interscience

THE APPLICATION POINT

THE APPLI'NEWS

November 2023

Annex 1

One of the changes in the **new Annex 1 of the European Pharmacopoeia** concerns the **quality control of primary packaging** (i.e., the first container of the product, such as a vial, syringe, or other) for pharmaceutical products. Previously, this control was only conducted by the primary packaging manufacturer. Now, pharmaceutical product manufacturers must also perform this control upon **receiving the primary packaging**. *For instance, if Aptar produces a syringe piston and conducts quality control at the end of production for each batch. And if Sanofi uses this piston in the syringe for its vaccines then, according to* ***Annex 1, quality control for each batch of syringe pistons upon receipt*** *must now be performed.* Here is a **protocol that we can propose** for this new issue:

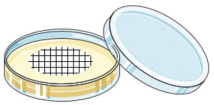
Collect the sample with **BagPage® XR** sterile sampling bag.	Dilute at 1/10th with Dilu***Flow*® Elite 1 kg**.	Homogenize the sample in a **BagMixer® 400 SW** lab blender.	Plate the suspension for micro-organism research with easy**Spiral®** automatic platers using the constant mode on TSA medium.	Pass the suspension through a filtration membrane and place on a Petri dish with TSA medium.

THE APPLICATION QUESTIONS

Question n°1 :

"How should I advise my clients if they want to use the ***ScanStation*** *with* ***filtration membranes****?"*

Previously, for clients using **filtration membranes** with the **ScanStation**, we used to recommend using black membranes for light colonies and white membranes for dark colonies. Recently, the research department made **improvements in the ScanStation software for colony counting on filtration membranes**. Now, the **ScanStation is capable of reading filtration membranes very well**, including light colonies on white membranes. This enhancement significantly broadens the possibilities for **water analysis**, particularly for **beverage quality analysis**.



Question n°2 :

"Is it possible to ***connect our DiluFlow to a media auto-preparator****?"*

We don't have a compatibility list for **Dilu*Flow*** / media auto-preparator. **Each request must be tested on a case-by-case basis** with the **customer support or application department**.

Thanks for reading me ! If you have a question or a topic you would like to discuss in the next APPLI'NEWS, please send it to isanseau@interscience.com