nitrogen for the site, Corden Pharma Colorado's nitrogen use reduction efforts in 2015 and 2016 are shown to have a positive impact on global energy use:

Combined Energy Use (Electricity, Natural Gas, & Offsite Nitrogen Energy Equivalents)



NOTE: Electricity unit conversions made using Colorado Industrial Energy Challenge methodology, accounting for typical coal plant thermal efficiency.

Air Emissions

The following table displays Corden Pharma Colorado's air emissions, divided into Toxic Release Inventory (TRI) compounds, Hazardous Air Pollutants (HAPs), and Volatile Organic Compounds (VOCs). From 2015 to 2016, overall VOC emissions decreased by 38 percent and HAP emissions decreased by 45 percent. An overall reduction in production resulted in the decrease.

	1989 (Baseline)	2012	2013	2014	2015	2016
Reported under SARA Title III, Toxic Inventory Report (TRI) ⁴ [values in pounds]						
Acetone ³	242,500	250	1,100	490	1,400	3,200
Acetonitrile ^{1,2}	--	5,040	4,196	2,460	2,600	2,100
Cyclohexane ²	--	70	--	--	--	--
Dimethylformamide ^{1,2}	--	250	93	70	130	150
1,4-Dioxane ^{1,2}	--	--	--	--	60	260
Hexane ^{1,2}	36,600	7,200	8,400	2,800	2,600	1,400
Hydrochloric acid ¹	4,000	110	40	420	160	190
Methanol ^{1,2}	109,600	4,600	4,780	6,100	9,100	4,900
Methyl chloride ^{1,2}	6,700	--	--	--	--	--
n-Methyl-2-pyrrolidinone ²	--	6	3	50	10	7
Methyl Tert-Butyl Ether ^{1,2}	--	2,690	3,820	4,310	4,230	680
Methylene chloride ¹	103,300	2,030	1,750	5,150	1,840	1,230
Pyridine ²	--	2	2	42	2	3
Toluene ^{1,2}	284,400	2,830	3,410	483	550	240
Triethylamine ^{1,2}	--	--	--	--	3	19
Total TRI air emissions (tons)	375	12	13	11	11	5
% change from previous year	--	0%	8%	-15%	0%	-55%
% change from 1989	--	-97%	-97%	-97%	-97%	-99%

Total HAP emissions (tons)	293	12	13	11	11	6
% change from previous year	--	0%	8%	-15%	0%	-45%
% change from 1989	--	-96%	-96%	-96%	-96%	-98%

Total VOC emissions (tons)	490	15	16	12	13	8
% change from previous year	--	7%	7%	-25%	8%	-38%
% change from 1989	--	-97%	-97%	-98%	-97%	-98%

¹ These chemicals are also classified as HAPs and are included in the HAP total above.

² These chemicals are also classified as VOCs and are included in the VOC total above.

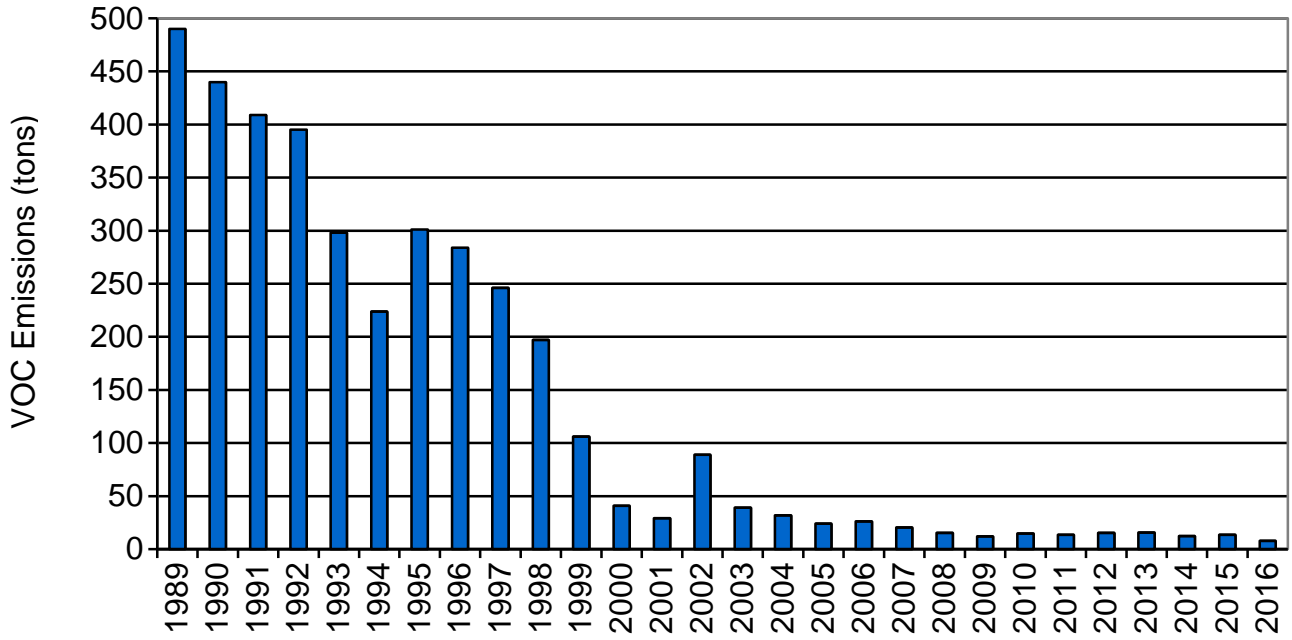
³ Acetone is no longer included in TRI. It is also no longer classified as a VOC. After 1996, it is not included in the VOC total.

