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Consistency in Physical Data of Unisart® CN Membranes

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Introduction

Being the first industrial manufacturer of nitrocellulose membranes in 1927, Sartorius combines in-depth know-how of the membrane manufacturing process with extensive expertise in diagnostic applications. Modern state-of-the-art casting lines are used to produce large lots of nitrocellulose membranes with high inter- and intra-lot consistency. Each lot must pass stringent quality control standards throughout all manufacturing steps according to a Quality Management that is certified in compliance with ISO 9001. This makes Sartorius Unisart® CN Membranes the ideal substrate for reliable lateral flow immunoassays.

Process Monitoring During Unisart® CN Membrane Manufacturing

The casting of Unisart® CN Membranes at Sartorius is tightly controlled with a real-time process intelligence using multivariate data analysis (SIMCA®-online). This allows to track more than 10,000 vital parameters of the manufacturing process and to react immediately to occurring deviations.

The down-web capillary flow rate of water and the membrane thickness are measured and documented for every lot for a large number of samples during production. Figures 2 and 3 display the typical distributions for our Unisart® CN Membrane portfolio.

The data can be described with a Gaussian, where certain fit parameters allow us to characterize the properties of the normal distributions (Figure 1). The mean value μ and standard deviation σ are useful in describing the percentage of samples with properties in a certain interval. For example, 95.5% of all data can be described by μ ± 2σ. Ideally, the mean value μ lies in the middle of the specification limits with a tight distribution around it (i.e., small σ).

The presented data showcases the consistency in our membranes' capillary flow rate and thickness (Figures 2 + 3).

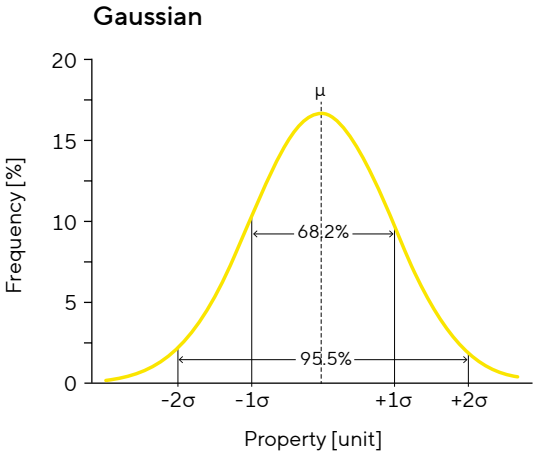

Figure 1: *Gaussian Function With Mean Value μ and Percentages Included in μ±1σ and μ±2σ.*

Consistent Capillary Flow Rate of Unisart® CN Membranes

Capillary flow rate is one of the main membrane characteristics which determines the suitability of a membrane for a specific lateral flow immunoassay (LFA). Depending on the assay, a membrane with either lower or higher capillary flow rate may be required. One important influencing factor is the viscosity of the sample liquid. Sample liquids with higher viscosities such as milk may call for a faster membrane (e.g., Unisart® CN 95).

However, this needs to be tested for the specific LFA. Sartorius offers Unisart® CN Membranes with a wide range of capillary flow rates to meet this need (Table 1).

Figure 2 and Table 2 show that our typical distributions are well in agreement with the specified capillary flow rates.

Table 1: *Physical Properties of Unisart® CN Membranes According to Specification.*

Unisart®	Capillary Flow Rate [s/40mm]	Thickness [μm]
CN 95 backed	65 - 115	240 - 270
CN 110 backed	90 – 130	185 – 215
CN 140 unbacked	90 - 150	120 - 160
CN 140 backed	95 - 155	225 - 255
CN 150 backed	90 – 180	240 – 280
CN 180 backed	135 – 175	225 - 255

Table 2: *Parameters of the Normal Distribution of the Capillary Flow Rate for Unisart® CN Membranes.*

	Capillary Flow Rate [s/40mm]	
Unisart®	Specification Middle	Mean μ ± Standard Deviation σ
CN 95 backed	90	88 ± 7
CN 110 backed	110	109 ± 7
CN 140 unbacked	120	118 ± 5
CN 140 backed	125	122 ± 5
CN 180 backed	155	155 ± 11

