RIKEN KEIKI

M210-17014

Applications in Pharmaceutical Market and Introduction to Gas Detectors and Alarms for Safety and Security

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Document contents

- About Riken Keiki
- Why do we need gas detectors?
  Risks associated with toxic gases
- Applications in pharmaceutical market
- Major examples of accidents
- Product information
- International agents

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About Riken Keiki

About Riken Keiki

RIKEN KEIKI

RIKEN

1939

Riken Keiki

Headquarters
To be completed in September 2018 (conceptual drawing)

Riken Keiki was originally established to commercialize and sell detectors for preventing explosions in coal mines and on oil tankers.

About Riken Keiki

Methane gas measurements in coal mine

Optical Gas Indicator Model 3 (1939)

Certification
National heritage of analytical and scientific instruments
2014

Company profile

Company name	Riken Keiki Co., Ltd.	
Established	March 15, 1939	
Location	Headquarters: Development Center:	2-7-6 Azusawa Itabashi-Ku, Tokyo 2-3 Minamisakae-cho, Kasukabe-shi, Saitama
Factories	Hakodate-shi, Hokkaido; Sakurai-shi, Nara (affiliated company)	

Headquarters

To be completed in September 2018
(conceptual drawing)

Development Center

About Riken Keiki

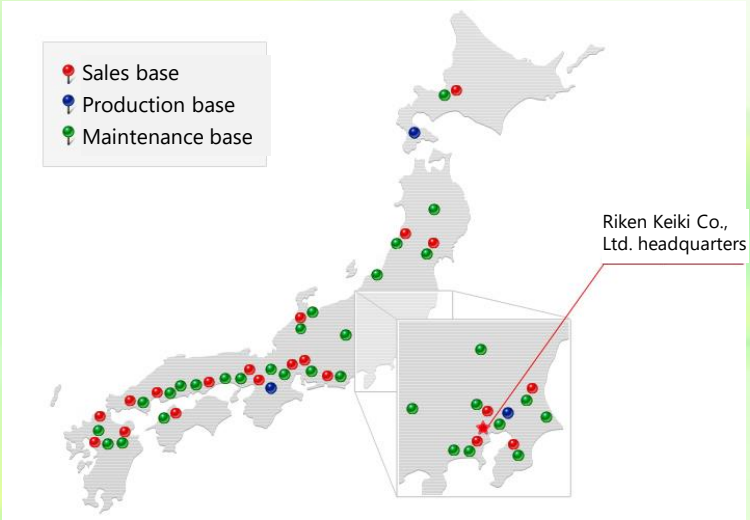
Headquarters
(Itabashi-Ku, Tokyo)

Development Center
(Kasukabe-shi, Saitama)

To be completed in September 2018
(conceptual drawing)

Locations of sales offices

◆Domestic◆



◆Global◆

Company profile

Various bases	Domestic sales and branch offices: 20 locations Service stations: 32 locations Global bases: 7 locations
Major sales items	Combustible gas detectors and alarms Gas detectors and alarms designed to prevent oxygen deficiency accidents Toxic gas detectors and alarms Combined gas detectors and alarms Various measuring instruments for environmental measurements and other instruments
Capital	2,565.5 million yen
Number of employees	965 (non-consolidated), 1,127 (consolidated) * As of September 30, 2017

Hakodate Factory
(Hakodate-shi, Hokkaido)

Nara Factory
(Sakurai-shi, Nara)

Company history

1939	Riken Keiki Co., Ltd. established to produce and sell optical gas detectors, photo-elasticity apparatuses, and other precision instruments invented and developed by RIKEN
1959	Start production and sale of combustible gas alarms and detectors (catalytic combustion type).
1967	Start production and sale of oxygen measuring instruments (OX-1).
1970	Start production and sale of monitoring tape type measuring instruments (FP-200).
1972	Start production and sale of non-dispersive infrared measuring instruments (RI-550).
1975	Start production and sale of electrochemical type measuring instruments (EC-231).
1986	Start production and sale of photoemission yield spectrometers (AC-1).
2009	70th anniversary of founding
2014	Start production and sale of portable X-ray diffractometers equipped with XRF (DF-01).
2015	Start production and sale of portable multi gas detectors (GX-6000), first product of its kind in Japan capable of housing photoionization detectors (PID).

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Why Do We Need Gas Detectors?
Risks Associated with Toxic Gases

Need for gas detectors (combustible gases)

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Criteria set by United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

According to the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS), a combustible gas (or flammable gas) is defined as follows:

A combustible or flammable gas is a gas having an explosive (flammable) range when mixed with air under atmospheric conditions of 20°C and standard pressure of 101.3 kPa.

Gases falling under this definition are further subdivided into the following two categories based on the severity of the associated risk:

Category 1 (Danger: Extremely flammable gas)

Gases capable of igniting at 20°C and standard pressure of 101.3 kPa when occurring in a mixture of 13% or less by volume with air or having an explosive (flammable) range of at least 12% when mixed with air regardless of the lower explosion (flammable) limit

Category 2 (Warning: Flammable gas)

Gases, other than those in Category 1, which are gaseous at 20°C and a standard pressure of 101.3 kPa and have an explosive (flammable) range when mixed with air

We need gas detectors because flammable gas leaks can lead to explosions.

Need for gas detectors (definition of permissible concentration)

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Definition of permissible concentration

Even when workers are exposed to hazardous substances at work sites, no adverse health effects should emerge as long as the airborne concentration of the **hazardous** substance remains below the permissible concentration.

Recommended permissible concentrations have been set by the American Conference of Governmental Industrial Hygienists (ACGIH) and the Japan Society for Occupational Health. We use the **ACGIH** permissible concentrations.

Types of permissible concentrations

- **TWA (Time Weighted Average)**
  Time Weighted Average refers to time-weighted average concentrations over an 8-hour workday and 40-hour workweek of routine work to which workers may be repeatedly exposed without adverse health effects.