⁴ Shaded blocks indicate that TRI reporting for that chemical was not required during that year. They are not included in the TRI emissions total.

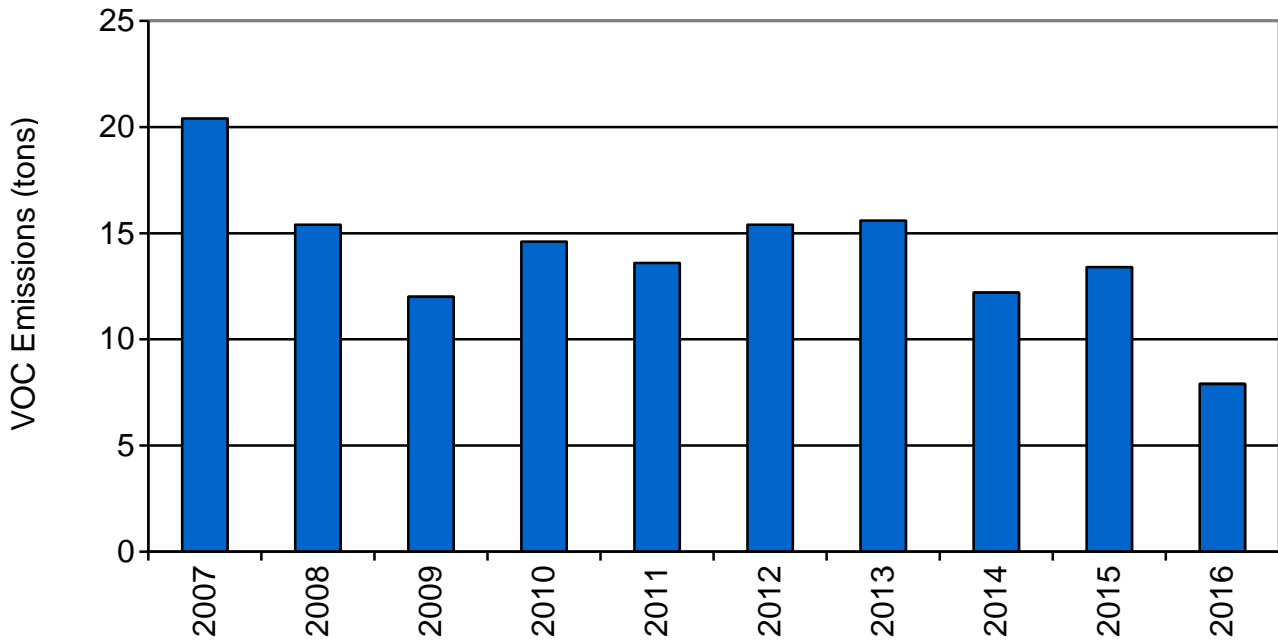
HAP = Hazardous Air Pollutant

VOC = Volatile Organic Compound

Volatile Organic Compounds (VOC) Air Emissions Trend, since 1989



Volatile Organic Compounds (VOC) Air Emissions Trend, Last 10 Years



General Waste Recycling

In 2016, Corden Pharma Colorado recycled a considerable amount of general waste. The totals presented here do not include recycling of removed manufacturing equipment. In 2016, Corden Pharma Colorado recycled over 62,000 pounds of office paper, shredded documentation, newspaper, cardboard, magazines, and phone books. These efforts helped Corden Pharma Colorado save an estimated 540 trees from destruction.

Type of Material	Pounds Recycled
Paper and Cardboard	62,000
Metals	1,100
Plastic	2,100
Compost	~10,000