



PHENOTYPIC CHARACTERIZATION OF STENOTROPHOMONAS MALTOPHILIA AS A TRACKING TOOL FOR INVESTIGATION IN A PHARMACEUTICAL INDUSTRY

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RESUMO

Stenotrophomonas maltophilia is an opportunist human pathogen that represents a risk when found in microbiological analysis during the production chain of pharmaceuticals. The objective of this study was to evaluate the phenotypic profile of *S. maltophilia* strains as a tool for investigation in a pharmaceutical industry. Two hundred and sixty-four *S. maltophilia* strains isolated from 16 different areas (codified as A-P), from 2014-2021, from 10 different types of samples were evaluated: purified water (PWI, n=141), intermediate process solutions (IPS, n=48), active pharmaceutical ingredients (API, n=24), water for injection (WFI, n=16), 13 validation process samples (SVP, n=13), potable water (PTW, n=8), reagents (REA, n=7), environmental monitoring (EMO, n=4), intermediate product (INP, n=2), and final product (FPR, n=1). The strains were identified using the Vitek®2 with reliability $\geq 89\%$, and phenotypic profile resulted from 47 biochemical tests were categorized and evaluated with Bionumerics 8.0 for similarity coefficient calculation using Pearson correlation and clustering method UPGMA. The profiles that presented similarity $\geq 85\%$ were clustered in the same group. The Simpson's index (SI) was applied to calculate the resolution power of Vitek®2 for typing strains. The 264 strains were assigned in 59 phenotypic profiles (I-LIX) and the calculated SI was 0.91. Similarity analysis showed eight groups and three singletons: Group 1 (Profiles I, II, XXXVI, XXXIX, XLIII, LI, LII and LIII, n=23), Group 2 (Profiles XLIV and XLVI, n=2), Group 3 (Profiles V, XII, XIII, XVII, XX, XXXIII, XXXIV, XLI, XLVII, XLVIII, L, LIV and LV, n= 65), Group 4 (Profiles III, VII, XI, XIX, XVIII, XXV, XXVI, XXVII, XXIX, XXX, XXXV, XXXVIII, XLII, XLV and XLIX, n=132), Group 5 (Profiles IV, VIII, IX, X, XV, XVI and XXVIII, n=22), Group 6 (Profiles XIV, XXXI, XXXII, LVI, LVII and LIX, n=9), Group 7 (Profiles XXI and XXII, n=3), Group 8 (Profiles VI, XXIII and LVIII, n=3), Singleton 1 (Profile XL, n=1), Singleton 2 (Profile XXXVII, n=3) and Singleton 3 (Profile XXIV, n=1). Regarding the largest groups identifies (n>20), Group I was isolated in five areas mainly from water samples (n=13, 56.5%) and IPS (n=9, 39.1%). Group 3 was isolated in 11 areas mainly from water samples (n=41, 63.1%) and IPS (n=14, 21.5%), from 2015-2021. Group 4, the largest group, was found in 14 areas mainly from water samples (n=87, 65.9%) and IPS (n=25, 18.9%), from 2015-2021. These results indicate that the water used to produce IPS can be the source of contamination. Groups 5 was isolated in six areas mainly from water samples (n=12, 54.5%) and API (n=8, 36.4%) from 2015-2019, indicating that the water used to produce the API can be the source of

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contamination. In conclusion, the evaluation of the phenotypic profile of *S. maltophilia* was considered an interesting tool for a fast and initial investigation in a pharmaceutical industry, since it revealed possible common sources of contamination in the production chain. However, other genotyping methods as multi-locus sequence typing (MLST) are necessary in order to corroborate this results showing better resolution regarding the clonality origin of these strains.

PALAVRAS-CHAVE: epidemiology, MLST, molecular characterization, *Stenotrophomonas maltophilia*

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