



OSeeT

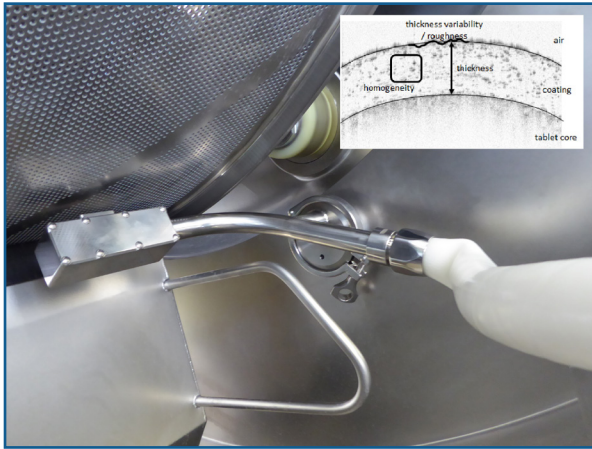
Optical Coherence Tomography for in-line measurement of the physical dimensions of film-coatings in both pan coated tablets and pellets in fluid beds.

TOTAL QUALITY CONTROL

The OSeeT probe offers an unprecedented speed and level of detail, providing deep insights into your coating process, improving quality & efficiency.

THE TECHNOLOGY

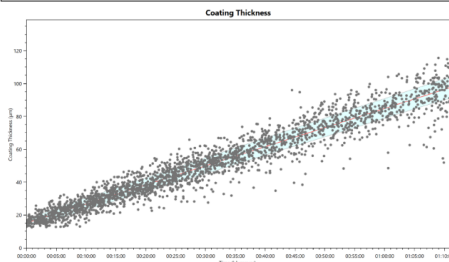
Phyllon's OSeeT Pharma 1D is based on optical coherence tomography (OCT), licensed from RCPE. OSeeT is a rapid, direct measurement technique and uses the variation in refractive indices of different structures to acquire cross-sectional images. These images are evaluated for mean coating thickness, inter- and intra-tablet thickness variations (CoV), surface roughness and homogeneity of the layer. Crucial insights can be achieved during development and production to obtain a higher coating quality for every batch, independent of processing equipment and scale.



The OseeT probe can be used to measure physical dimensions of film-coatings in both pan coated tablets (Picture Credit: L.B. Bohle Maschinen + Verfahren GmbH) and pellets in fluid beds (Picture Credit: GLATT Process Technology)

Results Monitoring

Results from Results Monitoring			
Mean Thickness:	97.40 μm ($\pm 10.65 \mu\text{m}$)	Thickness RSD:	$\pm 10.94 \%$
Mean Roughness:	7.05 μm ($\pm 43.91 \%$)	# Datapoints:	2247
Mean Homogeneity:	68.27 % ($\pm 22.27 \%$)		



The software evaluates coating thickness & quality attributes throughout the process.

THE ADVANTAGES

Non-Destructive

The OSeeT probe provides direct, contactless evaluation of coating thickness and quality without affecting the structural integrity of the product and without need for MVDA modeling.

High Level of Detail

Image analysis provides detailed understanding of the film structure for visual comparison of batches. Moreover, root-cause analysis of undesired variations in coating thickness or other structural phenomena becomes directly possible.

Instantly Applicable & Easy-to-Use

OSeeT provides direct measurements without any additional chemometric calibration and features an intuitive software interface that requires no special scientific training.

Economic Cost Structure

OSeeT enables in-line process control at competitive capital costs and low total cost of ownership, providing a maximum return on investment.

Regulatory Compliance

OSeeT Pharma 1D is CFR 21 Part 11 / GAMP 5 and GMP / ATEX compliant.

SCOPE OF APPLICATION

Development Phase:

Design of process conditions / Optimization of coating conditions / Optimization of coating formulation / Comparative analysis / Regulatory support related to CMC section

Manufacturing scale:

In-process control / Real Time Release / Technology transfer & scale up / Validation batches

DEVELOPED BY



RCPE performs cutting-edge research in the field of process and product optimisation. The main focus is on the development of new drug delivery systems, the associated production processes and their monitoring. Application-oriented research and development projects are carried out in collaboration with industrial and scientific partners. RCPE's goal is to strengthen partners' competitive edge and their economic success in the market, by helping them develop novel products and production processes.

PRODUCED & DISTRIBUTED BY

Phyllon

pharmaceutical technology

Founded in Graz, Austria, in March 2016, to produce and distribute the innovative OSeeT technology, Phyllon's principals have extensive professional experience in the marketing, sales, distribution and servicing of pharmaceutical manufacturing equipment. Using their business experience and industry contacts, the team at Phyllon are well positioned to lead the industry in the field of Optical Coherence Tomography.

CONTACT

Phyllon GmbH
Inffeldgasse 13/4
A-8010Graz, Austria

Tel: +43 660 70 86 444

info@phyllon.at
www.phyllon.at