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Development of method validation for microbial identification using MALDI-TOF MS

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Recently, emerging industry trends in the biopharmaceutical industry have included drug discovery, drug development, biosimilar study, and drug manufacturing. Microbial contamination of biopharmaceuticals has inevitably been considered to be a significant issue for the process of manufacturing, negatively impacting the drug's potency, stability, and efficacy. Conventional standard microbiological methods, such as 16S rRNA gene sequencing, biochemical testing, etc., are currently used for routine monitoring of biopharmaceutical bacterial contaminants from water, air, and environmental surfaces. However, the rapid expansion of the biopharmaceutical growth has brought new challenges in reducing the time required for microbial identification. We developed the in-house method validation for microbial identification using MALDI-TOF MS. The qualitative parameters, specificity, precision, reproducibility, intermediate precision, and robustness were performed using 6 known microorganisms that are *Bacillus subtilis* subsp. subtilis TISTR 1460, *Bacillus licheniformis* TISTR 1109, *Staphylococcus aureus* NCTC 10788, *Escherichia coli* DH5-alpha, *Pseudomonas aeruginosa* DMST 15501 and Candida albican NCPF 3179. All organisms were cultured in LB agar and incubated at 30°C for 24-48 hours. The single colony of each strain was smeared on MALDI plate, overlaid with 70% Formic acid and 40 mg/ml α-cyano-4-hydroxycinnamic acid (CHCA) in Diluent solution (Acetonitrile, Ethanol, DI water type II, Trifluoroacetic acid (1:1:1:0.1 v/v)). After dried, sample coated MALDI plate was directly analyzed by MALDI-TOF MS, resulting peptide mass fingerprint (PMF) of sample. The PMF of each organism was then compared to the PMF of database to identify microorganism using SARAMIS. For both genera and species, MALDI-TOF MS had a 100% overall accuracy in identification. In all tests, the confidential value percentages (%CV) were higher than 90%, which was within accepted limits. The use of MALDI-TOF MS together with SARAMIS database has the capability to revolutionize microbial contamination identification and thus minimize the risk of microbial contamination occurring in biopharmaceutical production process.

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