

PME and PVC

Pharmaceutical Multi-Effect still and
Pharmaceutical Vapour Compression still



PME and PVC systems

from Spirax UltraPURE

Your perfect partner for clean utilities

The design of high purity steam and water systems can be a complex and highly involved discipline. To ensure your system is designed to current good manufacturing practice (cGMP), you need a partner who understands your application and can support you through the life of your clean utility project.

With over 100 years experience of system design, a global network of dedicated technical specialists, and the broadest range of equipment in the industry, Spirax UltraPURE is able to fully support you during your system design and satisfy your equipment needs.

Spirax UltraPURE is your perfect partner.



Documentation and validation

As part of a comprehensive, ASME audited, quality programme, each Spirax UltraPURE system is supplied with a detailed operation and maintenance manual, documenting all aspects of the materials, manufacturing procedures and testing

Factory Acceptance Testing (FAT)

Each system is subjected to a full wet / hot factory acceptance test, without exception. This includes checks of all alarms and interlocks as well as functional checks of the equipment to demonstrate performance.

IQ and OQ

As the pharmaceutical industry has evolved, so has our approach to validation. Where required, Spirax UltraPURE is qualified to offer complete Installation Qualification (IQ) and Operational Qualification (OQ) providing documented evidence that the supplied system is built and commissioned in accordance with your specification as well as FDA and cGMP standards.

Validation packages are prepared parallel to the manufacture of the system and are available for review during the factor acceptance test. Spirax UltraPURE technicians can also perform these procedures at the time of start-up and commissioning.

Overview

Type	PME (Pharmaceutical Multi-Effect still)	PVC (Pharmaceutical Vapor Compression still)
Feedwater requirements	To produce Water For Injection (WFI), the PME requires high quality feedwater that has been treated with a pre-filter, softener and a mixed bed DI / RO system or USP grade purified water.	The PVC needs only softened feedwater to produce Water For Injection (WFI). Resulting in lower pre-treatment investment and running costs.
Financial considerations	The PVC does have a higher initial investment cost than the PME, however the PVC can provide significant energy savings and a short payback period for WFI requirements over 20 gpm and / or where WFI requirement is high in relation to that of purified water.	
Maintenance issues	The PME has no mechanical working parts and therefore maintenance is minimal.	The PVC is a rotary piece of equipment and therefore requires more maintenance than a Multi-Effect still. However, as softened water can be used as the feed source maintenance of pre-filters and mixed bed DI, RO can be eliminated, offering a large reduction in total plant maintenance costs.
Capacity scope	13 – 2 600 gph	30 – 6 600 gph



Pharmaceutical Multi-Effect still (PME)

from Spirax UltraPURE

About the multi-effect distillation system (PME)

The Spirax UltraPURE Pharmaceutical Multi-Effect still (PME) is a simple and energy efficient method of producing pyrogen free water for injection, compliant to the latest recognized International Pharmacopeia Standards.

The PME system has no moving parts and therefore requires less maintenance as well as being quieter in operation than traditional vapor compression units.

Each unit is designed and manufactured in accordance with latest cGMP, following the criteria set out in the ISPE Baseline Guide for Water and Steam Systems and the latest edition of ASME BPE.

Operating principle of multi-effect distillation system

The Spirax Ultrapure PME works by the 'rising film external evaporator' or 'thermosyphone' principle.

1. Feedwater is pumped through the condenser and blowdown cooler to pre-heat. It then travels into the first-effect separation column and circulates into the evaporation column.
2. Plant steam is used to boil the feedwater in the evaporation column to produce pure steam.
3. The pure steam then travels into the upper region of the separation column via a number of directional changes and finally through a demister device, to remove entrained moisture.
4. The pure steam is passed through the second-effect evaporation column where its latent heat is transferred to the feedwater, while condensing into WFI.
5. The process is repeated again in the next effect and so on.
6. Pure steam produced in the last effect is condensed in the feedwater preheater.



Key features and benefits



Key features

Key reasons

Key benefits

External evaporator column

External evaporator enables disassembly of unit with no additional height required.

Allows quick and simple disassembly for inspection and maintenance.

Compact / short evaporator column

Short tubes ensure that stress fatigue is minimal, a common issue with longer tubes used in the falling film evaporator designs.

Less susceptible to stress fatigue resulting in long trouble free life.

