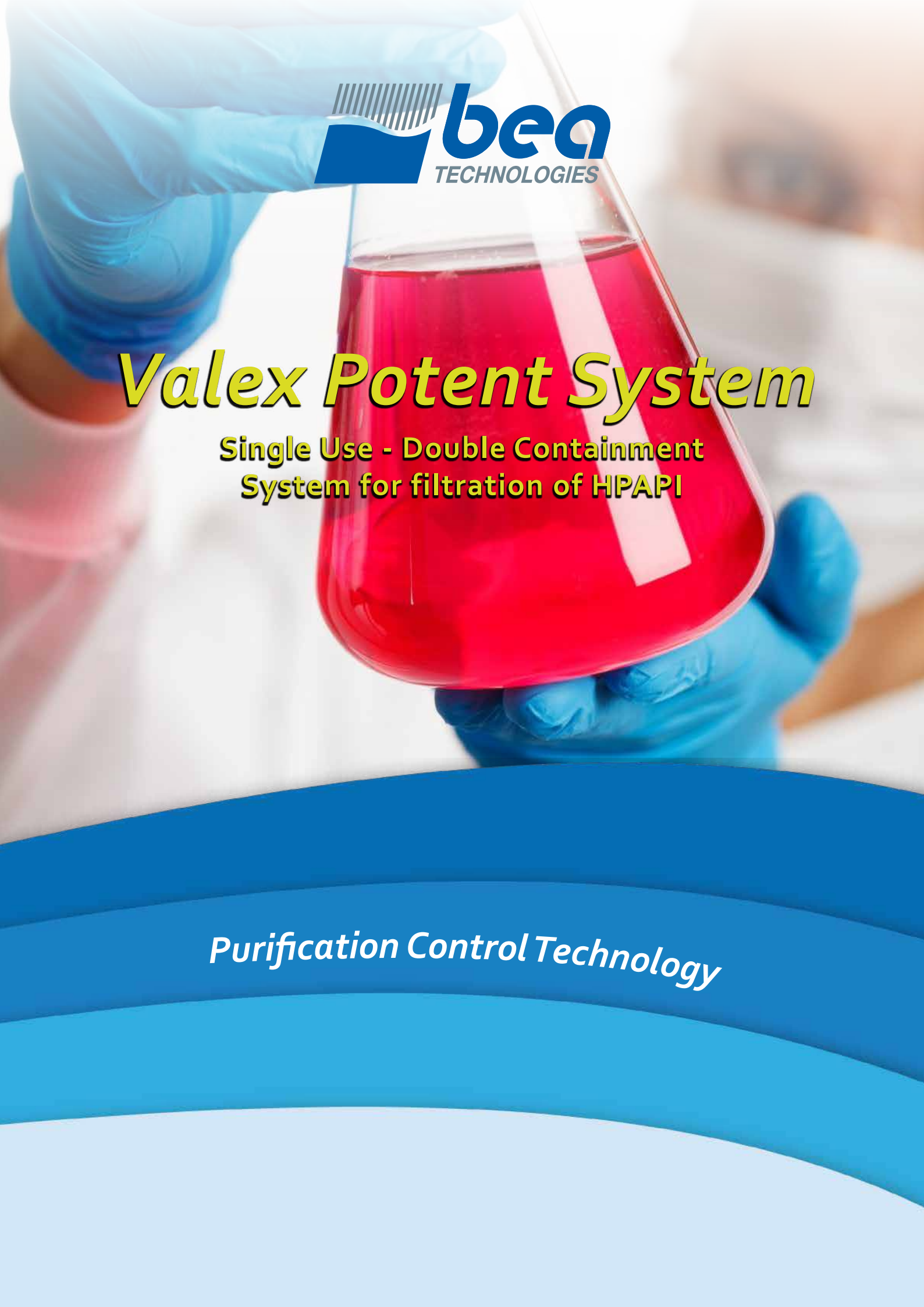


Valex Potent System

Single Use - Double Containment System for filtration of HPAPI

Purification Control Technology











The future of HEALTHCARE

New healthcare challenges and an increasingly ageing population will deeply influence the expectations on the healthcare industry in the coming century. Countless patients worldwide will require the most effective drugs and best medical care. They put their trust not only in the improvement of the healthcare system but also in the industry that supports it and provides the latest pharmacological innovations.

