National Pollutant Inventory

Emission Estimation Technique Manual

for

Medicinal and Pharmaceutical Product Manufacturing

EMISSION ESTIMATION TECHNIQUES
FOR
MEDICINAL AND PHARMACEUTICAL PRODUCT MANUFACTURING

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1.0 Introduction

The purpose of all Emission Estimation Technique (EET) Manuals in this series is to assist Australian manufacturing, industrial, and service facilities to report emissions of listed substances to the National Pollutant Inventory (NPI). This Manual describes the procedures and recommended approaches for estimating emissions from facilities engaged in the manufacture of pharmaceutical and medicinal related product.

The medicinal and pharmaceutical product manufacturing activities covered in this Manual apply to facilities primarily engaged in the manufacture of drugs, medicines, medicinal chemicals, herbal medicines, or other pharmaceutical products for human or veterinary use. The manufacture of pesticides is not covered by this Manual.

EET MANUAL :	Medicinal and Pharmaceutical Product Manufacturing
HANDBOOK:	Medicinal and Pharmaceutical Product Manufacturing
ANZSIC CODE :	2543

This Manual was drafted by the NPI Unit of the Queensland Department of Environment on behalf of the Commonwealth Government. It has been developed through a process of national consultation involving State and Territory environmental authorities and key industry stakeholders.

2.0 Process Description

The pharmaceutical industry consists of facilities that are primarily involved in processing or manufacturing medicinal chemicals and pharmaceutical products. The industry also includes establishments that formulate pharmaceutical products and are involved in grinding, grading, and milling of botanical products. The pharmaceutical sector manufactures bulk substance pharmaceutical intermediates and active ingredients that are further processed into finished products.

2.1 Medicinals and Botanicals

Facilities in the medicinals and botanicals sector are primarily engaged in manufacturing bulk organic and inorganic medicinal chemicals and their derivatives and processing (grading, grinding, and milling) bulk botanical drugs and herbs. The sector is composed of facilities that manufacture products of natural origin, hormonal products and basic vitamins, as well as those that isolate active medicinal principals such as alkaloids from botanical drugs and herbs. These substances are used as active ingredients for pharmaceutical preparations. Facilities often produce both medicinal and botanical pharmaceutical preparations at the same facility.

2.2 Pharmaceutical Preparations

The pharmaceutical preparations sector is made up of facilities that process and manufacture raw materials into pharmaceutical preparations for human and veterinary uses. Finished products are sold in various dosage forms including, tablets, capsules, ointments, solutions, suspensions, and powders. These products are developed primarily for the use of dental, medical, or veterinary professionals, for administration to patients and the general public. Pharmaceutical products are often classified in terms of their availability to the general public (eg. prescription, and over-the-counter (OTC) drugs).

2.3 In Vivo and In Vitro Diagnostic Substances, and Biological Products

The in vivo and in vitro diagnostic substances sector includes facilities that manufacture in-vivo (tested inside a living organism), and in vitro (tested outside of a living organism) diagnostic substances. Products include chemical, biological, and radioactive substances used in diagnosing and monitoring health.

The biological products sector produces bacterial and virus vaccines, toxoids, serums, plasma, and other blood derivatives for human and veterinary use, other than in-vivo and in-vitro diagnostic substances.

The production of pharmaceutical products has three main stages: research and development; the conversion of organic and natural substances into bulk pharmaceutical substances or ingredients through fermentation, extraction, or chemical synthesis; and, the formulation of the final pharmaceutical product.

It is impossible to provide a single process flow diagram for the pharmaceutical industry, as each bulk substance differs in its manufacture, and several intermediates may be produced in a step-wise fashion prior to the manufacture of the final active ingredient. However, an example chemical synthesis process is provided at Figure 1 to identify the equipment used, and at which points emissions and wastes might be generated.

Figures 2 and 3 show simplified process flow diagrams for natural and biological extraction, and fermentation processes respectively. As each facility in Australia is unique, you are encouraged to develop a flow diagram for your own operations detailing the input of materials and listed substances, and the waste sources and emissions resulting from the operation of each process.