- **STEL (Short Term Exposure Limit)**
  Short Term Exposure Limit refers to exposure that does not lead to adverse health effects if each exposure does not exceed 15 minutes, the number of daily exposures does not exceed four, and the exposures are separated by at least one hour.

- **C (Ceiling value)**
  Ceiling Value refers to the upper limit that can never be exceeded.

We need gas detectors because leaks exceeding permissible concentrations can lead to accidents.

How human body reacts to oxygen-deficiency

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O2 Concentration 21%

Symptoms

Natural air

O2 Concentration 18%

Symptoms

Limit level for not causing serious health problems. Continuous ventilation is required

O2 Concentration 16%-12%

Symptoms

Rapid breathing, Increase in pulse rate, Loss of concentration, Headache, Nausea, Ear ringing

O2 Concentration 14%-9%

Symptoms

Stupor, Headache, Nausea, Cyanosis, Faintness on the entire body

O2 Concentration 10%-6%

Symptoms

Comatose, Loss of consciousness, Muscle spasm on the entire body

O2 Concentration 6% or less

Symptoms

Unconsciousness, Comatose, Cessation of breathing, Cardiac arrest, Die in 6 minutes

Effects of hydrogen sulfide (H_2S) on human body

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Concentration (ppm)	Effects and Toxicity
0.025	Smell vaguely. (It varies according to the individual.)
0.3	Smell clearly.
3 - 5	Smell moderate degree of objectionable odor.
10	Lower-level to irritate eyes' mucus membranes.
20 - 40	A strong odor. Lower-level to irritate lungs' mucous membranes.
100	Sense of smell is impaired in 2 - 15 minutes. Eyes and respiratory tract are irritated in 1 hour. 8 - 48 hours continuous exposure can lead to death.
170 - 300	1 hour exposure is the limit for not causing serious health problems.
400 - 700	Life-threatening exposure in 0.5 - 1 hour.
800 - 900	Bring on loss of consciousness, cessation of breathing and death.
1000	Bring on immediate loss of consciousness and death.

Effects of carbon monoxide (CO) on human body

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Concentration (ppm)	Effects and Toxicity
100	No noticeable effects even after breathing for a few hours.
200	A mild headache in around 1.5 hours.
400 - 500	Headache, nausea and ear ringing in around 1 hour.
600 - 1000	Loss of consciousness in around 1 - 1.5 hours.
1500 - 2000	Headache, vertigo and disabling nausea in around 0.5 - 1 hour, and losing consciousness.
3000 - 6000	Headache, vertigo, disabling nausea...etc. in a few minutes. 10 - 30 minutes exposure can lead to death.
10000	Bring on immediate loss of consciousness and death.

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Applications in Pharmaceutical Market

Applications in pharmaceutical market

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1. **Overall flow of processes in pharmaceutical manufacturing plant**
   - 1-1: Preparing raw materials
   - 1-2: Producing solid drug
2. **Details of each process**
   - 2-1: Weighing
   - 2-2: Reaction of chemical substances and preparing raw materials
   - 2-3: Purifying raw materials
   - 2-4: Inspecting raw materials
   - 2-5: Storage
   - 2-6: Raw material granulation, mixing, and tableting
   - 2-7: Product packaging
   - 2-8: Other

1. Overall flow of processes in pharmaceutical manufacturing plant

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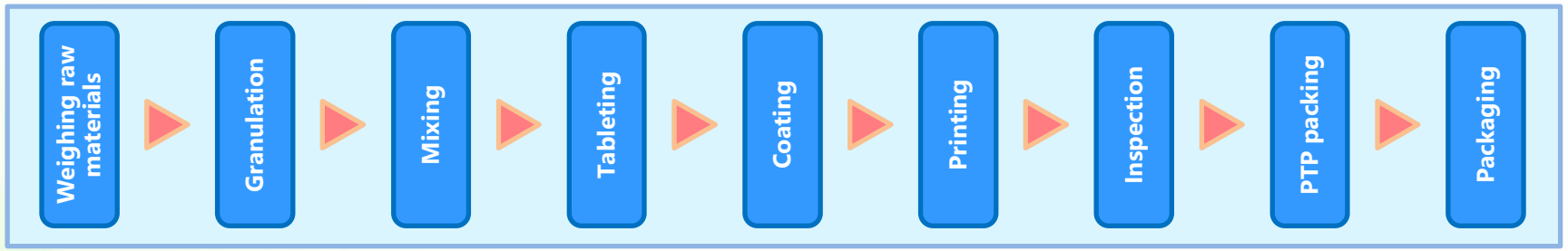
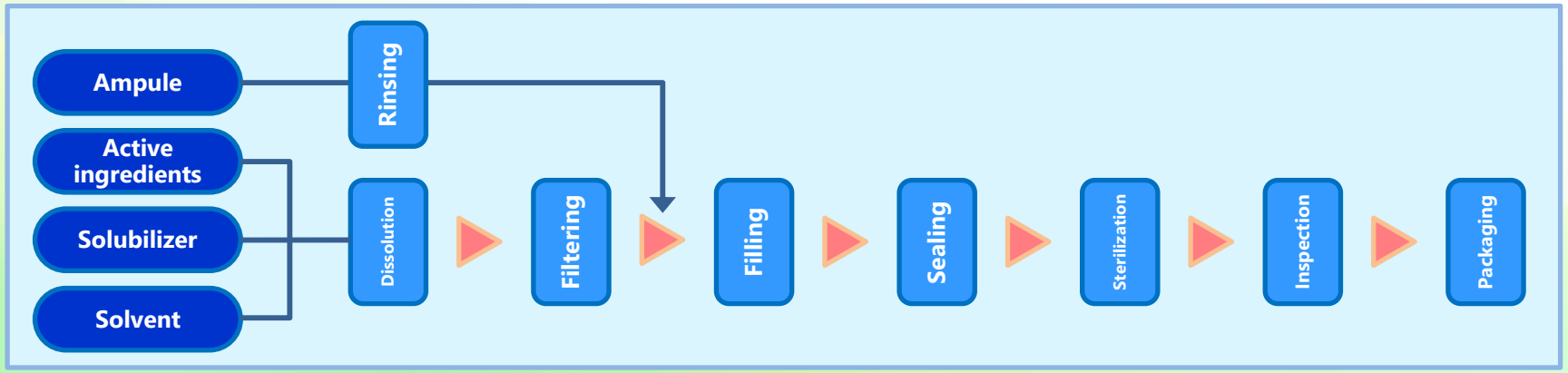
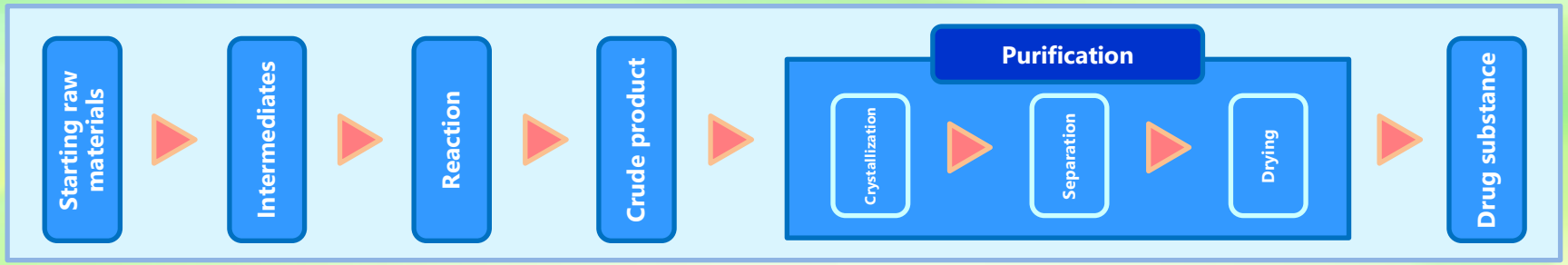
Solid drug



