APPLICATION OF FOURIER-TRANSFORM INFRARED SPECTROSCOPY (FT-IR) FOR *Staphylococcus epidermidis* TYPING AS A TOOL FOR CONTAMINATION CONTROL STRATEGY IN A PHARMACEUTICAL INDUSTRY FACILITY

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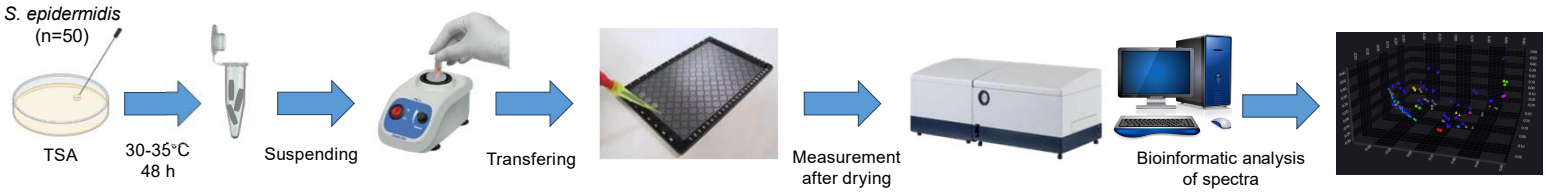
Introduction

The typing of micro-organisms in pharmaceutical factories often relies on expensive and time-consuming molecular techniques. So, the implementation of cheap, fast and reliable typing methods in the routine would speed up the investigation procedures improving the contamination control strategy. The Fourier-transform infrared (FT-IR) spectroscopy is a method that generates spectra, that enables microorganisms typing within 3 h.

Objective

This study aimed to evaluate the FT-IR for the typing of *S. epidermidis* strains isolated from an immunobiological pharmaceutical industry in Brazil.

Methodology



Results

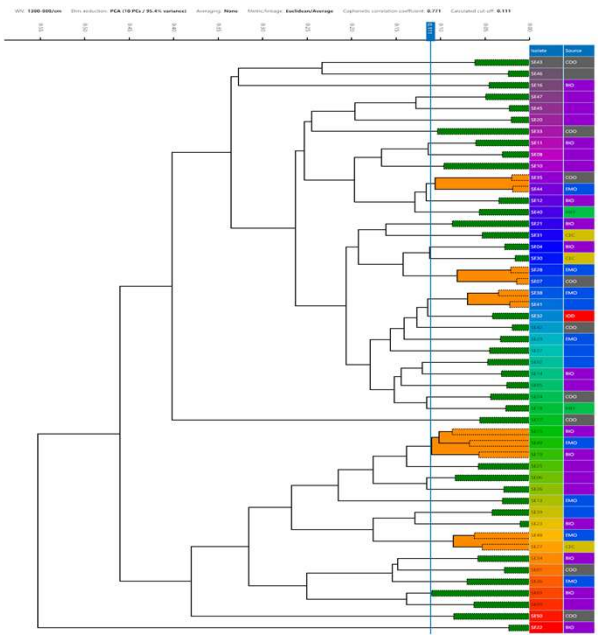


Figure 1 – Dendrograms obtained by clustering FTIR spectra for *S. epidermidis* (n=50) isolated from a pharmaceutical industry. The vertical dashed lines represent the cut-off value. Information regarding origin are provided. COC: certification of operator, BIO: bioburden analysis, EMO: environmental monitoring, MEF: medial fill, CEC: cell culture, IOD: investigation of deviation.

Forty-four FT-IR profiles were obtained, a ratio of 1.14 strain/profile (Figure 1). From the five clusters formed, Cluster 1, 2 and 3 (6 strains) were isolated from environmental monitoring of air and operators (EMO). Cluster 4 (3 strains) was isolated from EMO and bioburden assays, suggesting that the environment could be the main source of bacterial contamination in the product analyzed in bioburden assay. Cluster 5 (2 strains) was isolated from EMO and from a cell culture lineage used in quality control assays, suggesting that the environment could also be the main source of cell contamination. The identification of the Cluster in the Scatter Plot graphic is showed in Figure 2.

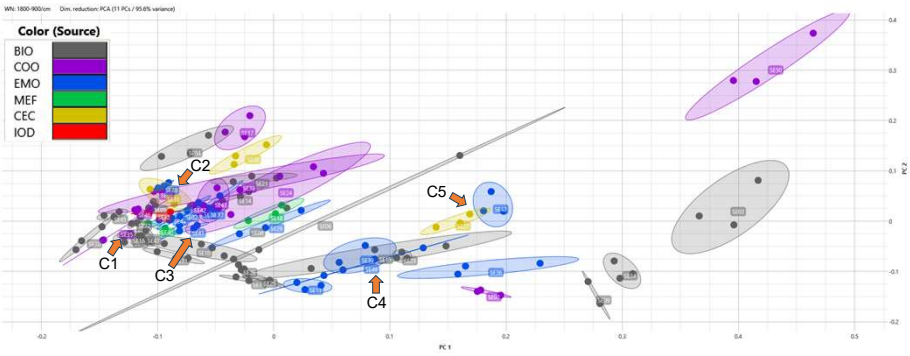


Figure 2 – Scatter Plot of Principle component analysis (PCA) obtained by clustering FTIR spectra for *S. epidermidis* (n=50) isolated from a pharmaceutical industry. Each spectrum is plotted according to its PC1 versus PC2 (principal component) values for x versus y, respectively.

LEARNING OBJECTIVES

FT-IR using IR Biotyper® seems to be a promising technique for *S. epidermidis* strains typing and tracking possible sources of contamination in the immunobiological facility evaluated in this study. This equipment allows the creation of a specific database for each bacterial species, which can be updated continuously and used for analysis by time space of specific product groups and/or areas in the facility, among others. The methodology applied in this study can be used as part of the contamination control strategy to develop preventive and corrective measures to eliminate microbial contamination.

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Instituto de Tecnologia em Imunobiológicos Bio-Manguinhos

INCQS Instituto Nacional de Controle de Qualidade em Saúde

CAPES

CIE Centro de Integração Empresa-Escola