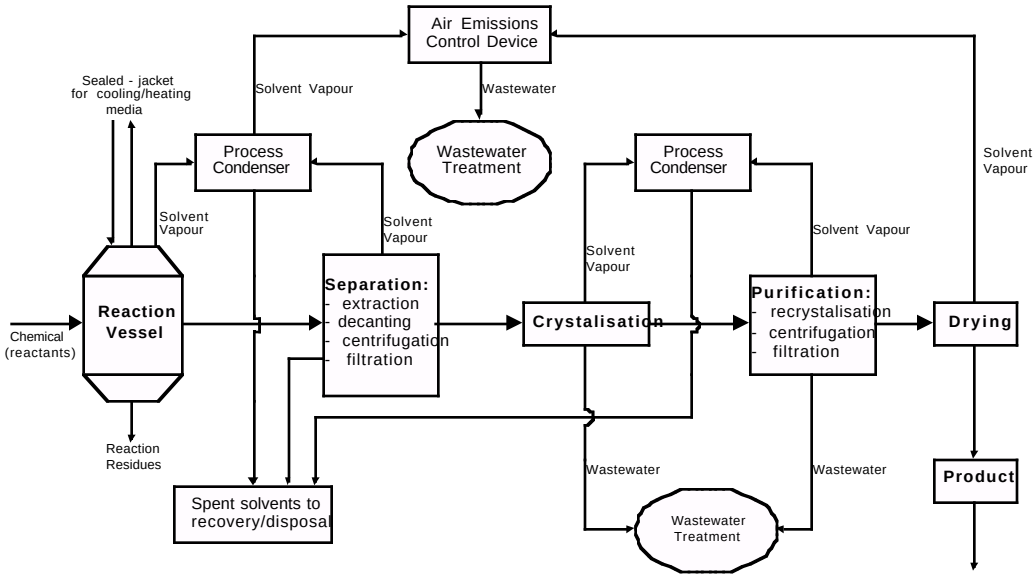

Figure 1. Simplified Process Flow Diagram for Chemical Synthesis

USEPA. September 1997. *EPA Office Compliance Sector Notebook Project*

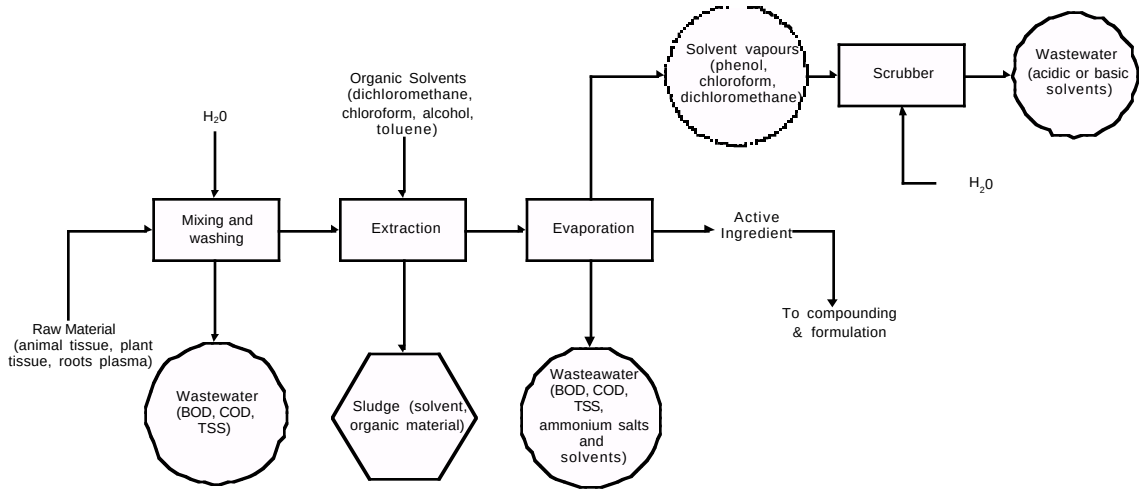

Figure 2. Simplified Process Flow Diagram for Natural and Biological Extraction

USEPA. September 1997. *EPA Office Compliance Sector Notebook Project*

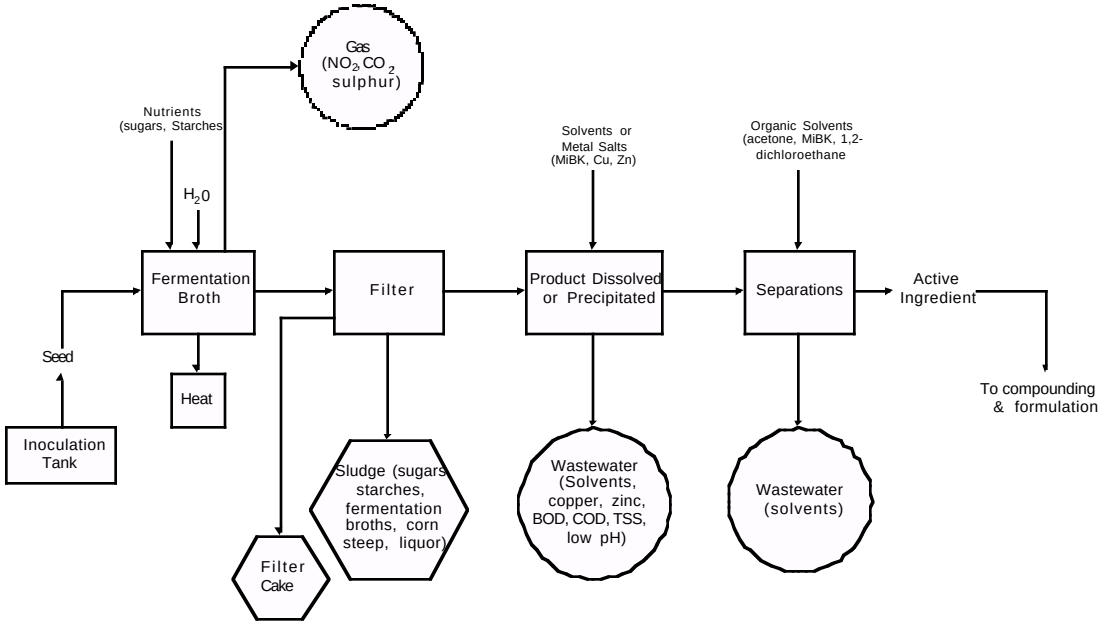

Figure 3. Simplified Process Flow Diagram for the Fermentation Process

USEPA. September 1997. *EPA Office Compliance Sector Notebook Project*

Figure 4 shows a simplified process flow diagram for compounding, formulation, and packaging, and emission and waste points.

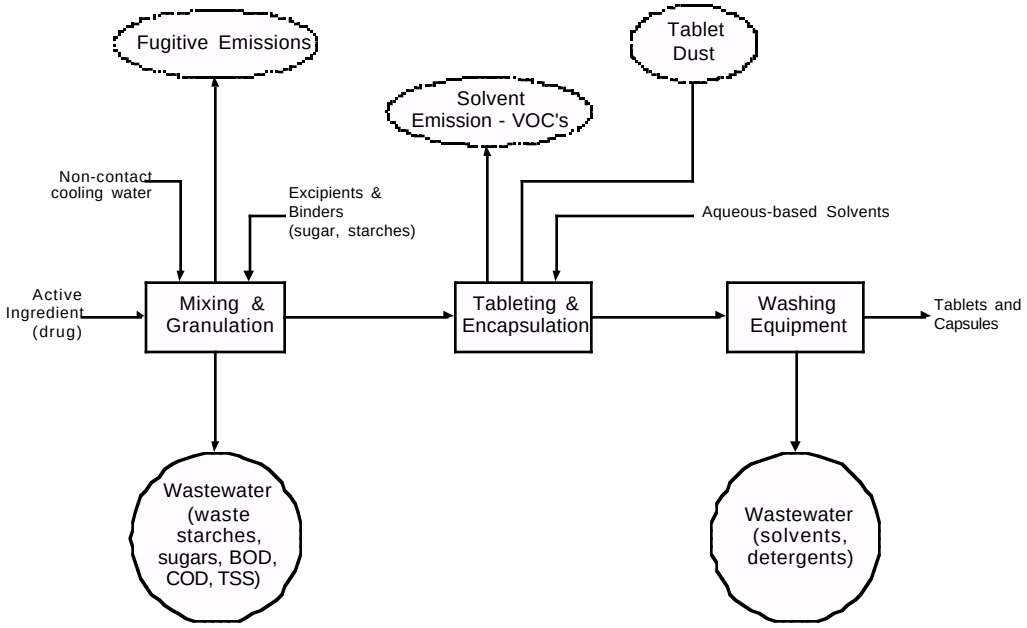

Figure 4. Simplified Process Flow Diagram for Compounding and Formulating

USEPA. September 1997. *EPA Office Compliance Sector Notebook Project*

3.0 Emission Estimation

Estimates of emissions of listed substances to air, water and land should be reported for each substance that triggers a threshold. The reporting list and detailed information on thresholds are contained in *The NPI Guide* at the front of this Handbook.

In general, there are four types of emission estimation techniques (EETs) that may be used to estimate emissions from your facility. These are described in *The NPI Guide*. Select the EET, or mix of EETs, which is most appropriate for your purposes. If you estimate your emission by using any of these EET's, your data will be displayed on the NPI database as being of 'acceptable reliability'. Similarly, if your relevant environmental authority has approved the use of emission estimation techniques that are not outlined in this Handbook, your data will also be displayed as being of 'acceptable reliability'.

For example, you might choose to use a mass balance to best estimate fugitive losses from pumps and vents, direct measurement for stack and pipe emissions, and emission factors when estimating losses from storage tanks and stockpiles.