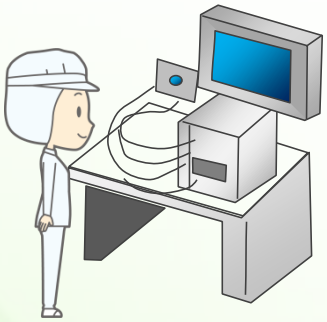
Injections



Drug substance

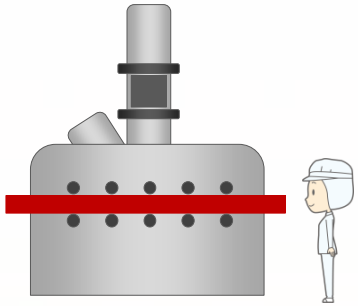


1-1: Preparing raw materials



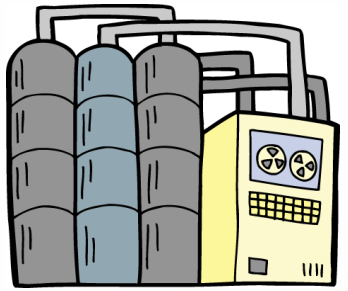
Weighing chemical substances

⇒ Go to 2-1.



Reaction of chemical substances
⇒ Preparing raw materials

⇒ Go to 2-2.



Purification (crystallization, separation, drying)

⇒ Go to 2-3.

Inspecting raw materials

⇒ Go to 2-4.

Storing raw materials

⇒ Go to 2-5.

To production of solid drug

1-2: Producing solid drug

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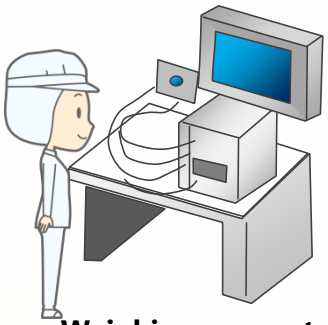
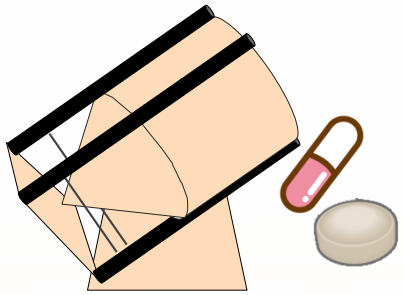
From preparation of raw materials



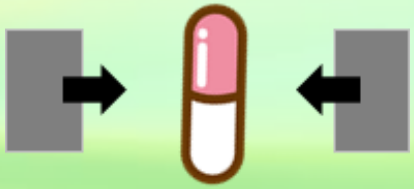
Weighing raw materials

⇒ Go to 2-1.



Raw material granulation, mixing, and tableting

⇒ Go to 2-6.



Product inspection

Product packaging

⇒ Go to 2-7.

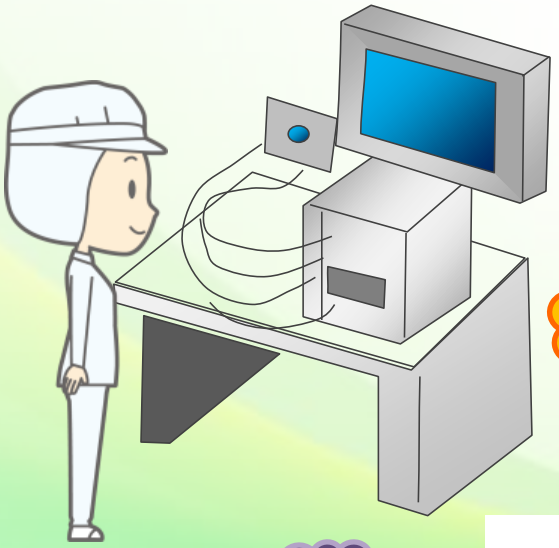
Product storage

⇒ Go to 2-5.

2-1: Weighing

Description: Volatile organic compounds (VOCs) are sometimes used when preparing raw materials or in the weighing process in producing the solid drug. Weighing is also performed with nitrogen substitution.