Highly efficient

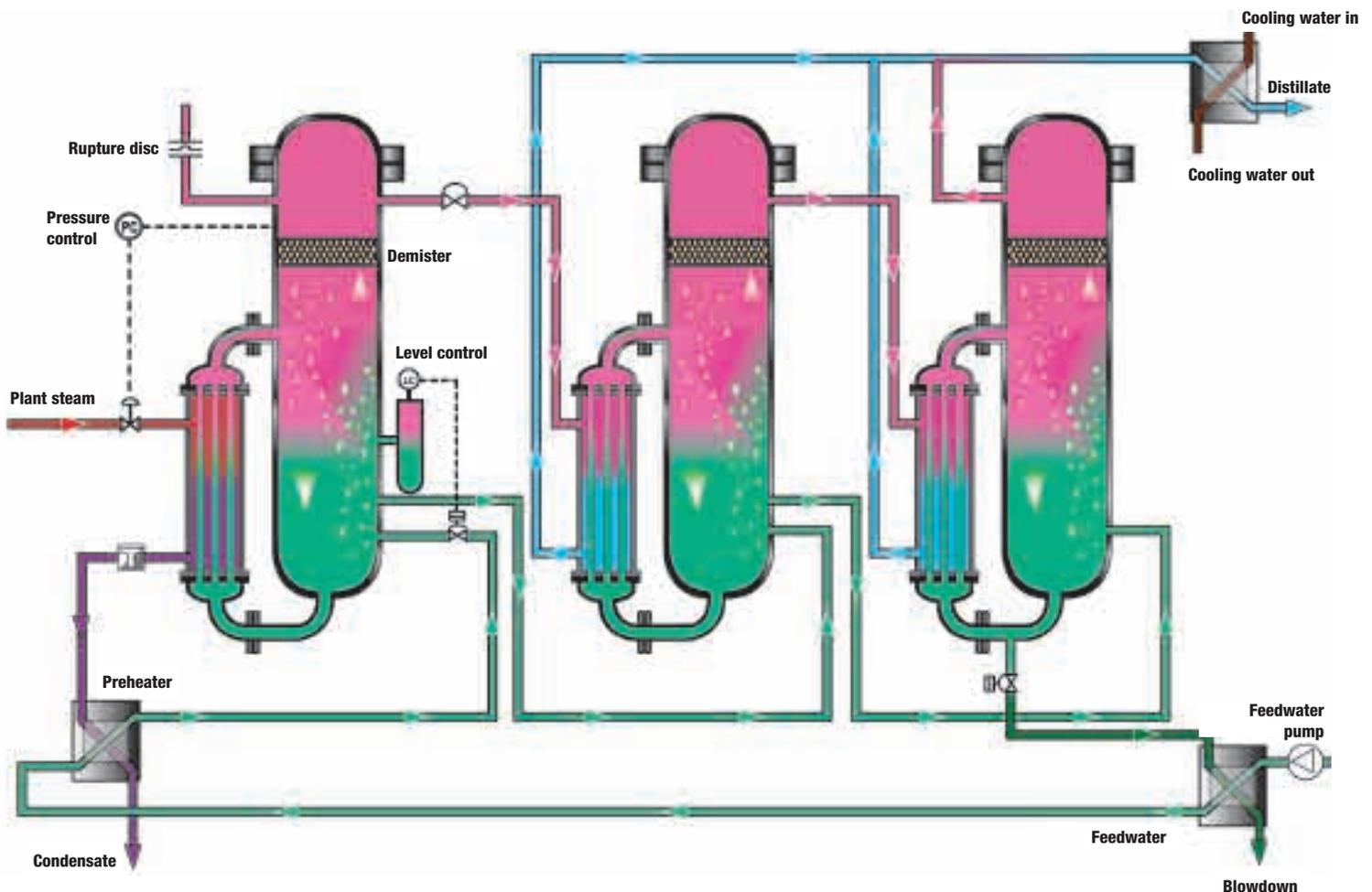
The design utilises the sensible heat in blowdown and the latent heat in the pure steam to heat the feedwater.

In the world of increasing energy costs the PME helps to save energy and money.

Part of a dedicated high purity product range from Spirax Sarco

The PME is only part of a comprehensive range of products developed specifically for high purity applications.

Providing customers a single source option for all your high purity needs.