You are able to use emission estimation techniques that are not outlined in this document. You must, however, seek the consent of your relevant environmental authority. For example, if you already undertake direct measurement, you may use this information for NPI reporting purposes (if you do not undertake direct measurement, the NPI does not require you to do so).

3.1 Emissions To Air

Air emissions may be categorised as :

Fugitive emissions

These are emissions that are not released through a vent or stack. Examples of fugitive emissions include dust from stockpiles, volatilisation of vapour from vats or open vessels, and material handling. Emissions emanating from ridgeline roof-vents, louvres, and open doors of a building as well as equipment leaks, and leaks from valves and flanges are also examples of fugitive emissions. Emission factor EETs are the usual method for determining losses through fugitive emissions.

Point source emissions

These emissions are exhausted into a vent or stack and emitted through a single point source into the atmosphere. An air emissions control device such as a carbon adsorption unit, scrubber, baghouse, or afterburner may be added to the stack prior to the atmospheric release.

3.2 Emissions To Water

Emissions of substances to water can be categorised as discharges to:

- Surface waters (eg. lakes, rivers, dams, and estuaries);
- Coastal or marine waters; and
- Stormwater.

The discharge of listed substances to a sewer or tailings dam does not require you to report to the NPI (See also Section 3.0 of *The NPI Guide*). The main source of wastewater from this industry is usually from air pollution control equipment such as wet scrubbers.

The most appropriate method for determining emissions to the environment via wastewater is to use direct measurement, however, you may use other EETs for the purposes of reporting to the NPI.

3.3 Emissions To Land

Emissions of substances to land on-site include solid wastes, slurries, sediments, spills and leaks, storage and distribution of liquids, and the use of chemicals to control various elements of the environment where these emissions contain listed substances. These emission sources can be broadly categorised as :

- surface impoundments of liquids and slurries
- unintentional leaks and spills.

4.0 Raw Material Inputs And Pollutant Outputs

Pharmaceutical batch processes use numerous raw materials, and generate emissions and wastes containing NPI-listed substances. These wastes and emissions will depend on the raw materials and equipment used, as well as the manufacturing process employed. In designing bulk manufacturing processes, consideration is given to the availability of the starting materials and their toxicity, as well as to the wastes (eg. mother liquors, filter residues, and other by-products) and the emissions generated.

When bulk manufacturing reactions are complete, the solvents are physically separated from the resulting product. Because of purity concerns, solvents are rarely reused in a pharmaceutical process. They may be sold for non-pharmaceutical uses, used for fuel blending operations, recycled, or transferred off-site for incineration.

Table 1 identifies the raw materials, associated emission and waste streams containing NPI listed substances, and some of the more common technologies used to control these emissions and wastes

Table 1. Typical Material Inputs and Pollutant Outputs in the Pharmaceutical Industry[1,a]

Process	Material Input	Air Emissions	Water Emissions or Transfers	Residual Wastes
Chemical Synthesis				
Reaction	Solvents, catalysts, reactants (benzene, chloroform, dichloro methane, toluene, methanol, ethylene glycol, methyl isobutyl ketone, xylenes, hydrochloric acid, etc)	VOC emissions from reactor vents, manholes, material loading and unloading, acid gases (halogen acids, sulphur dioxide, nitrous oxides); fugitive emissions, from pumps, sample collections, valves, tanks	Process waste waters with spent solvents, catalysts, reactants; pump seal waters, wet scrubber waste water, equipment cleaning waste water	Reaction residues and reactor bottom wastes
Separation	Separation and extraction solvents (methanol, toluene, *n*-hexane, etc.)	VOC emissions from filtering systems which aren't contained; and fugitive emissions from valves, tanks, and centrifuges	Equipment cleaning wastewaters, spills, leaks, spent separation solvents	
Purification	Purification solvents (methanol, toluene, acetone, hexanes, etc.)	Solvent vapours from purification tanks; fugitive emissions	Equipment cleaning wash waters, spills, leaks, spent purification solvents	
Drying	Finished active drugs or intermediates	VOC emissions from manual loading and unloading of dryers	Equipment cleaning wast waters, spills, leaks	
Natural Product Extraction	Plants, animal tissues, extraction solvents (ammonia, phenol, chloroform, toluene, etc.)	Solvent vapours and VOCs from extraction chemicals	Equipment cleaning wash waters, spent solvents (ammonia); natural product extraction wastewater	Spent raw materials
Fermentation	Inoculum, sugars, starches, nutrients, phosphates, fermentation solvents (ethanol, amyl alcohol, methanol, methyl isobutyl ketone, acetone, etc.)	Odouriferous gases, extraction solvent vapours, particulates	Spent fermentor broth, fermentation wastewater	Waste filter cake, fermentation residues
Formulation	Active drug, binders, sugar, syrups, etc.	Tablet dusts, other particulates	Equipment cleaning wash waters (spent solvents), spills, leaks, wash waters	Particulates, waste packaging, rejected tablets, capsules, etc.