BEA Technologies responds to this challenge with constant vigilance, innovation and determination. Our goal is to supply the pharmaceutical and biotechnology industry with the best Iters and tools to support the research and production of new drugs that patients will require in the coming years.

INTRODUCTION

Highly potent active pharmaceutical ingredients (HPAPIs) represent significant innovation for pharmaceutical companies in preparing new medicines for patients. They emply new, small molecules which are active in lower doses, with reduced side effects. A significant proportion of new active ingredients under development will be classified as highly potent, suggesting an increase in the therapeutic efficacy of these products. While most of the HPAPIs will be used as anti-cancer, others may be classified as hormones, narcotics and retinoids.

Production of HPAPI - a challenge

The introduction of highly potent APIs incurs new manufacturing problems and challenges.
The production of HPAPIs using hormones and cytostatic drugs can have carcinogenic or mutagenic effects to exposed operators. They should therefore be handled with specific precautions in respect to:

OPERATOR SAFETY

CROSS CONTAMINATION BETWEEN PRODUCTS

ENVIRONMENTAL PROTECTION

To comply with current best practice, it has been necessary to develop up-graded engineering design for filtration technologies involved in the purification of HP drugs. This requirement to take into account the toxicity and potency implications of the substances involved.

BEA Technologies has evaluated the challenges and has developed a range of filter and separation equipment for the safe production of HPAPI products, which carefully consider handling and containment.
The combined expertise in polymer science and capsule engineering have cooperated to develop a line of housings and disposable capsules safe designed to be used for the purification of Highly potent API's.

BEA Technologies is continually studying more efficient ways to target drug production of small batches to provide effective, high levels of protection from the effect of toxic, mutagenic or irritant drugs which pose significant challenges to the pharmaceutical industry.

This unique solution - Valex Potent System, provides a "double barrier" and has been tested and supplied to production sites. It can accelerate the process of filtration and purification of compounds requiring high level of protection for operators before final release.

VALEX - POTENT System

SINGLE USE - DOUBLE CONTAINMENT

System for filtration of HPAPI

VALEX - POTENT System

is a compact Single - Use system specifically designed to conduct critical filtration and purification of HPAPI and other hazardous substances used in pharmaceutical facilities. This unique solution VALEX-POTENT System, provides a "double barrier" and has been recently supplied to CMO production sites. It can accelerate the process of filtration and purification of compounds requiring high level of protection for operators before final release. BEA Technologies is studying more efficient ways to target drug production of small batches to provide effective, high levels of protection from the effect of toxic, mutagenic or irritant drugs which pose significant challenges to the pharmaceutical industry.

The inspiring philosophy of the SYSTEM is to satisfy precise requirements of processes using up-to-date technology and to be at the same time easy to handle in full safety conditions for operators.

To manage the required flow, the inlet and outlet connections of the single modules of the system are located to the top of the filter module with "TC" PP fittings; then the single modules are connected in parallel to a header of incoming product (tank) and to the header of the filtered product.

The Filter modules are consisting of internal filter element contained in a plastic capsule fully sealed except for the inlet and outlet connections. This solution is preventing the leakage of any substance filtered. Moreover to guarantee the "Double containment" the capsule containing the filter is further mounted inside a S.S. 316 external housing , that will collect any eventual leakage of substance in case that should be an "hammer stroke" which might damage the capsule PP housing.

The system allows to install many different filter capsules inside the same S.S. external housings, to provide the maximum flexibility to filter different products.

Valex Potent System
FILTER CAPSULES

The heart of the system is a filter capsule which, depending on the particular filter media incorporated, can retain particle contaminants or bacteria and microorganisms. The Valex Potent System is designed to be customized to specific applications or quantities of product to be purified. The standard solution is based on sub-micron filtration to retain even small traces of contamination and activated carbon particles.

The filter element is supplied in a PP polymer capsule, characterized by high chemical compatibility and mechanical resistance to prevent the leakage of any hazardous liquids. This allows work in full safety conditions during change-out.

