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DIPARTIMENTO DI MEDICINA MOLECOLARE E TRASLAZIONALE

SEMINARIO

**Water Proton NMR: Noninvasive Analytic
for Biopharmaceutical Manufacturing and
Quality Control**

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Tutti gli Interessati sono invitati a partecipare

Abstract

Water is by far the dominant component of most pharmaceutical solutions. As the solvent, water has extensive interactions with the drug substance. It is possible to use water proton NMR (w NMR) for nondestructive analysis of pharmaceutical solutions with desktop NMR spectrometers. Examples of using w NMR to monitor protein concentration, protein aggregation, amide hydrolysis, surfactant micellization, dendrimer folding, nanoparticle formulation will be presented. Data will also be presented on FDA-approved products, including differentiating brand and generic complex drugs, and detecting dose error in prefilled injection pen of insulin. On-going work focuses developing flow- w NMR as an in-line process analytic technology for continuous biomanufacturing.