Adapted by QLD Department of Environment, 1998

4.1 Raw Materials

Hundreds of raw materials are required for the processes of chemical synthesis used by the industry, and many are NPI listed substances. These include organic and inorganic compounds and are used in gas, liquid, and solid forms. Plant and animal tissues are also used by the pharmaceutical manufacturing industry to produce various biological and natural extraction products.

Each manufacturing or formulation facility in Australia is unique, differing from other facilities in size, types of intermediates, bulk substances, or products produced, amounts and types of solvents used, and thus, in the raw materials used, and emissions and wastes generated. Most bulk pharmaceutical reactions require organic solvents to dissolve chemical intermediates and reagents. Because of the high reactivity of many pharmaceutical reagents and intermediates, solvents must be non-reactive, provide an environment which allows efficient heat transfer during endothermic or exothermic reactions, and facilitate efficient electron transfer.

Often, halogenated solvents such as dichloromethane, provide the optimum choice for pharmaceutical reactions. The most commonly used solvent in the pharmaceutical industry is methanol, an oxygenated organic solvent. Other common solvents used are ethanol, acetone, and isopropanol. Table 2, 3, and 4 show the typical solvents (and whether or not they are hazardous air pollutants and NPI-listed) used in chemical synthesis, biological and natural extraction, and fermentation processes, respectively.

Table 2. Solvents Used in the Chemical Synthesis Process

Substance	Hazardous Air Pollutant	NPI Listed Substance	Substance	Hazardous Air Pollutant	NPI Listed Substance
acetone		X	formaldehyde	X	X
acetonitrile	X	X	formamide		
ammonia		X	furfural		
n-amyl acetate			n-heptane		
amyl alcohol			n-hexane	X	X
aniline	X	X	isobutyl aldehyde		
benzene	X	X	isopropanol		
n-butyl acetate			isopropyl acetate		
n-butyl alcohol			isopropyl ether		
chlorobenzene	X		methanol	X	X
chloroform	X	X	methylamine		
chloromethane	X		methyl cellulose		
cyanide		X	dichloro methane	X	X
cyclohexane		X	methyl formate		
1,2-dichloro-benzene			methyl isobutyl ketone	X	X
diethylamine			2-methyl pyridine		
diethyl ether			petroleum naphtha		
n,n-dimethyl-acetamide			phenol	X	X
diethylamine			polyethylene glycol		
n,n-dimethyl-aniline	X		n-propanol		
n,n-dimethyl-formamide	X		pyridine		
dimethyl sulphoxide			tetrahydrofuran		
1,4-dioxane	X		toluene	X	X
ethanol		X	trichlorofloro-methane		
ethyl acetate		X	methyl ethyl ketone	X	X
ethylene glycol	X	X	triethylamine	X	
			xylenes	X	X

Adapted from USEPA Profile on the Pharmaceutical Manufacturing Industry, 1997 and the draft National Environment Protection Measure on the National Pollutant Inventory, 1998.

Table 3. Solvents Used in Biological and Natural Product Extraction

Substance	Hazardous Air Pollutant	NPI Listed Substance	Substance	Hazardous Air Pollutant	NPI Listed Substance
acetone		X	ethylene glycol	X	X
acetonitrile	X	X	formaldehyde	X	X
ammonia		X	*n*-heptane		
n-amyl acetate			*n*-hexane	X	X
amyl alcohol			isopropanol		
n-butyl alcohol			isopropyl acetate		
chloroform	X	X	isopropyl ether		
1,2-dichloroethane		X	methanol	X	X
diethylamine			dichloro methane	X	X
diethyl ether			petroleum naphtha		
n,n-diethyl formamide	X		phenol	X	X
dimethyl sulphoxide			*n*-propanol		
1,4-dioxane	X		pyridine		
ethanol		X	tetrahydrofuran		
ethyl acetate		X	toluene	X	X

Adapted from USEPA Profile on the Pharmaceutical Manufacturing Industry, 1997 and the draft National Environment Protection Measure on the National Pollutant Inventory, 1998.