The capsule sealing is guaranteed by a double white KAFLON O-ring assuring the highest compatibility. To guarantee DOUBLE CONTAINMENT, the capsule is mounted inside a metal S.S. 316 housing, which ensures retention of any liquid or vapor in the event of leakage from the internal capsule.

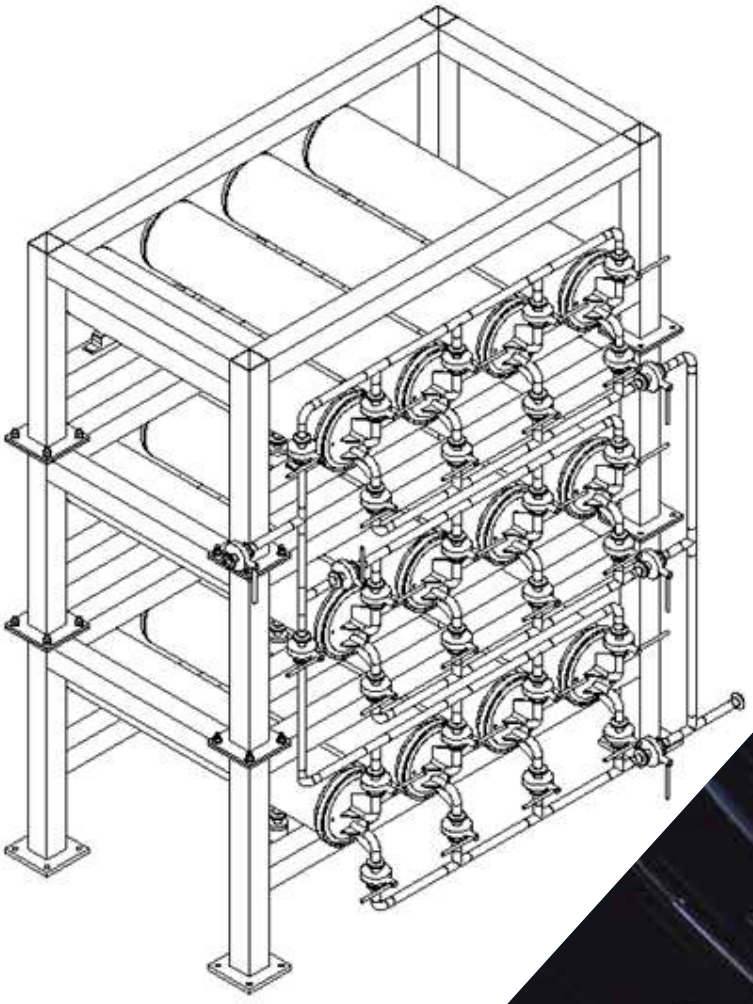
There is a wide range of filter materials which can be fitted in Valex Potent capsules:

PARTICULATE REMOVAL:

- *Polypropylene*
- *Polyester*

BACTERIA, MICROORGANISM, ENDOTOXIN, CELL DEBRIS RETENTION:

- *Nylon 66 and positive charged Nylon 66 membrane*
- *PES membrane*
- *PVDF Hydrophilic membrane*

