GMP SA
Av. des Baumettes 17
CH-1020 Renens

Tél. 021 633 21 21
Fax 021 633 21 29
info@gmp.ch – www.gmp.ch

GMP
GENERAL
MICROTECHNOLOGY
& PHOTONICS

SYSTEMS FOR INDUSTRY
RESEARCH
TELECOM & MEDICINE

VASCO KIN™ Nano-Particle Size Analyzer

An innovating, fully flexible approach to the Particle Size Analysis based on Dynamic Light Scattering (DLS)

VASCO KIN™, a nano-particle size analyzer from Cordouan Technologies represents a new step in the DLS technique for nano-particle size analysis. It shows flexibility on two different levels.

FULLY FLEXIBLE

Firstly, in the terms of measurement configuration, the remote probe (inherited from a precedent model VASCO FLEX™) allows measurements *in-situ* and contactless; ideal for the situations when the sampling could modify the sample state or in case of measurements in limited space like in glove box.

Then, in the terms of data analysis, the NANOKIN™ software contains unique and innovating features as a software correlation with photon count storage which gives an access to the full recorded data in one single measurement, with a possibility to re-create a correlogram to any chosen period of time during and after measurement or kinetics analysis with a time resolution of 200ms.

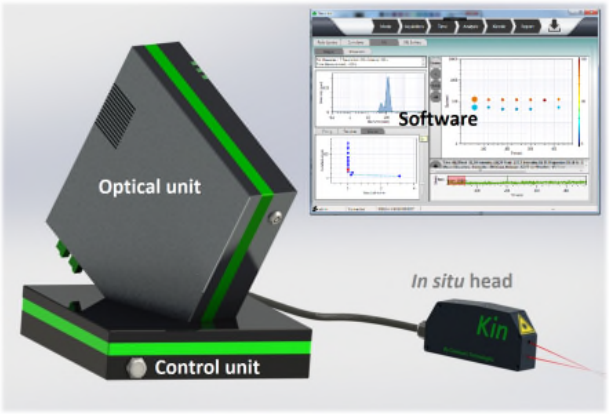

Figure 1: VASCO KIN™ set-up: an optical unit, a control unit, an in-situ head and a dedicated software.

VASCO KIN™

The nano-particle size analyzer VASCO KIN™ uses a Dynamic Light Scattering technique; based on the analysis of scattered light fluctuations caused by the Brownian motion of particles, DLS is a mature and very powerful technique of choice in colloidal sciences and proteins characterization study. It allows accurate particle size measurements from one nanometer up to a few microns in few seconds.

VASCO KIN™ composes of an optical unit, a control unit and an in-situ head connected by a special umbilical optical fiber to the optical unit.

The *in-situ* head injects a laser beam into the sample and collects the light scattered by the sample in the backward direction at an angle of 170°. Inside the optical unit, a highly sensitive single photon Avalanche Photodiode Detector (APD) - connected to a dedicated fast acquisition electronic board - monitors the fluctuations of scattered light intensity in real time. The intensity of the light is registered for time-resolved analysis during and after measurements.

APPLICATION EXAMPLE: In-situ protein aggregation monitoring in injectable vaccines syringes

In order to demonstrate the capabilities of the VASCO KIN™ to achieve contactless *in-situ* measurement, we have made series of particle size measurement on a commercial injectable flew vaccine syringe**.**

This vaccine is a complex medium made of a mixture of many different ingredients: deactivated and fragmented Flew Virus from three different stem cells, several excipients, and traces of chicken eggs proteins (ovalbumin), etc.

Aggregation of proteins and active principle ingredients (API) in injectable biopharmaceutical products remains a major concern impacting the stability and usability of a product. Indeed, the protein aggregation can occur during all stages of the lifetime of a protein. Its mechanism is still not well understood. In a context of more and more stringent international health regulations about the control of biopharmaceutical products, the in-situ monitoring of the denaturation and degradation process of therapeutic proteins during production and storage can be a key competitive advantage for manufacturers and researchers.

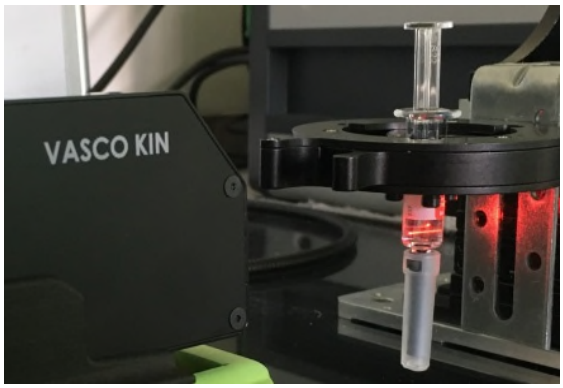

Figure 2: Measurement set-up with the VASCO KIN™ remote head mounted on a dedicated translatable stage

The measurements were performed directly on the vaccine syringe placed in a dedicated mount in front of the *in-situ* head.
To evidence possible vaccine aging effects, we measured two vaccines. The first one was stored in a fridge at 7°C and another vaccine stored at room temperature for 8 months. The two vaccines were then measured in exactly the same conditions the same day. The detailed results, presented in an application note accessible at on our website under link, display clearly that the vaccine stored at room temperature shows noticeable changes in the particle size distribution in comparison with the vaccine stored in a fridge. The later shows three well defined peaks corresponding to three distinct populations. The vaccine stored at room temperature appears like a broad continuum from 10 nm to 10 µm and beyond.

***A UNIQUE SOLUTION**:*
Even if this single result is not enough to explain the differences observed in the two samples, it shows, for the first time - as far as we know - the possibility of measurements in the hermetically sealed container (an injectable syringe, in this example) and opens a new domain of applications of DLS technology.