Hazardous risks: **VOCs may lead to poisoning, while nitrogen leaks may cause oxygen deficiencies.** ⇒ **Detecting VOCs to prevent poisoning**
Detecting oxygen concentration to prevent oxygen deficiencies



Fixed PID VOC Monitor
Model: RVOC

Indoor Oxygen Monitor
Model: OX-600

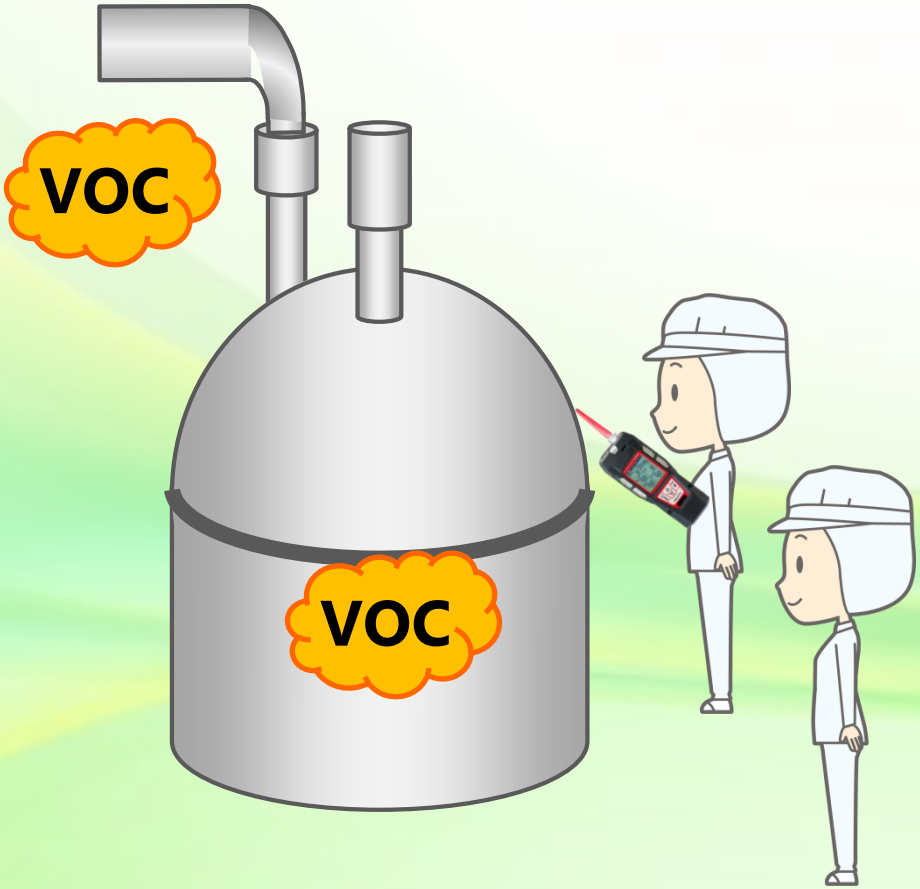
Personal Single Gas Monitor
Model: OX-03

Personal Four Gas Monitor
Model: GX-6000

2-2: Reaction of chemical substances and preparing raw materials

Description: In reaction processes in which raw materials are placed in a reaction tank and mixed, the raw materials are heated and cooled to initiate the chemical reactions that create the required compounds.

Hazardous risks: The volatile organic compounds (VOCs) generated in the reactions may lead to poisoning. ⇒ **Detecting VOCs to prevent poisoning**



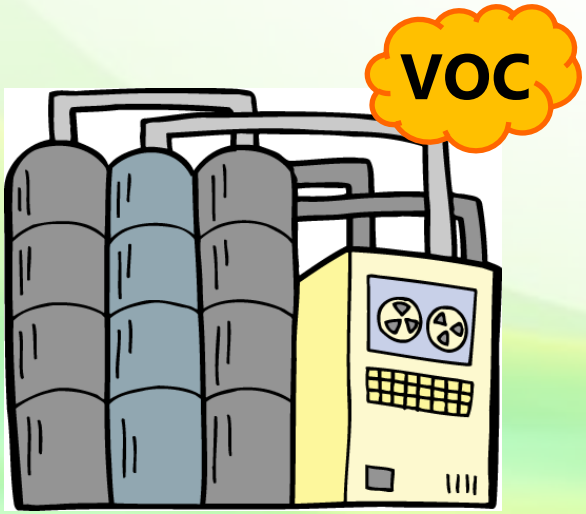
Fixed PID VOC Monitor
Model: RVOC

Personal Four Gas Monitor
Model: GX-6000

2-3: Purifying raw materials

Description: The purification processes involve crystallization, separation, and drying. In the crystallization process, the compound is cooled and crystallized. In the separation process, the crystallized solution containing crystals is separated in a centrifugal separator to remove excess liquid and extract crystals. The separated crystals are dried in a vacuum dryer.

Hazardous risks: **Volatile organic compounds (VOCs) occurring in the crystallized solution may lead to poisoning.** ⇒ **Detecting VOCs to prevent poisoning**