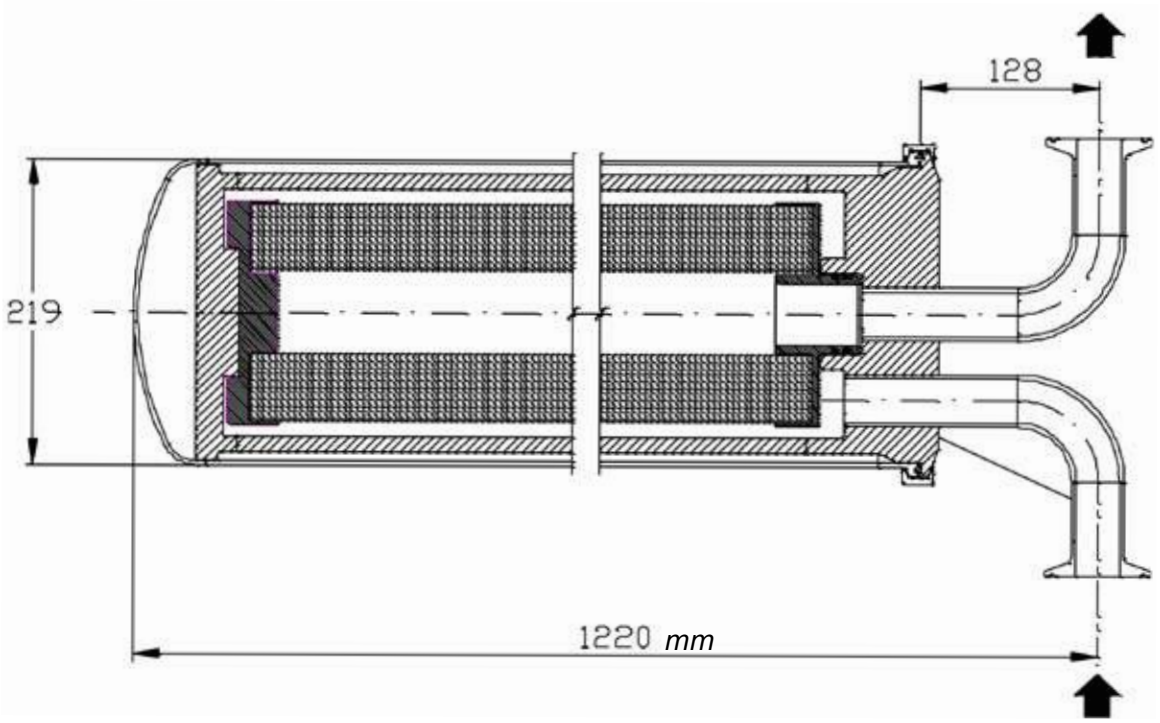


CUSTOMIZED MODULAR DESIGN

In order to use most known standard equipment the Filtration System has been developed with a Modular philosophy selected to be able to provide configurations from 4 housings to 20 housings connected, in parallel, to IN/OUT common headers (which can be in PP or SSI).

Technical specifications
"Valex Potent" System

CONFIGURATION:	*from 4 to 20 housing in parallel*
FLOW RATE x EACH CAPSULE:	*from 5000 to 11000 l/h*
FILTERING SURFACE UP TO:	*11 m² each capsule*
BATCH CAPACITY:	*depending from configuration*
FILTRATION RATINGS Prefilters:	*from 0.5 to 50 micron(s)*
FILTRATION RATINGS filters:	*from 0.2 to 2.0 micron(s)*
DESIGN PRESSURE:	*0 – 6000 mbar / 87 psi*
OPERATIVE PRESSURE:	*maximum 5000 mbar / 72,50 psi*
DESIGN TEMPERATURE:	*65° C*
OPERATIVE TEMPERATURE:	*10 – 50 °C*
INLET CONNECTIONS:	*TC 1½"*
OUTLET CONNECTION:	*TC 1½"*
PLASTING PIPE MATERIAL:	*Polypropylene*
MATERIAL OF THE CAPSULE:	*Polypropylene*
EXTERNAL DOUBLE CONTAINMENT:	*S.S. 316 housing*



FRIENDLY USER MANAGEMENT

One of the most important target was to obtain a system offering a FRIENDLY USER MANAGEMENT that provides an easy system and a simple approach to manage operating procedures for installation, changeout and disposal of exhausted filter capsules.

DOCUMENTATION

The Valex Potent System is supplied with a full "OPERATOR MANUAL" carefully explaining each step for installation, loading, venting, filtration and draining. The manual is reporting even the list of spare parts suggested for standard use.

VALIDATION & LABORATORY

BEA's Laboratory Service is well experienced to provide customer support for the following studies: Scale-up and Validation Plan, Lab analysis, Assessment and Reporting.

TESTING & MARKING

Valex Potent System is supplied in compliance with required pharma regulations both for Design construction and chemical compatibility. The internal components are checked and accepted and the assembled system is subjected to the final acceptance test before shipment.

BEA Technologies Spa

Via Newton, 4 - 20016 - Pero (Milano) - Italy
Phone +39 02 339 271 | Fax: +39 02 339 0713

info@bea-italy.com | www.bea-italy.com

MG-VPS-030-UK-18