



Master thesis

Topic: Characterization of Gel Wax-Based Tissue Mimicking Phantoms: An Integrated Approach to Performance Qualification, Process Monitoring, and Stability Testing

Summary:

The characterization of gel-wax tissue-mimicking phantoms is crucial for advancing the field of optoacoustic imaging (OAI), particularly in process validation, monitoring, and stability testing. This study aims to advance the standardization of phantoms for multispectral optoacoustic tomography (MSOT) in OAI. The research is driven by the need for consistent quality in phantom production, adhering to Federal and Drug Administration (FDA) guidelines and international regulations, aiming to standardize phantom testing for OAI.

In this study, gel wax-based phantom samples were developed. A Process Failure Modes and Effects Analysis (pFMEA) was performed to identify and mitigate potential failure modes in the production process. The Double Integrated Sphere (DIS) was used to measure the reflectance and transmittance of the rectangular phantom material samples, each with a 2.5 to 3.5 mm thickness range in a controlled wavelength range of 400-900 nm. For each sample 25 data points were measured to ensure replicability and reproducibility. The collected data were then processed using Inverse-Adding Doubling (IAD) software to determine the optical absorption and reduced scattering coefficients. The results at the wavelength of 800 nm were used in the process characterization to optimize the factors that significantly influence the optical properties of the phantoms. The shelf life of the phantoms was systematically evaluated to determine their stability over time.

Design of Experiments (DOE) was used to identify the optimal factor levels for achieving the desired optical properties, and the manufacturing process's reliability and adherence to specifications were validated using the Operational Qualification and Performance Qualification (OQPQ) process. The shelf-life analysis confirmed the phantoms' durability and suitability for long-term use.

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