

THE PHARMACEUTICAL APPROACH TO THE PROCESSING OF DONOR HUMAN MILK IN A HUMAN MILK BANK



S. FRAGA¹, C. CUNHA¹, C. SAMPAIO¹, S. PISSARRA², D. SILVA³, P. SOARES¹, T. SOARES¹, R. BARBOSA¹

¹UNIDADE LOCAL DE SAÚDE SÃO JOÃO, PHARMACY, OPORTO, PORTUGAL

²UNIDADE LOCAL DE SAÚDE SÃO JOÃO, NEONATAL INTENSIVE CARE UNIT, OPORTO, PORTUGAL

³UNIDADE LOCAL DE SAÚDE SÃO JOÃO, PEDIATRIC SERVICE, OPORTO, PORTUGAL

CONTACT: Susana Fraga | susana.fraga@ulssjao.min-saude.pt



WHAT WAS DONE?

Pharmacy implementation of the Donor Human Milk (DHM) processing circuit (by pasteurization) and its conditions.

WHY WAS DONE?

Human milk is the preferred feeding for newborns, especially preterm infants, due to their needs' specificity. When breast milk is not sufficient, which is common in neonatal intensive care units (NICU), DHM obtained from human milk banks (HMBs) is the best alternative. Its unique composition has nutritional and biological properties making it more than food, almost a medicine. ^{1,2}

Human Milk Banks (HMBs) must use rigorous quality assurance practices to protect infants and milk processing, and post-pasteurization procedures are important in maintaining high-quality breast milk and safeguarding its quality.

The compounding pharmacist has all the knowledge and experience needed to implement processing circuits based on good handling practices and sterile technique, combined with quality assurance procedures to ensure their safety.

HOW WAS IT DONE?



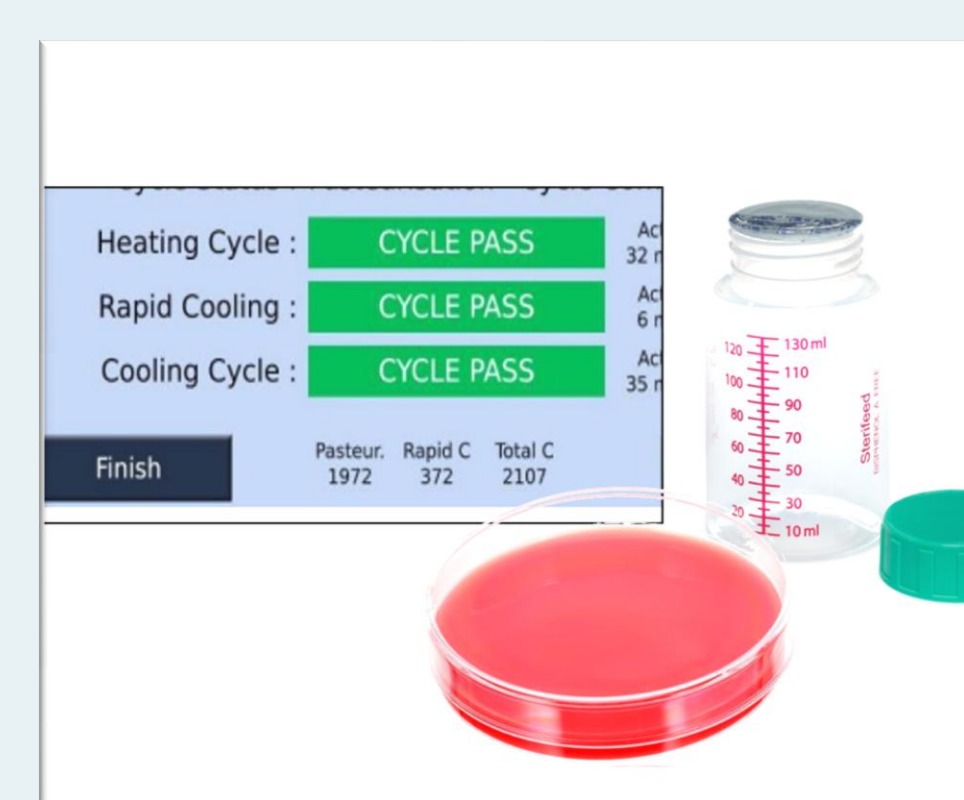
Bibliographical research and critical analysis of the functioning of HMB worldwide, with multidisciplinary meetings to define the best and most secure quality practices. ^{1,2,3,4}



Equipment choice, in accordance with recommendations and assessment of their technical requirements



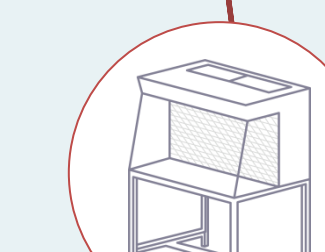
Adaptation of the informatic medical integrated system to the DHM prescription, processing, quality control and dispensing circuit.




Design of the DHM circuit based on good practices for the safe use of products of human origin and on a robust quality assurance plan.


WHAT HAS BEEN ACHIEVED?

 A DHM circuit was put into practice, with pharmacist intervention in DHM processing, quality control, and batch release.

 Procedures for aseptic handling, quality control with check points and risk analysis, packaging, and labeling of DHM were outlined.

 Work instructions were also established for handling equipment (pasteurizer, bottle sealer, laminar flow chamber) as well as procedures for cleaning facilities and material/equipment, with training sessions for the professionals involved.

 Guidelines for the correct use of equipment in accordance with its recommendations and technical requirements were established.

 The multidisciplinary circuit was adapted to the organizational management of the Neonatal Intensive Care Unit (NICU), HMB, and Pharmacy, certified on April, 18th 2023 according to ISO 9001:2015 recommendations.

WHAT NEXT?

Opening more HMB worldwide is an inevitability. Prevailing know how at the level of hospital pharmacies represent several advantages to these projects, based on experience and expertise in manipulating biological products and maintaining a controlled circuit based on safety and quality standards.

Poster PC13470



1. Weaver, G., Bertino, E., Gebauer, C., Groslien, A., et al. - Recommendations for the Establishment and Operation of Human Milk Banks in Europe: A Consensus Statement From the European Milk Bank Association (EMBA). *Frontiers in pediatrics*. vol.7, N° 53 (2019). Available <https://doi.org/10.3389/fped.2019.00053>

2. Moro, G. E., Billeaud, C., Rachel, B., Calvo, J., et al. - Processing of Donor Human Milk: Update and Recommendations From the European Milk Bank Association (EMBA). *Frontiers in pediatrics*. vol.7, N° 49. (2019). Available <https://www.frontiersin.org/articles/10.3389/fped.2019.00049/full>

3. European Directorate for the Quality of Medicines & HealthCare (EDQM) - Guide to the quality and safety of tissues and cells for human application. 4th edn. (2019) Council of Europe, Strasbourg.

4. Australian Government Department of Health and Aged Care. Operational guidelines for milk banks in Australia and New Zealand. In: Department of Health and Aged Care, ed; 2022. Available <https://www.health.gov.au/sites/default/files/documents/2022/07/operational-guidelines-for-milk-banks-in-australia-and-new-zealand.pdf>