Fixed PID VOC Monitor
Model: RVOC

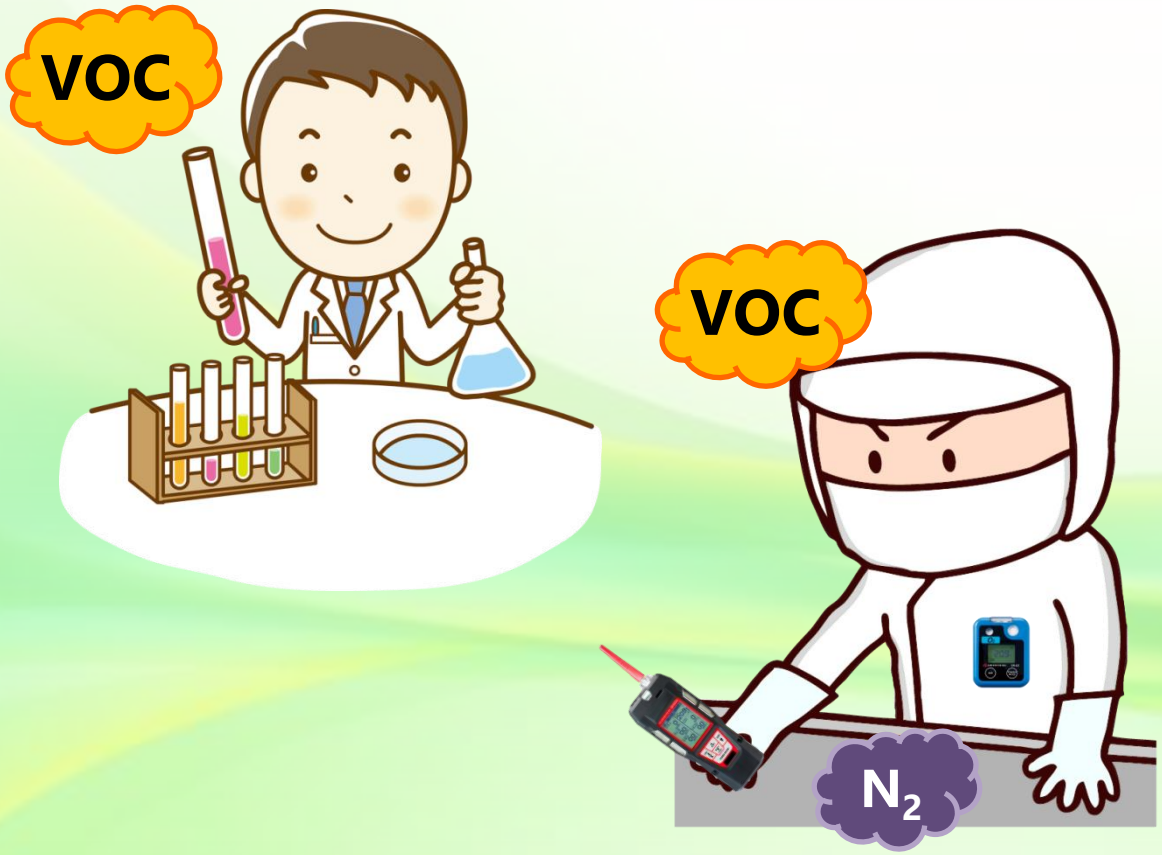
Personal Four Gas Monitor
Model: GX-6000

2-4: Inspecting raw materials

Description: The drug substance obtained is subjected to various analyses and tests to rigorously assess quality and safety.

Hazardous risks: **The volatile organic compounds (VOCs) used in the analyses and tests can lead to poisoning.**
Leaks of gases used in the analyzer or processes under nitrogen substitution such as those in a glove box may cause oxygen deficiencies.

⇒ **Detecting VOCs to prevent poisoning**
Measuring oxygen concentrations to prevent oxygen deficiencies



Fixed PID VOC Monitor
Model: RVOC

Personal Single Gas Monitor
Model: OX-03

Personal Four Gas Monitor
Model: GX-6000

2-5: Storage

Description: The raw materials, completed ingredients, and final products are stored in suitable environments at temperatures from -80°C to room temperature.

Hazardous risks: **Scattering of raw materials and ingredients (such as volatile organic compounds) due to inappropriate storage may lead to poisoning.**
Insufficient ventilation in the storage warehouse may cause oxygen deficiencies.

⇒ **Detecting VOCs to prevent poisoning**
Measuring oxygen concentrations to prevent oxygen deficiencies

Fixed PID VOC Monitor
Model: RVOC

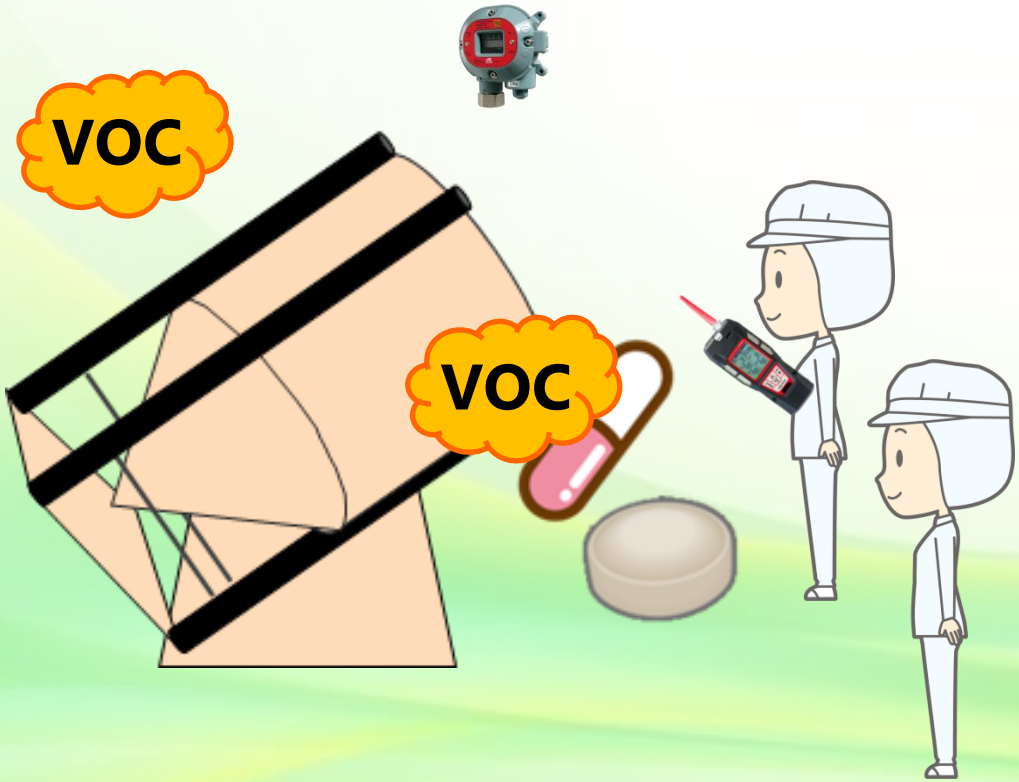
Personal Four Gas Monitor
Model: GX-6000

2-6: Raw material granulation, mixing, and tableting

Description: The solid drug is produced through raw material granulation, mixing, and tableting.

