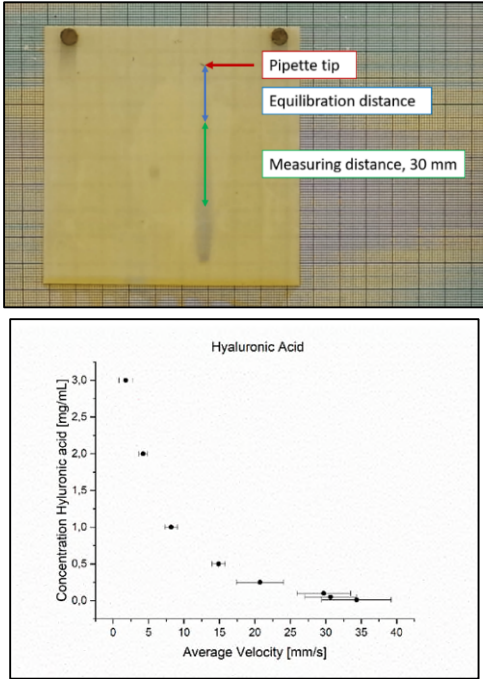


Measurement of mucoadhesion

Method name	Measurement of mucoadhesion (Focus: Eye)
Organ system	Eye & Mucous membranes
Subject area	Drug development
Area of application	Testing of bioequivalent properties, formulation development
Relation of the method to the 3Rs	Replacement & Reduction, Prediction of efficacy by change in clearance
Figure	 <p>The figure shows a DC plate coated with mucins (upper figure). The plot shows the velocity (measure of adhesion) against the concentration of hyaluronic acid as a common excipient.</p>
Brief description	<p>The test method aims to evaluate mucoadhesion properties based on adhesion forces; the viscosity and rheology of the samples being compared are assumed to be similar. Validation of the method was conducted according to PharmBioTec's quality assurance system and following the ICH Q2 (R1) guideline. The comparative experiments are performed under non-GMP conditions, typically using 12 replicates which are statistically evaluated. Two samples are compared by forming the T/R ratios and testing the 90% confidence interval. A ratio between 0.8 and 1.25 indicates equivalence of both samples. (Statistical consideration analogous EMA/CHMP/QWP/608924/2014).</p>
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Publication	Wengschick, Sara et al. 2022. "Method for Measuring Mucoadhesion of Ophthalmics Considering Regulatory Aspects." <i>European Journal of Pharmaceutics and Biopharmaceutics</i> 174(March): 101–5.