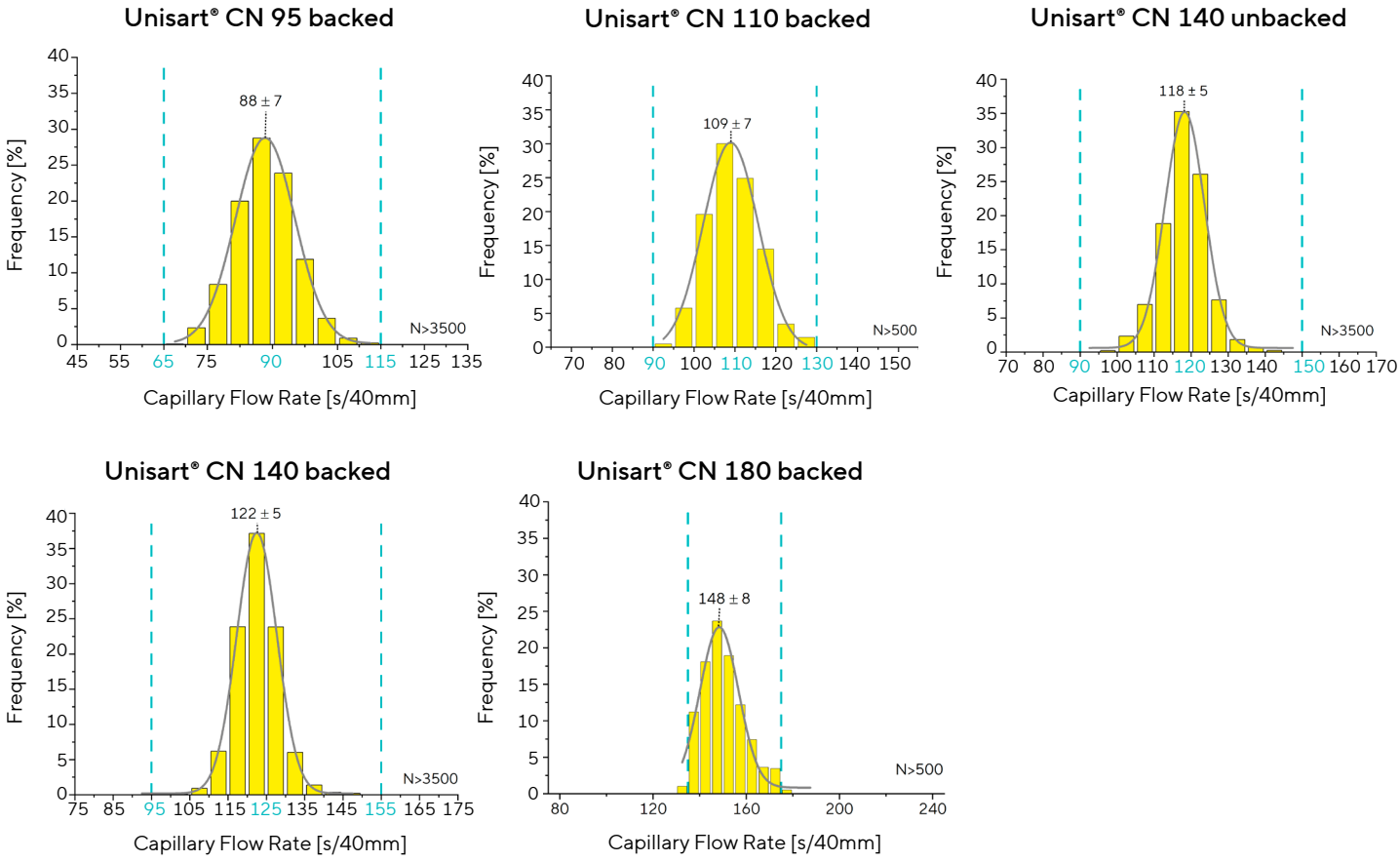

Figure 2: *Typical Distributions of the Membranes' Capillary Flow Rate for Unisart® CN Membranes. Teal-Colored Vertical Lines Indicate the Minimum and Maximum Specification Limits. Grey Lines Represent a Gaussian Fit to the Data. Membrane that does not meet specifications is not released.*

Consistent Thickness of Unisart® CN Membranes

Another important membrane property that is closely monitored during the casting process is membrane thickness (Figure 3). Membrane thickness impacts the bed volume as well as the widths of test and control line. Therefore, a constant membrane thickness is important to ensure constant product quality in LFAs. Membranes that are cast without a PET backing (Unisart® CN 140) rely on thickness to ensure manufacturability with this product. As the data shows, the mean value of the thickness lies in the middle of the specification limits and all values show a very narrow distribution (Table 3). Accordingly, we ensure that Unisart® CN Membranes are produced consistently and therefore are well-suited for the manufacturing of LFAs.