Hazardous risks: **The volatile organic compounds (VOCs) generated during the processes may cause explosions or poisoning.**

⇒ **Detecting VOCs to prevent poisoning and explosions**



Fixed PID VOC Monitor
Model: RVOC

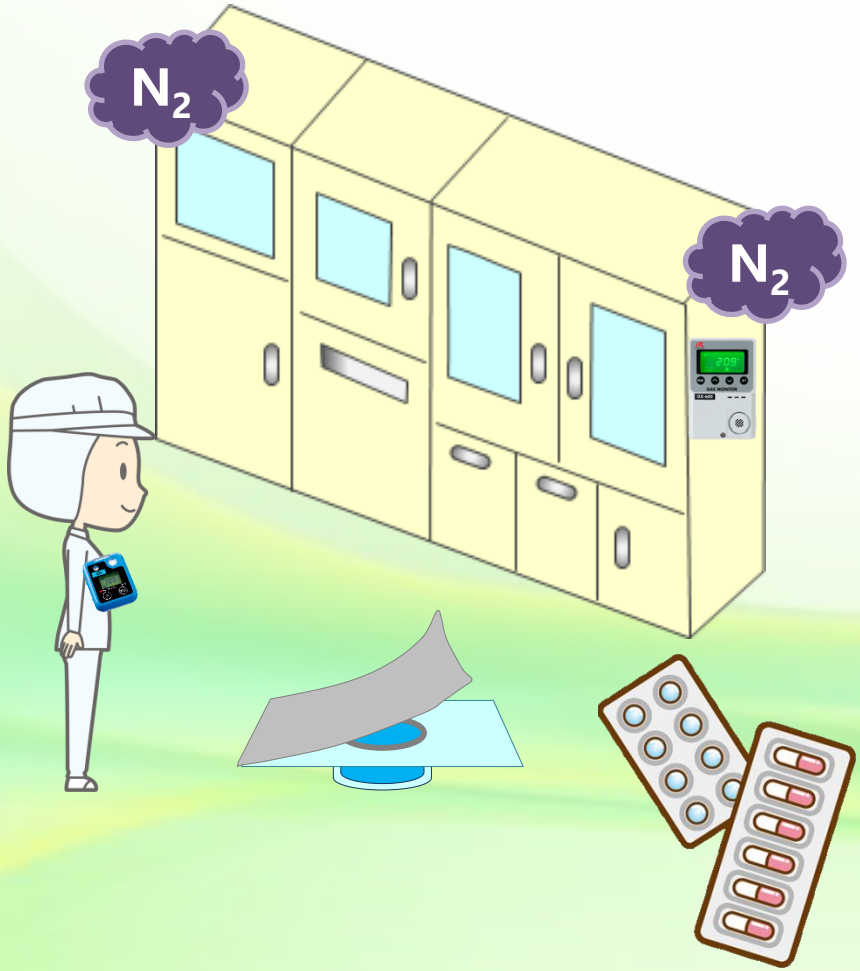
Smart Transmitter/ Gas Detector
Model: SD-1

Personal Four Gas Monitor
Model: GX-6000

2-7: Product packaging

Description: Some products that have passed inspection and are being packaged are nitrogen packed.

Hazardous risks: **N_2 leaks during nitrogen packing may result in oxygen deficiencies.** ⇒ **Measuring oxygen concentrations to prevent oxygen deficiencies**



Indoor Oxygen Monitor
Model: OX-600

Personal Single Gas Monitor
Model: OX-03

2-8: Other

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⊖ Leaks of LPG and town gas used as the heat source of evaporators and dryers may cause explosions.

⊜ Work involving N_2 substitution equipment or glove box or work in areas with insufficient ventilation may result in oxygen deficiencies.

⊛ Leaks of hydrogen, helium, liquid N_2, or other gases from gas chromatography equipment or other analyzers may result in oxygen deficiencies in work areas.

④ Volatile organic compounds (VOCs) generated in processes using organic solvents (containing VOCs) may cause explosions or poisoning.

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Major Examples of Accidents

Prepared by extracting and processing materials from the Safety at Work Site (Ministry of Health, Labour and Welfare: http://anzeninfo.mhlw.go.jp/index.html)

Workers were poisoned while rinsing crystals with acetonitrile in a centrifugal separator.

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[Location of accident]

While rinsing crystals in a centrifugal separator in drug production

[Cause of accident]

The crystals produced in the reaction tank were transferred to a centrifugal separator, filtered, and rinsed with acetonitrile. When the rinsing proved insufficient, the decision was made to rub and rinse the crystals by hand in the centrifugal separator. The local ventilation duct of the centrifugal separator was removed because it interfered with the work, resulting in inhalation exposure to acetonitrile vapor among workers.

[Damage/injuries]

On the next day, four workers engaged in the rubbing and rinsing of crystals complained of ill health and weakness. They went to the hospital and were diagnosed with acetonitrile poisoning.

Wearing gas detectors on a routine basis enables early detection of used gas leaks and improves work safety.