Table 4. Solvents Used in Fermentation Processes

Substance	Hazardous Air Pollutant	NPI Listed Substance	Substance	Hazardous Air Pollutant	NPI Listed Substance
acetone		X	*n*-heptane		
acetonitrile	X	X	*n*-hexane	X	X
ammonia		X	isopropanol		
n-amyl acetate			isopropyl acetate		
amyl alcohol			methanol	X	X
n-butyl acetate			methyl cellulose		
n-butyl alcohol			dichloro methane	X	X
chloroform	X	X	methyl isobutyl ketone	X	X
n,n-diethyl formamide	X		petroleum naphtha		
ethanol		X	phenol	X	X
ethyl acetate		X	toluene	X	X
formaldehyde	X	X	triethylamine		

Adapted from USEPA Profile on the Pharmaceutical Manufacturing Industry, 1997 and the draft National Environment Protection Measure on the National Pollutant Inventory, 1998.

4.2 Estimating Emissions of Listed Substances

Emissions consist almost entirely of organic solvents that escape from dryers, reactors, distillation systems, storage tanks, and other operations. These emissions are exclusively non-methane organic compounds. Emissions of other listed substances are negligible (except for particulate matter in unusual circumstances), and are not treated in this Manual.

It is not practical to attempt to evaluate emissions from individual steps in the production process, or to associate emissions of any NPI listed substance with individual pieces of equipment, because of the great variety of batch operations that may be undertaken at a single production facility. It is more reasonable to obtain data on total purchases of listed substances at your facility, and to assume that these represent replacements for solvents lost by evaporation. Air emission estimates can be calculated by subtracting the materials that do not enter the air because they have been incinerated, have been transferred off-site, or have been incorporated into the pharmaceutical product by chemical reaction. NPI substances incorporated into manufactured product do not have to be reported as an emission of that substance.

If facility-specific information is not available, industry wide data may be used instead, or the emission factors provided in this Manual. Table 5 lists annual purchases by US pharmaceutical manufacturers and shows the ultimate disposition of each solvent by the industry in that country. This kind of data is currently unavailable for the Australian manufacturing industry, but given the similarities between Australian and US industries, it is quite appropriate to use the US data provided in this Manual

Emissions can be estimated by using your own facility's data on purchases of individual solvents, and computing the quantity of each that evaporates into the air, or is transferred off-site to sewer, incineration, or in solid waste. This estimation can be done from either the information given in Table 5, or through information obtained from your own facility's purchasing and processing records. If solvent volumes are given rather than weights, the liquid densities identified in Table 5 can be used to compute weights.

The emission factors in this Manual are derived from Table 5, and are provided as an example of how to calculate emission factors for your facility.

Table 5. Solvent Purchases and Ultimate Disposition by US Pharmaceutical Manufacturers

Solvent	Annual Purchase (tonnes)	Ultimate Disposition (%)					Liquid Density (g/litre)
		Air emission	Sewer	Incineration	Solid waste	Final product	
acetic acid	930	1	82			17	1044
acetone	12 040	14	22	38	7	19	792
acetonitrile	35	83	17				792
benzene	1 010	29	37	16	8	10	876
chloroform	500	57	5		38		1500
ethanol	13 230	10	6	7	1	76	792
ethyl acetate	2 380	30	47	20	3		900
ethylene glycol	60		100				1116
formaldehyde	30	19	77			4	[b]
n-hexane	530	17		15	68		660
methanol	7 960	31	45	14	6	4	792
dichloro methane	10 000	53	5	20	22		1332
methyl ethyl ketone	260	65	12	23			804
methyl isobutyl ketone	260	80				20	804
toluene	6 010	31	14	26	29		864
1,1,2-tri-chloroethane	135	100					1356
xylenes	3 090	6	19	70	5		864

USEPA 1995

[a] These data were reported by 26 member companies of the US Pharmaceutical Manufacturers' Association, accounting for 53% of pharmaceutical sales in 1975.

[b] Sold as aqueous solutions containing 37% to 50% formaldehyde by weight.

[c] Only solvents listed on the NPI are included.

5.0 Emission Factor Rating

Every emission factor has an associated emission factor rating (EFR) code. This rating system is common to EETs for all industries and sectors and therefore, to all Industry Handbooks. They are based on rating systems developed by the United States Environmental Protection Agency (USEPA), and by the European Environment Agency (EEA). Consequently, the ratings may not be directly relevant to Australian industry. Sources for all emission factors cited can be found in the references section of this document. The emission factor ratings will not form part of the public NPI database.

When using emission factors, you should be aware of the associated EFR code and what that rating implies. An A or B rating indicates a greater degree of certainty than a D or E rating. The less certainty, the more likely that a given emission factor for a specific source or category is not representative of the source type. These ratings notwithstanding, the main criterion affecting the uncertainty of an emission factor remains the degree of similarity between the equipment/process selected in applying the factor, and the target equipment/process from which the factor was derived.