Pharmaceutical Vapor Compression distillation system (PVC)

from Spirax UltraPURE

About the vapor compression distillation system (PVC)

The Spirax UltraPURE Pharmaceutical Vapor Compression system (PVC) is the only system of its type that has been designed specifically for the pharmaceutical market. It brings together a revolutionary new energy efficient design that combines sanitary construction and quiet operation with ease of maintenance.

More suitable for larger applications, those over 20 gpm, the PVC system can be up to 3 times more efficient than other systems. The PVC offers the additional benefit of being able to utilise lower purity feedwater to produce WFI, reducing overall plant investment and maintenance issues.

Each unit is designed and manufactured in accordance with the latest cGMP. This follows the criteria set out in the ISPE Baseline Guide for Water and Steam Systems and the latest edition of ASME BPE, to produce pyrogen free water for injection, compliant to the latest recognised International Pharmacopeia Standards.

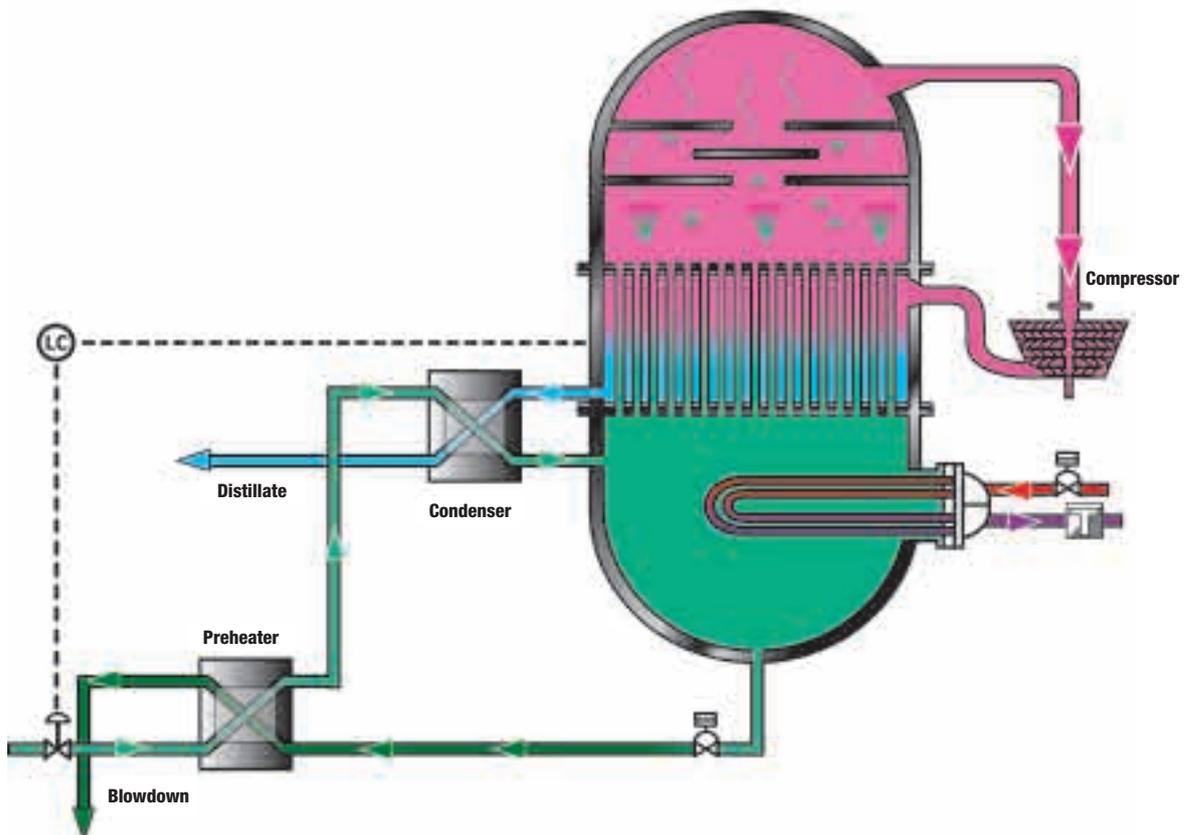
Operating principles of vapour compression distillation unit

1. Pre-heated feedwater enters the bottom of the evaporator.
2. Plant steam raises the temperature of the feedwater to create low-pressure pure steam.
3. Pure steam passes through a number of baffle plates to remove any entrained moisture.
4. Pure steam travels to the compressor, which raises the pressure of the pure steam.
5. This higher-pressure pure steam is used to replace the plant steam in boiling the feedwater to create low-pressure pure steam, and in doing so condenses to create water for injection.



