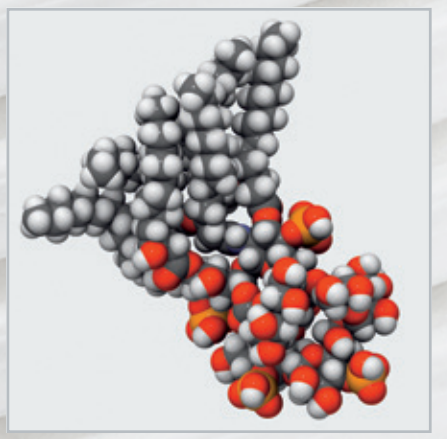
SWISS QUALITY.
SINCE 1938.

FILTROX









PURAFIX® ET-R

Endotoxin removal
Scalable and easy to use

BVS Korea
Homepage: https://www.bvskorea.com
Shopping mall : https://smartstore.naver.com/bvskorea
Blog : https://blog.naver.com/bvskr
Kakao Channel : https://pf.kakao.com/_xowUixj
Youtube : https://youtube.com/@bvskorea
Tel : 02-546-6211/070-7584-5986

Introduction

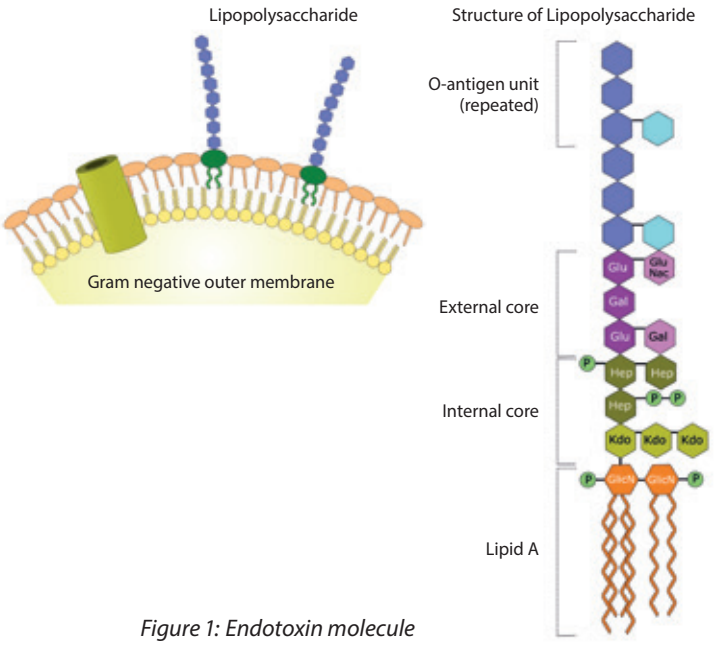


Figure 1: Endotoxin molecule

Endotoxins are degradation products from dying gram-negative bacteria and complex aggregates of acidic lipopolysaccharides (LPS). Each is composed of lipophilic lipids and hydrophilic polysaccharides. In humans, endotoxins can cause immune responses such as fever (pyrogenic threshold is approximately 0.1 ng/kg body weight). Unlike bacteria themselves, endotoxins are extremely heat and pH stable and therefore withstand sterilization methods.

During protein purification, the reduction of endotoxins is one of the most important and difficult steps. It often includes complex purification strategies (e.g. chromatography steps) with more or less satisfactory results.

In general, the removal of contaminants in downstream processing becomes more costly the later in the process a contamination is removed. PURAFIX® ET-R depth filter sheets are the solution for endotoxin removal earlier in the process.

Depth filter media are used in the clarification of cell cultures. Especially at an early stage of a clarification process, depth filter media are used for the removal of micron-sized particles. With their three-dimensional structure and large inner surface area, depth filter sheets are ideal to serve as a basis for functional properties, which can interact with specific contaminants. This combination of particle-removal capabilities of traditional depth filtration with the reduction of specific contaminants at an early stage of the downstream process allows for reduction in size or complete removal of costly purification steps, resulting in time and cost savings.

The PURAFIX® ET-R depth filter sheet combines the removal of micron-sized particles with the specific removal of endotoxins, also at neutral pH and high salt loads.

Typical cell or cell debris removal systems for gram-negative bacteria can reduce the endotoxin count from initially up to 1 million endotoxin units (EU/mL) down to around 5000 EU/mL.

Traditionally, those 5000 EU/mL have to be removed in a costly, late-stage endotoxin removal step using chromatography. The PURAFIX® ET-R depth filter sheet can remove >95% of the 5000 EU/mL amount, allowing for a significant reduction in size of the endotoxin removal stage.

The PURAFIX® ET-R depth filter sheet with its flexible scalability allows for an easy and cost-efficient reduction of endotoxins. Depth filters are easily scalable from process development to production. PURAFIX® ET-R depth filter sheets are available from laboratory-size 2-inch capsules up to 16-inch lenticular modules and as flat filter sheets in various dimensions.

