

## OlimPeak® Certified Filters by Teknokroma



### Introduction

Filtrating samples prior to injection will prolong column, frits and valves life, and reduce down time due to less instrument maintenance.

The quality of the filtrate from any sample is dependent on a number of variables, such as, the membrane, the membrane support (if used), the resin used to mold the filter housing, and last but not least, the analyst.

In any laboratory filtration where the purity of the filtrate is important, the analyst must remember three very important words, slower is better. Filtration improves when the sample passes through the filter slowly. Attention should be paid when using a high volume syringe (more than 10 ml), in order to avoid the maximum operating pressure.

### Integrity of the Membrane

The best method to guarantee the integrity of the membrane is the control of the bubble point.

The bubble point is the minimum pressure required to create a steady flow of bubbles from a fully wetted membrane (water for hydrophilic materials and alcohols for hydrophobics). Microporous membranes in contact with the wetting liquid, fill their pores following principles associated with the capillary forces. To vent the filled pores requires a differential pressure to be applied across them.

Principal factors affecting bubble point test are: surface tension of the liquid, surface free energy of the membrane, size of pores, temperature and wetting procedure.

In a simplified math-form, the required pressure to vent a liquid filled pore **P**, has an inverse relationship to the pore diameter, **d** as described by this bubble point equation:

$$P = \frac{K4\sigma \cos\theta}{d}$$

**P**: Bubble point pressure

**σ**: Surface tension of wetting fluid

**θ**: Contact angle of liquid-solid

**K**: Pore shape factor constant (since pores are not simple cylinders in the real filter membranes).

**d**: pore diameter.

## OlimPeak® Certified Filters by Teknokroma

### Introduction of the New line of Olimpeak™ syringe filters

Teknokroma introduces into the market the new range of Certified Syringe Filters **Olimpeak™**.

This new line of Olimpeak™ Certified Filters offers a step further in traceability, method validation and GLP.

**Certified Olimpeak™** syringe filters are made using polypropylene medical grade housing with Luer Lock and Luer slip fittings in compliance with ISO 594-1. Each filter is sealed using an external ring insert to maintain the membrane integrity and best performance. Olimpeak™ syringe filters are color coded for an easy identification.

All syringe filters are manufactured in compliance with ISO 9001 and technical procedures and tested according international standards of ISO 17025. Our manufacturing methods eliminate variable results through controlled manufacturing consistency batch to batch, and filter to filter. Samples and raw data of all syringe filter batches and membranes are stored during 5 years from production for reference.

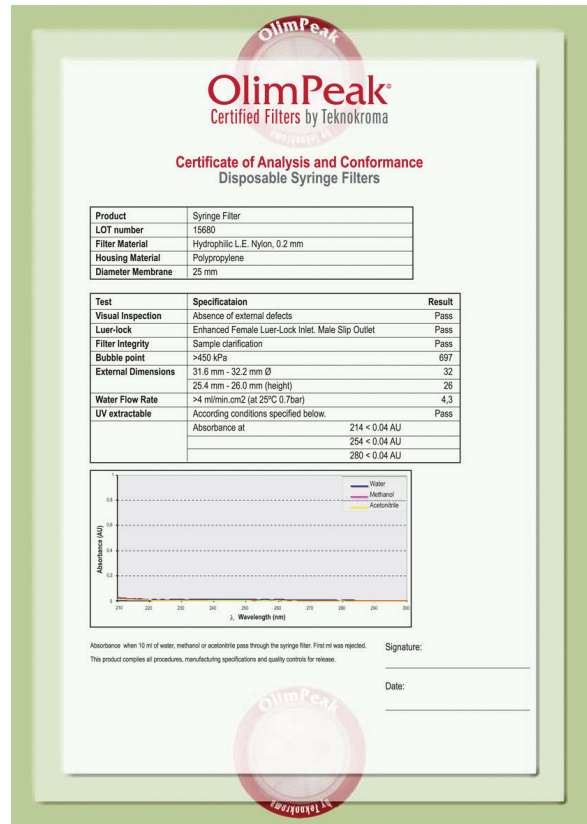
Our new **Certified Syringe Filter Olimpeak™** offer the best value. All filters are supplied with a Certificate of Quality batch to batch as guarantee of product performance and quality.

Each lot is quality monitored for:

- 100 % of the syringe filters are visually inspected following quality specifications
- Each batch of filters is tested for external dimensions
- Bubble Point
- Burst Pressure
- Filter Integrity
- Water Flow Rate
- UV Extractables and compliance with all technical procedures.
- Manufacturing specifications and quality controls for release

Test are carried out by an independent laboratory

*(\*) For critical applications using chromatography detection at < 210 nm it is recommended to reject the first filtrate ml.*



Olimpeak™ Certificate

Teknokroma's Syringes filters are of high quality and their level of extractables is very low. The encapsulating process forces the sample to pass only through the membrane .

They chemically resist a wide range of chemical products and solvents.

Teknokroma's filters avoid any leak or any contamination due to the use of high quality materials.

### Easy Identification for Method Validation



In addition to the color code, every single unit of Olimpeak™ Certified Syringe Filter is printed with the membrane type, pore size and batch number. This information makes them unique for traceability, GLP's and validation purposes.

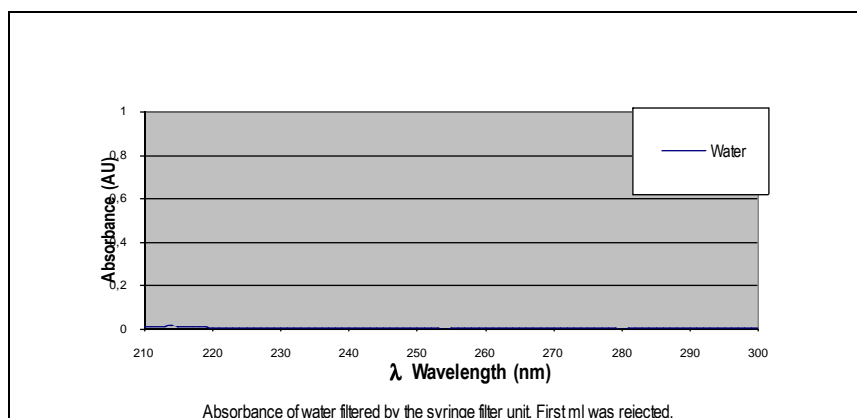
# OlimPeak®

Certified Filters by Teknokroma

## Certificate of Analysis and Conformity Disposable Syringe Filters

R.Cellulose 0.45 µm 25 mmØ. Lot. 195684

Test	Specification	Result
Visual	Absence of external visual defects	Pass
Luer-lock	Enhanced Luer-Lock (ISO 594-1)	Pass
Filter integrity	Sample clarification by filtration test	Pass
Bubble point	>200 kPa	270
Ext. Dimensions	31.9±0.3 mmØ x 25.7±0.3 mm (height)	Pass
Water Flow Rate	>15 ml/min.cm <sup>2</sup> (at 25°C 0.7bar)	35,0
UV extractable	According conditions specified below. Absorbance at:	<b>Water</b>
		214 < 0.04 AU
		254 < 0.04 AU
		280 < 0.04 AU



This product complies all procedures, manufacturing specifications and quality controls for release.

Signed

Quality Manager

Date

June 18, 2013

Product manufactured in compliance with ISO 9001 and technical procedures.