Organic solvent poisoning during the process of drying pharmaceutical intermediates

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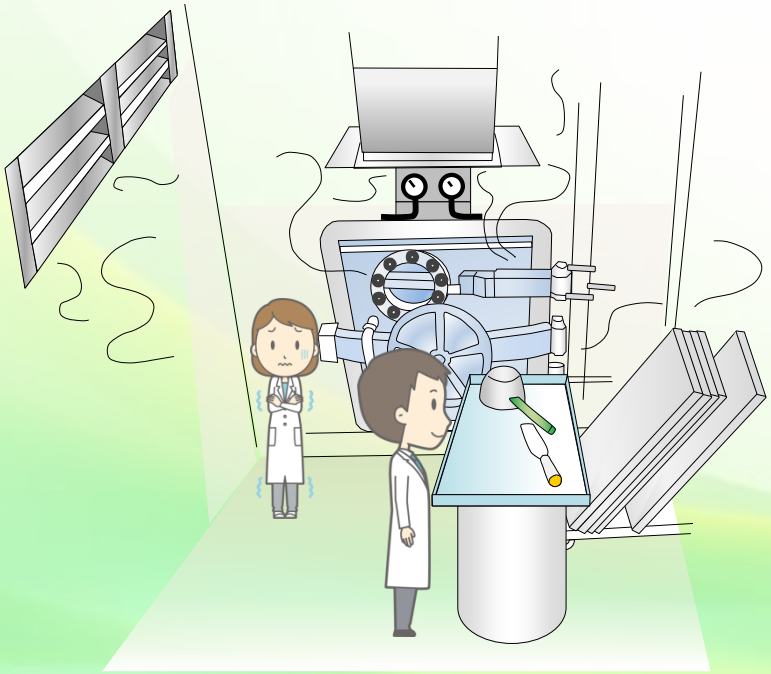

[Location of accident]

At a pharmaceutical manufacturing plant during the process of drying pharmaceutical intermediates containing large amounts of acetone (solvent)

[Cause of accident]

In producing drugs and other products, workers were exposed to high concentration acetone while carrying intermediates to the drying room after filtering, transferring the intermediates to trays, and placing trays on the shelves of the low-temperature dryer.

[Damage/injuries]

After completing work in the drying room, two workers complained of physical discomfort. They were examined at the hospital, diagnosed with organic solvent poisoning, and hospitalized for treatment.

Wearing gas detectors on a routine basis enables early detection of used gas leaks and improves work safety.

During the production of pharmaceutical intermediates, an abnormal reaction rapidly increased internal pressure inside a reaction vessel, resulting in rupture of the vessel.

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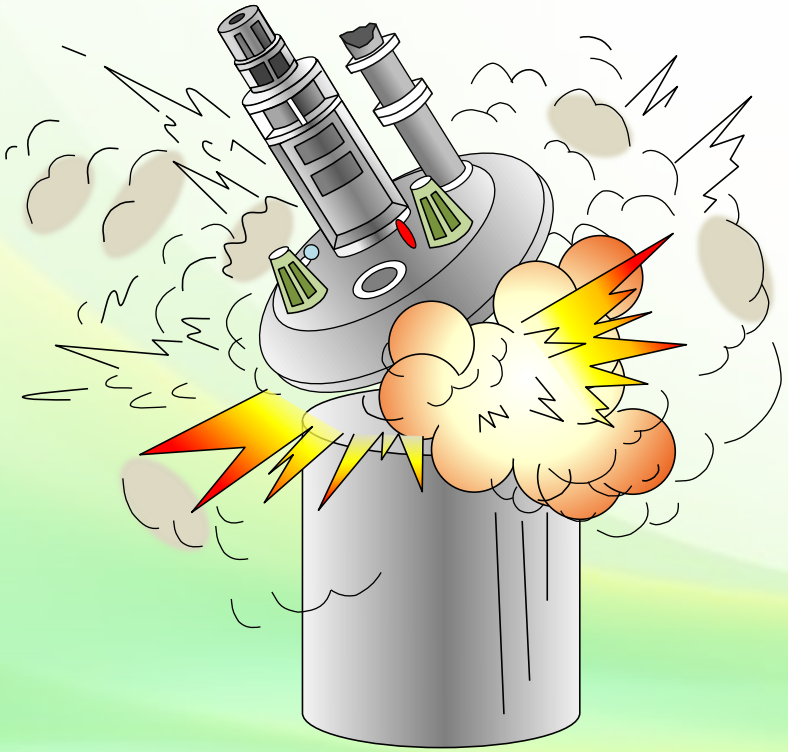

[Location of accident]

During degassing at a plant producing pharmaceutical intermediates and other substances

[Cause of accident]

Steam was used for degassing during production (to remove phosgene gas and other by-product gases in a 6 kl can used as the reaction vessel). Abnormal chemical reactions were induced by a temperature increase, etc. in the 6 kl can. The cover of the 6 kl can came loose from the clamp, and the can ruptured.

[Damage/injuries]

Five workers were exposed to reaction products scattered from the 6 kl can. One died.

Wearing gas detectors on a routine basis enables early detection of used gas leaks and improves work safety.

During the production of pharmaceutical intermediates, sodium hydride ignited and toluene vapor caught fire, resulting in burn injuries.

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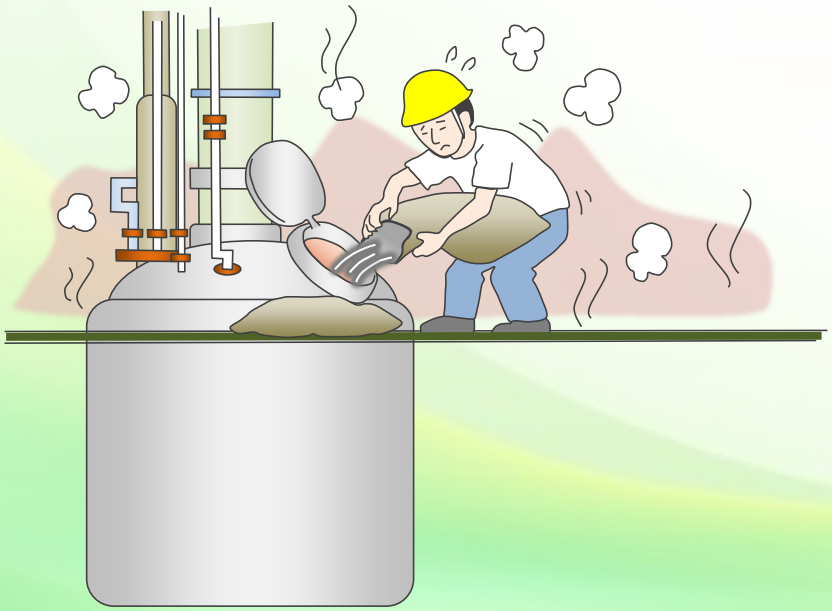

[Location of accident]

During the production of pharmaceutical intermediates at a drug manufacturing plant from toluene, a Class 2 organic solvent

[Cause of accident]

While feeding sodium hydride (NaH), a water-prohibited dangerous substance, into a sodium reaction tank containing anhydrous toluene, a worker removed his jacket and began working in a t-shirt. NaH reacted with the sweat falling from his face and arms and ignited. Toluene vapor within the reaction tank caught fire near the feed port.

