

Virus-Like Particle Characterization Using New AF4 Channel Technology

Virus-Like Particles (VLP) used for vaccination and immune stimulation, are of growing interest in the pharmaceutical sciences. For quality assurance there is a tremendous need for techniques that characterize different VLP fractions (fragments, monomers, dimers, trimers and aggregates). We have recently demonstrated that the separation and subsequent quantification of different VLP species is possible by AF4. However, some disadvantages, like long equilibration and analysis times, as well as the need for high sample amounts and large eluent volumes, been overcome by using new, shortened channel geometries.

A stressed VLP sample was analyzed by AF4 (equipped with multi-angle light scattering and UV detection) by using either Wyatt's standard channel (25 cm) or a smaller channel (18 cm) with a spacer height of 350 μm .

Comparative AF4 measurements of VLPs with the standard channel (25 cm) and the new channel (18 cm) revealed almost similar peak heights when 20 μg VLP were injected in the standard channel or when 10 μg VLP were injected in the new channel, respectively (Figure 1). Increased peak heights obtained with the new channel are due to sharper peak resolutions. Thus, analysis is possible with significantly less sample amount (Figure 2). At the same time, analysis time and solvent volume were reduced (Table 1).

The standard channel technology has limitations concerning sample amount and separation time. By contrast, applying Wyatt's new channel technology analysis of far lower VLP amounts is possible in clearly shorter time and remarkably lower eluent volumes. Thus, it can be stated that the new channel technology is a clear improvement for VLP characterization as compared to the standard channel.

Table 1. Comparison between standard channel and shorter channel.

| | Standard Channel (25 cm) | New Channel (18 cm) |
|-------------------|-----------------------------|------------------------|
| time/run | 56 mins | 31 mins |
| eluent volume/run | 159 mL | 70 mL |
| injection amount | 20 μg | 2.5-10 μg |

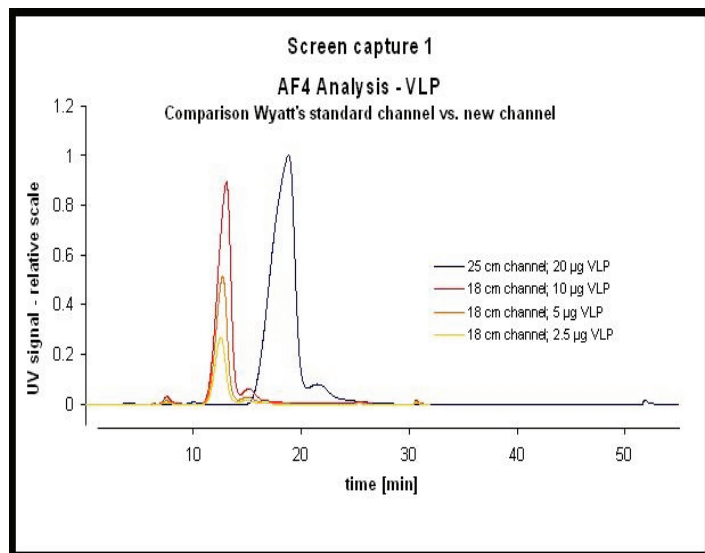


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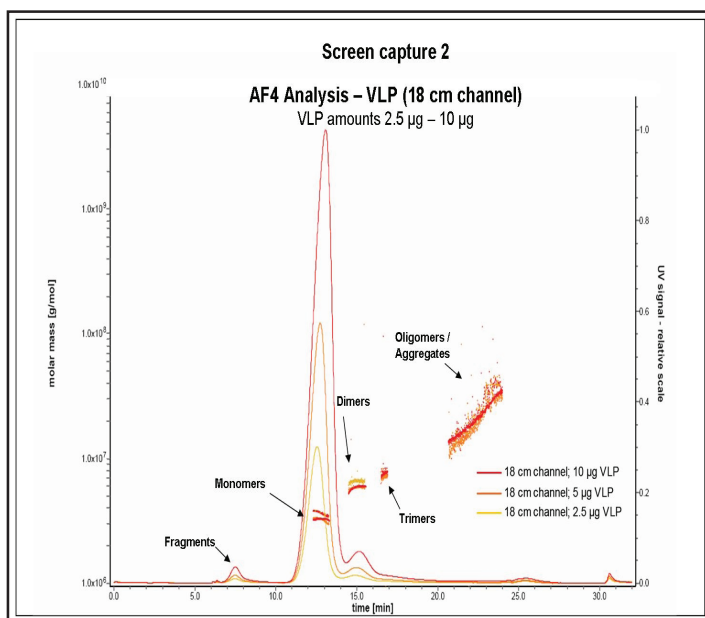


Figure 2. Different injection amounts compared.

