

TITLE: ESTABLISHMENT OF METODOLOGY FOR *Candida albicans* PRODUCTION AS CERTIFIED REFERENCE MATERIAL USED IN QUALITY CONTROL FOLLOWING SERIES 30 GUIDELINES

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The species *Candida albicans* is the most pathogenic yeast and it is the most commonly found in systemic and superficial infections. Besides the clinical importance, this yeast is cited in several pharmacopoeias and official compendium for the control of quality culture media. Certified Reference Material (CRM) has great importance for laboratories' quality control, since its use has been key to achieving measurement results with assured metrological traceability. The biological CRM acquirement by Brazilian laboratories has been very difficult due to the absence of these materials in the national industry and the high costs related to import; in addition, there is the natural instability of microorganisms. This work aims to develop methodology for the production of *C. albicans* as CRM to be used in quality control of products, contributing to the advancement of the MRC production process in the biological area. These CRMs can be used in products quality control laboratories, such as the Central Laboratories of Public Health, for the laboratories of the National Quality Control Institute for Health and public and private institutions that perform products quality control tests in microbiology. The results presented concerns the project phase that includes the selection of a cryoprotectant and cultivation methodology suitable for the preservation of the fungus, in which the range Colony Forming Units (CFU) on the established rate after lyophilization is not greater than 100 CFU. After this phase, a pilot batch will be produced, so that the authentication test, homogeneity and stability are conducted. The results obtained in the periods before and after lyophilization were reproducible, indicating a positive implementation of the methodology both as regards the cryoprotectant selection and the cultivation methodology, thus the 20% skim milk was established as cryoprotectant. This work will contribute to the technological development and innovation of the *Coleção de Micro-organismos de Referência em Vigilância Sanitária* (CMRVS), a biological collection of Fiocruz, which will be part of the future Health Biological Resource Center at Fiocruz, which will lead the thematic area of Health in the Brazilian Network of Biological Resource Centers, currently coordinated by Fiocruz.

Keywords: Certified Reference Material, Quality Control, *Candida albicans*

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