[Damage/injuries]

The victim sustained burn injuries from exposure to this fire. After the burns were cooled with water, the victim was transferred to the hospital and diagnosed with second degree burns.

Wearing gas detectors on a routine basis enables early detection of toxic gas leaks and improves work safety.

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Product Information

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Portable Multi Gas Detector

Model: GX-6000

Features

- A single unit can simultaneously display up to six types of gases, including VOCs. This is the first product of its kind from a Japanese manufacturer.
- The PID sensor enables measurements of more than 200 types of chemical substances subject to regulation.
- Ideal for checking the risks and hazards of chemical substances as required under the Industrial Safety and Health Act
- Support for multilingual display (Japanese, English, French, Spanish, etc.)
- Equipped with convenient new functions, including panic alarm and LED flashlight

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Features

- Equipped with photoionization detector (PID) optimum for VOC detection
  Support for three measurement ranges (0-10/100/1,000 ppm)
  Sensor structure resists effects of humidity and keeps foreign materials away from lamp.
  Measurement cycles configurable up to 5 minutes and 50 seconds at intervals of 10 seconds (Default: 1 minute)
- Various functions with high working efficiency
  Easily installed in control system (4-20 mA output)
  Switchable type (RVOC-10s) models are available.

Fixed PID VOC Monitor

Model: RVOC

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SD-1
SD-1RI
(For combustible gases)

SD-1GH
(For combustible/ toxic gases)

SD-1EC
(For carbon monoxide/ hydrogen sulfide)

SD-1OX
(For oxygen)

Smart Transmitter/
Gas Detectors

Model: SD-1 series

Features

- Suitable for use as an explosion-proof product, even in a hydrogen/acetylene atmosphere
- Waterproof/dustproof enclosure (IP 65 equivalent) allows deployment in severe environments.
- Supports HART Communication Protocol, allowing transmission of more information over legacy analog 4-20 mA connection.

  * Excluding SD-1 (TYPE NC)
- SD-1RI, SD-1EC, and SD-1OX are SIL 2 certified in all parts of the functional safety standard, marking a first for Japanese manufacturers.
- Using the suction cap for the SD-1 series and connecting the detector to a suction pump or an aspirator unit enables suction type operation.

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Indoor Oxygen Monitor

Model: OX-600

Features

- Large, easy-to-read three-color LCD screen display

First alarm (orange)

Second alarm (red)

- Equipped with pressure correction function to prevent fluctuating readings due to atmospheric pressure
- The product line offers three types of power supply specifications (AC power supply, DC power supply, and dry battery) to suit the power supply available at the installation location.
- Continuous operation for approximately one year on two AA alkaline batteries
  * No alarm; backlight switched off
- Remote measurement at distances of up to 20 m with the remote sensor (sold separately)

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GP-03 (For combustible gases)

OX-03 (For oxygen)

HS-03 (For hydrogen sulfide)

CO-03 (For carbon monoxide)

Features

- Models for use with rechargeable batteries have been added to the product line.
- Standard protective covers protect the main unit from scratches, dirt, and shock.
- Compact, lightweight design doesn't interfere with work.
- Inherently safe and explosion-proof enclosure is ideal for use in hazardous locations.

Personal Single Gas Monitors

Model: 03 series

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International Agents

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International Agents

North America

South America

Asia and Pacific

Russia and Central Asia

Europe

Middle East

Africa

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International agents (table of contents)

North America	U.S.A.				
South America	Brazil	Argentina	Peru	Chile	Uruguay
Asia and Pacific	China	South Korea	Taiwan	Singapore	Malaysia
	Indonesia	Thailand	India	Vietnam	Philippines
	Australia				
Europe	Germany	Greece	THE NETHERLANDS	Norway	Turkey
	U.K.				
Middle East	U.A.E.	Israel			
Africa	South Africa				
Russia and Central Asia	Russia				

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International agents（U.S.A.）

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FAX :	+1-510-441-5650
E-MAIL :	bob@rkiinstruments.com, sandra@rkiinstruments.com
PERSON :	MR. BOB PELLISSIER (PRESIDENT) MRS. SANDRA GALLAGHER (VICE PRESIDENT)
WEBSITE :	http://www.rkiinstruments.com/

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International agents（BRAZIL）

HIDEO NAKAYAMA IMP. EXP. COM. E INDUSTRIA LTDA

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TEL :	+55-21-2590-3496
FAX :	+55-21-2270-6390
E-MAIL :	hideko@nakayama.com.br
PERSON :	MR. HIDEO NAKAYAMA (PRESIDENT) MS. HIDEKO NAKAYAMA
WEBSITE :	http://www.nakayama.com.br/

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(KOREAN) http://rikenkeiki.co.kr/bn/
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HIGH INTEGRATED TECHNOLOGY, INC.

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GYEONGGI-DO, 17843, KOREA
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RIKEN KEIKI TAIWAN CO., LTD. HEAD OFFICE

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WEBSITE :	http://www.rikenkeiki.com.tw/admin/news/front/news.php

RIKEN KEIKI TAIWAN CO., LTD. TAICHUNG BRANCH

ADDRESS :	NO.2, ALY.14, LN.150-30, SEC.3, XITUN RD., XITUN DIST., TAICHUNG CITY 407, TAIWAN
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