RheoSense
Simply Precise®

Accurate Prediction of Auto-Injector Force: High Viscosity Testing on Fridge-Temp Samples with m-VROC® II

Auto-injectors are medical devices that allow one to effectively inject a pre-filled drug formulation with minimal effort and training. The typical auto injector is like a retractable pen with a syringe instead of an ink cartridge. After the tip of the auto-injector is pressed against the injection site, the needle is pushed outside the "pen" into the intramuscular or subcutaneous site, and a pre-loaded spring provides a force to the syringe plunger for injection. Appropriate characterization of injection force (IF) with small formulation volume can be gauged with the *m*-VROC® II or VROC® Initium One Plus.

Many injectable formulations, including mAbs and vaccines, must be stored at 2 – 8 ˚C to preserve their integrity. Although it's recommended to allow the formulation and autoinjector to equilibrate at room temperature for up to 30 minutes prior to administration, this is often not feasible or adhered to. This results in injection of a colder and more viscous sample with a higher IF, which may be impossible or too time-consuming to inject. Hence, it is important to accurately gauge the viscosity at temperatures ranging from 2 – 25 ˚C to predict the corresponding IF, injection time, and if the sample is injectable or not. It is also important to probe the viscosity at these temps for a wide shear rate range (up to 10,000 – 200,000 s^{-1}), which is required for accurate estimation of IF.

The plot below shows viscosity measurements obtained with *m*-VROC® II, equipped with the E05 chip, on a 500 µL high viscosity sample for shear rates up to 169,000 s^{-1}. The viscosity at 5 °C is 43 cP whereas that at 15 °C is 24 cP. These results display the high repeatability (%RSD = 0.4) and accuracy (0.55% difference compared to certificate of analysis) one can obtain with *m*-VROC® II for high viscosity samples for a wide range of shear rates at multiple temperatures relevant to auto-injectability applications. The understanding gained from VROC will help develop formulations and autoinjectors that can deliver appropriately, even well below room temperature.