The EFR system is as follows :

A	-	Excellent
B	-	Above Average
C	-	Average
D	-	Below Average
E	-	Poor
U	-	Unrated

Estimating your facility's emissions based on emission factors only, and without taking into account any control measures, may have an uncertainty as high as 100%.

Other EETs, such as release calculations based on mass balance of solvent consumption and without taking into account control measures, may have an uncertainty of 50%.

An EET based on an audit or direct measurement, and taking into account control measures, may have an uncertainty of 20% .

6.0 Emission Factors

An emission factor is a tool that is used to estimate emissions to the environment. In this Manual, it relates the quantity of substances emitted from a source to some common activity associated with those emissions. They are usually expressed as the weight of a substance emitted, divided by the unit weight, volume, distance, or duration of the activity emitting the substance (eg. kilograms of acetone emitted per tonne of product).

Emission factors are used to estimate a facility's emissions by the general equation:

$$E = A \times T \times EF \times [1 - (ER / 100)]$$

where :

E = emissions;
A = activity rate;
T = time (or another variable)
EF = uncontrolled emission factor; and
ER = overall emission reduction efficiency, %.

Emission factors developed from measurements for a specific facility, source, or process may sometimes be used to estimate emissions at other sites. Should a company operate several production units of similar size and using similar processes, and emissions were measured from one facility or unit-process, an emission factor could be developed and applied to similar sources. As previously mentioned, it is advisable to have the emission factor reviewed and approved by your local environmental authority prior to its use for NPI estimations.

Example 1.
Table 6. shows that 140kg of acetone are emitted for each tonne of pharmaceutical products produced from an uncontrolled source. It is assumed that the production plant operates for 1 500 hours per year.

$EF_{acetone}$	=	140kg / tonne
Pharmaceutical production rate	=	0.5 tonnes / hour
Acetone emissions	=	$EF_{acetone}$ x production rate x operating time
	=	140 x 0.5
	=	70 kg / hr x (1 tonne ÷ 1 000kg) x 1 500 hr / yr
	=	105 tonnes per year

Table 6. Emission Factors for Organic Emissions to Air from Pharmaceutical Manufacture [1,a]

Substance Emitted	Emission Factor (kg / tonne [a])	Emission Factor Code Rating
Acetic acid	10	U
Acetone	140	U
Acetonitrile	830	U
Amyl acetate	420	U
Benzene	290	U
Dichlorobenzene	20	U
Ethanol	100	U
Ethyl acetate	300	U
Formaldehyde	190	U
n-Hexane	170	U
Methanol	310	U
Methyl ethyl ketone	650	U
Methyl isobutyl ketone	800	U
Toluene	310	U
Trichloroethane	1000	U
Xylenes	60	U

[1] USEPA AP-42 Section 6.13-4 (1995)

[a] Factor units are kg of substance emitted / tonne of substance used or handled.

Table 7. Emission Factors for Nutrient Emissions to Water from Pharmaceutical Manufacture [1,a]

Process Description	Substance Emitted	Emission Factor (kg / tonne)	Emission Factor Rating Code
Fermentation Process[a]	Total Nitrogen	279	E
	Total Phosphorus	40	E
Biological and Natural Extraction [a]			
- Blood Fractionation	Total Nitrogen	6	E
	Total Phosphorus	4	E
- Vaccine Production	Total Nitrogen	6	E
	Total Phosphorus	4	E
Chemical Synthesis Products[a]	Total Nitrogen	54.5	E
	Total Phosphorus	7.4	E
Mixing, compounding and formulation[a]	Total Nitrogen	0.2	E
	Total Phosphorus	0.14	E

[1] Economopoulos Section 4-25 (1993).

[a] Factor units are kg of nutrient emitted / tonne of product produced.

Emission of total nitrogen and total phosphorus only need to be reported if the emissions occur to water. Nutrients in wastes to sewer do not require reporting.

Table 8. Emission Factors for Organics to Water from Pharmaceutical Manufacture [1,a]

Substance Emitted	Emission Factors (kg / tonne [a])	Emission Factor Code Rating
Acetic acid	820	U
Acetone	220	U
Acetonitrile	170	U
Amyl acetate	580	U
Benzene	370	U
Dichlorobenzene	980	U
Ethanol	60	U
Ethyl acetate	470	U
Ethylene glycol	1000	U
Formaldehyde	770	U
n-Hexane	Neg	U
Methanol	450	U
Methyl ethyl ketone	120	U
Methyl isobutyl ketone	Neg	U
Toluene	140	U
1,1,2-Trichloroethane	Neg	U
Xylenes	190	U

[1] USEPA AP-42 Section 6.13-4 (1995)

[a] Factor units are kg of substance emitted / tonne of substance used or handled.