Key features and benefits

Key features	Key reasons	Key benefits
3-phase moisture separation	<ol style="list-style-type: none"> 1. Large disengagement volume allows significant change in steam velocity, allowing moisture to fall out of steam. 2. Complex labyrinth impingement plate removes entrained moisture from steam. 3. Compressor creates a cyclone effect that forces any finer moisture out of the steam. 	Guaranteeing 99.8% steam dryness and a Log 4 reduction in pyrogen levels, exceeding current levels set by international pharmacopeia.
Vertical design	Vertical design ensures that the system is fully drainable.	Ensures sanitary design.
Unique multi-stage vertical compressor	Multi-stage design allows greater pressures to be developed within a single compressor.	Ability to increase pure steam pressure in a smaller package resulting in much greater efficiency size-for-size compared to traditional single-stage horizontal designs.
Compressor / condenser direct coupling	Allows compressor to be positioned at low level.	Simplifies maintenance.
Lower compressor speeds	Combination of vertical design and multi-stage compressor results in much lower compressor speeds, typically 50% less than traditional designs.	<ul style="list-style-type: none"> • Quieter operation (<85 db compared with >100 db for traditional design). • Eliminates the need for exotic materials for impeller tips. • Lower speeds allow the use of grease based bearing lubricant, overcoming the problem of oil contamination common with traditional designs.
Part of a dedicated high purity product range from Spirax Sarco	The PVC is only part of a comprehensive range of products developed specifically for high purity applications.	Providing a single source option for all your high purity needs.



Group companies

Africa

South Africa

Americas

Argentina
Brazil
Canada
Mexico
USA

Asia

China
India
Japan
Korea
Malaysia
Singapore
Taiwan
Thailand

Australasia

Australia
New Zealand

Europe

Austria
Belgium
Czech republic
Denmark
Finland
France
Germany
Italy
Norway
Poland
Portugal
Russia
Slovak republic
Spain
Sweden
Switzerland
UK

Sales offices

Africa

Egypt
Kenya
Nigeria

Americas

Colombia
Venezuela

Asia

Hong Kong
Indonesia
Pakistan
Philippines
Vietnam

Europe

Austria
Hungary
Ireland

Middle East

UAE

Distributors

Africa

Algeria
Cameroon
Ethiopia
Ghana
Ivory Coast
Libya
Malawi
Mauritius
Morocco
Namibia
Senegal
Sudan
Tanzania
Tunisia
Uganda
Zambia
Zimbabwe

Americas

Bolivia
Chile
Colombia
Costa Rica
Dominican Rep
Ecuador
El Salvador
Guatemala
Honduras
Jamaica
Nicaragua
Panama
Paraguay
Peru
Trinidad and Tobago
Uruguay
Venezuela

Asia

Bangladesh

Australasia

Fiji

Europe

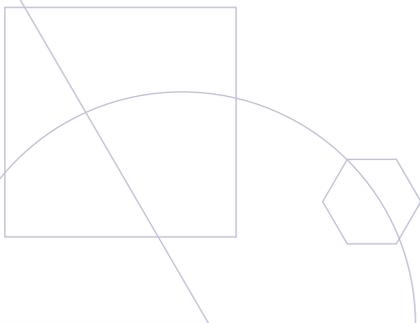
Bulgaria
Croatia
Cyprus
Estonia
Greece
Iceland
Latvia
Lithuania
Malta
Netherlands
Romania
Slovenia
Turkey

Middle East

Bahrain
Iran
Jordan
Kuwait
Lebanon
Oman
Qatar
Saudi Arabia
Syria



Some products, services or solutions may not be available in certain markets



Spirax-Sarco Limited
Cheltenham UK
GL53 8ER

t: +44 (0)1242 521361

f: +44 (0)1242 573342

e: cleansteam@SpiraxSarco.com

www.SpiraxSarco.com/cleansteam

Spirax UltraPure
1050 Corporate Avenue
Unit 114

North Port, FL 34289

Phone: (941) 473-2422

Fax: (941) 473-2144

www.spiraxultrapure.com

spirax
ultraPURE