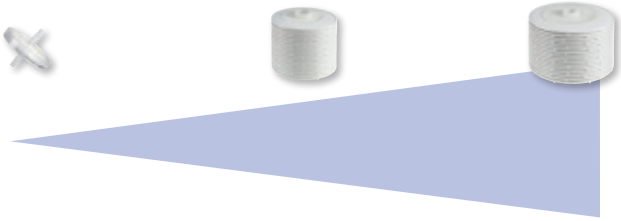


Figure 2: Scalability of the PURAFIX® ET-R system

Media grade selection

PURAFIX® ET-R grades are designed for different sizes, charges and phobicities of the target molecule.

E.g. if the target protein is hydrophilic and positive charged the ET-R1 or ET-R2 will work. For a more hydrophobic molecule the ET-R1 will be the first choice. However to be on the safe side a trial with the 2" capsule is recommended. The diagram below gives an indication which of the ET-R grades will work.

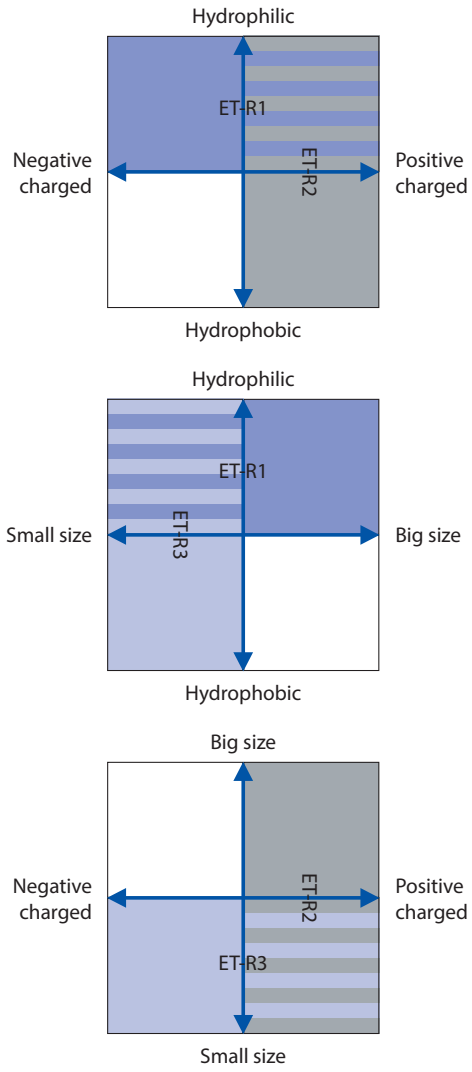


Figure 3: Media grade selection

PURAFIX® ET-R1 removes endotoxin when the target protein is small and hydrophilic.

PURAFIX® ET-R2 removes endotoxin when the target protein is medium sized, positive charged and hydrophilic.

Application

The PURAFIX® ET-R depth filter sheet combines the removal of micron-sized particles with the specific removal of endotoxins, at neutral pH and high salt loads.

Typical Midstream solution as centrifugation, separation, acoustic wave, depth filtration and so on, can reduce the endotoxin count down to ~5000 EU/mL.

PURAFIX® ET-R filtered in aqueous media

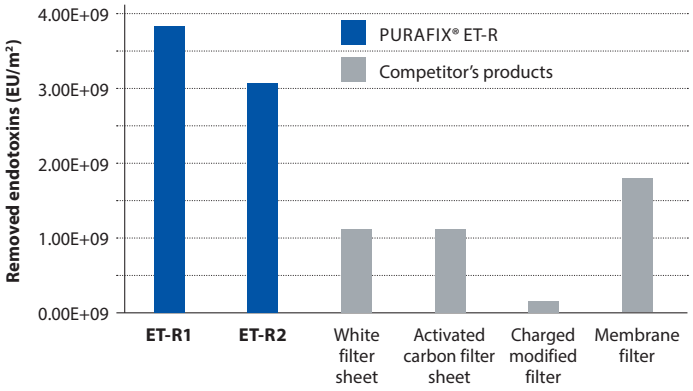
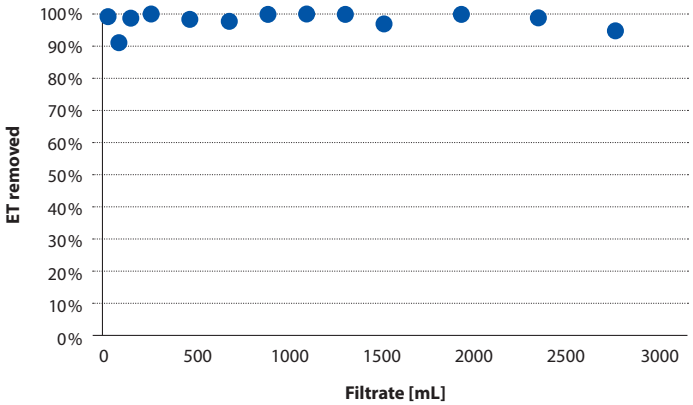


Figure 4: PURAFIX® ET-R competition comparison

PURAFIX® ET-R compared with competitive products, showing log reduction of EU/mL. In aqueous media PURAFIX® ET-R shows significantly better removal of Endotoxins than the competition.

Example PURAFIX® ET-R1

– Filtered volume: 3000 ml
– Flow rate: 300–350 l/m² * h
– pH: 7.4
– EU/ml: 3500
– Buffer: PBS



PURAFIX® ET-R can remove nearly 100% of free Endotoxin in an aqueous solution.