Table 9. Emission Factors for Listed Substances in Solid Wastes from Pharmaceutical Manufacture [1,2]

Process Description	Substance Emitted	Emission Factor (kg / tonne)	Emission Factor Rating Code
Preparation of synthetic active ingredients[a]	Chromium(total)	0.7	E
	Copper	0.1	E
	Mercury	0.02	E
	Zinc	70	E
Other[b]	Acetone	70	U
	Benzene	80	U
	Ethanol	10	U
	Ethyl acetate	30	U
	n-Hexane	680	U
	Methanol	60	U
	Toluene	290	U
	Xylenes	50	U

[1] USEPA AP-42 Section 6.13-4 (1995)

[a] Factor units are kg of substance emitted in waste / tonne of product produced.

[b] Factor units are kg of substance emitted in waste / tonne of substance used or handled.

[2] Economopoulos Section 5-16 (1993)

7.0 Control Technologies

As solvents are expensive, considerable effort is made to recover and re-use them. Hence, solvent emissions are controlled as part of the normal operating procedures in the pharmaceutical industry. In addition, most manufacturing is carried out inside facility buildings, where solvent losses must be minimised to protect the health of workers, and conform to occupational health and safety standards.

Water or brine-cooled condensers are the most common control devices used in the industry, with carbon adsorption units in occasional use. With each of these methods, solvent can be recovered. Where the main objective is not solvent reuse but rather, the control of an odorous or toxic vapour, scrubbers or incinerators are used. These control systems are usually designed to remove a specific chemical vapour, and will only be used when a batch of the corresponding drug is being produced. Usually, solvents are not recovered from scrubbers and reused and, of course, no solvent recovery is possible from an incinerator.

It is difficult to make a quantitative estimate of the efficiency of each control method because it largely depends on the process being controlled, and pharmaceutical manufacture involves hundreds of different processes. Incinerators, carbon adsorbers, and scrubbers have been reported to remove greater than 90 percent of the organics in the control equipment inlet stream. Condensers are limited in that they can only reduce the concentration in the gas stream to saturation at the condenser temperature, but not below that level. Lowering the temperature will lower the concentration at saturation, but it is not possible to operate at a temperature below the freezing point of one of the components of the gas stream.

Table 10 provides expected control efficiencies for emissions to air on commonly used abatement equipment. In the absence of precise data on the efficiencies of control equipment at your facility, you should assume that any abatement equipment used reduces emissions by 90 percent. Therefore, to obtain an emission total from a controlled source, multiply the uncontrolled emission total (obtained from either using the emission factors above, or another EET such as mass balance) by 0.1.

Table 10. Control Technologies for Air Emissions[1]

Method	Emission Type			Efficiency
	Organic Vapours	Inorganic Vapours	Particulates	(%)
Cyclones			X	98[a]
Fabric Filter			X	80-99
Wet Scrubbers	X[b]	X	X	80
Electrostatic precipitators			X	99.5-99.9
Carbon adsorption	X[c]	X		50-99
Fluidised-bed systems	X[d]			ND
Absorption	X[e]			90-99
Condensation	X	X[f]		50-95[g]
Thermal incineration	X			>99
Catalytic incineration	X			95-99

[1] Eastern Research Group, 1997.
[a] The greatest amount of control would be achieved for particles larger than 5µm.
[b] Depends on material, should be miscible in water.
[c] Carbon adsorption or fired-bed systems.
[d] Not widely used.
[e] Material must be readily soluble in water or other solvents.
[f] Depends on vaporisation point of material and the formation of azeotropic mixtures.
[g] Highly dependent on the emission stream characteristics.
ND = no data

8.0 References

Eastern Research Group. July 1997. *Introduction To Stationary Point Source Emission Inventory Development Volume II: Chapter 1.* Morrisville, NC, USA.

Economopoulos A. P. 1993. *Assessment of Sources of Air, Water, and Land Pollution. A Guide to Rapid Source Inventory Techniques and their use in Formulating Environmental Control Strategies. Part One: Rapid Inventory Techniques in Environmental Pollution.* World Health Organisation, Geneva, Switzerland.

USEPA. January 1995. *Compilation of Air Pollutant Emission Factors, Volume 1: Stationary Point and Area Sources, Fifth edition, AP-42. Section 6.13 Pharmaceutical Production.* United States Environmental Protection Agency, Office of Air Quality Planning and Standards. Research Triangle Park, NC, USA.

USEPA. September 1997. *EPA Office Compliance Sector Notebook Project. Profile of the Pharmaceutical Manufacturing Industry.* United States Environmental Protection Agency, Office of Enforcement and Compliance Assurance. Washington, DC, USA.