Table 3: *Parameters of the Normal Distribution of the Thickness for Unisart® CN Membranes.*

	Thickness [µm]	
Unisart®	**Specification Middle**	**Mean µ ± Standard Deviation σ**
CN 95 backed	255	256 ± 5
CN 110 backed	200	202 ± 2
CN 140 unbacked	140	141 ± 3
CN 140 backed	240	237 ± 3
CN 180 backed	240	239 ± 4

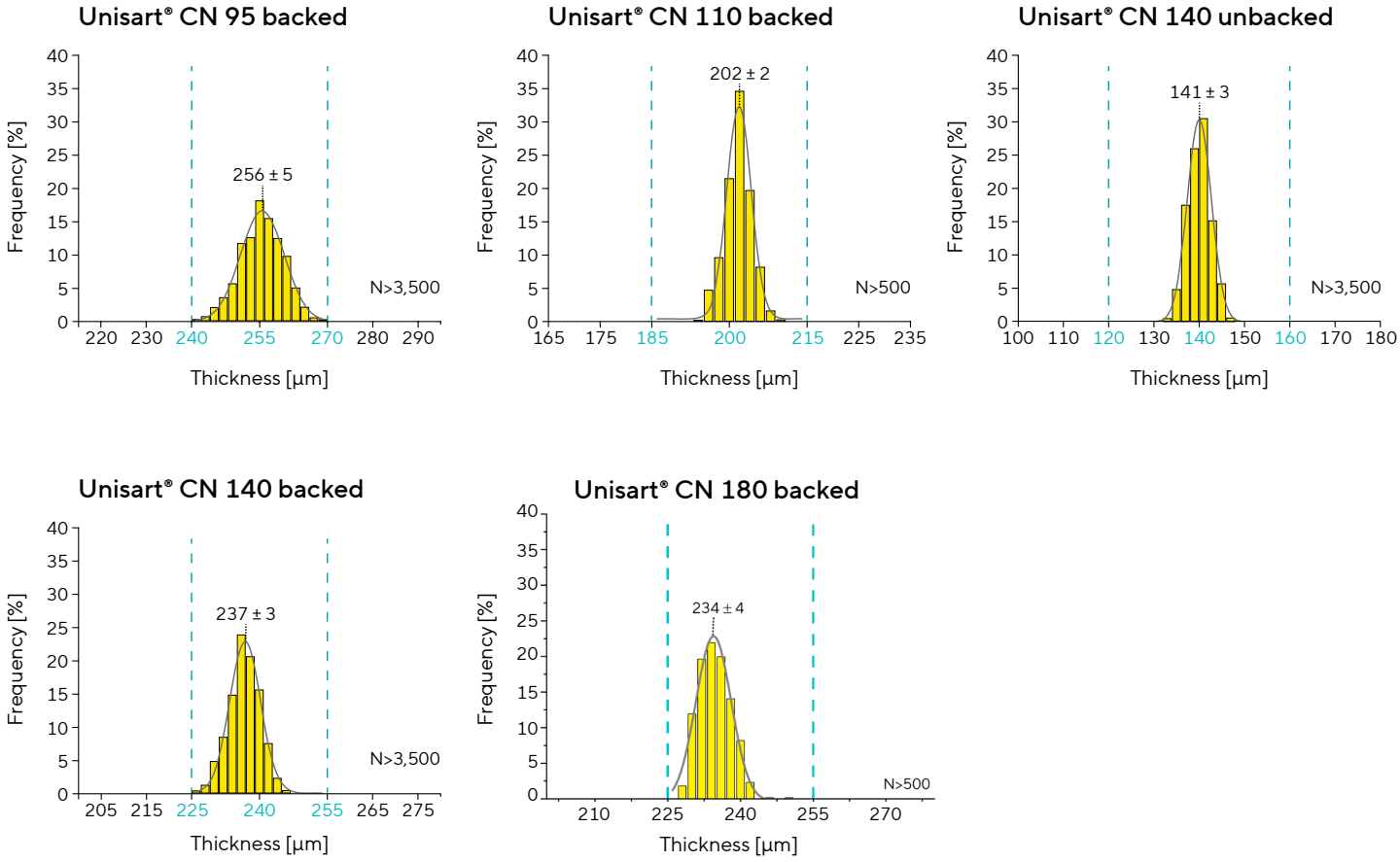

Figure 3: *Typical Distributions of the Membrane Thickness of Unisart® CN Membranes. Teal-Colored Vertical Lines Indicate the Minimum and Maximum Specification Limits. Grey Lines Represent a Gaussian Fit to the Data. Membrane that does not meet specifications is not released.*

Conclusion

In conclusion, the normal distributions show that at Sartorius we cast Unisart® CN Membranes in a well-controlled and precise process, yielding membranes with a high inter-and intra-lot consistency. Our real-time process monitoring via SIMCA®-online is a tool for tracing each final roll through the entire manufacturing process. This helps us to provide our customers with high quality Unisart® CN Membranes for their assay.

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