

Feedback on nominative parenteral lipids-vitamins admixtures production using LOGIPREN® software

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Introduction

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Better control of microbiological contamination risk

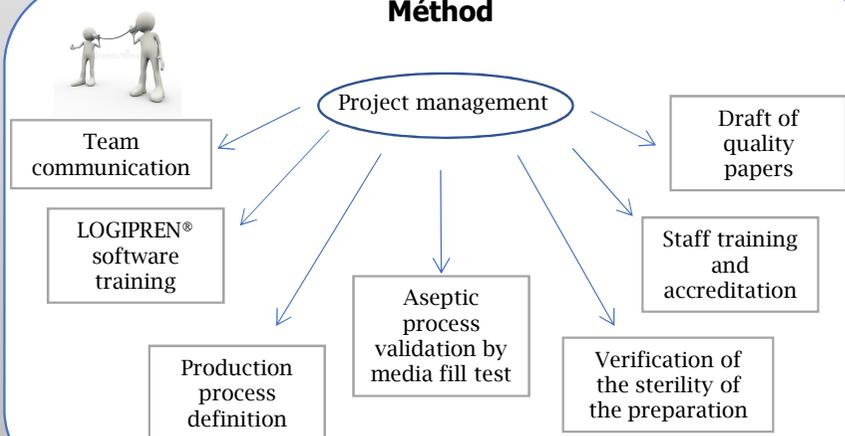


Syringes containing lipids-vitamins admixtures. Composition: Smoflipid® +/- Vitalipid® +/- Soluvit®

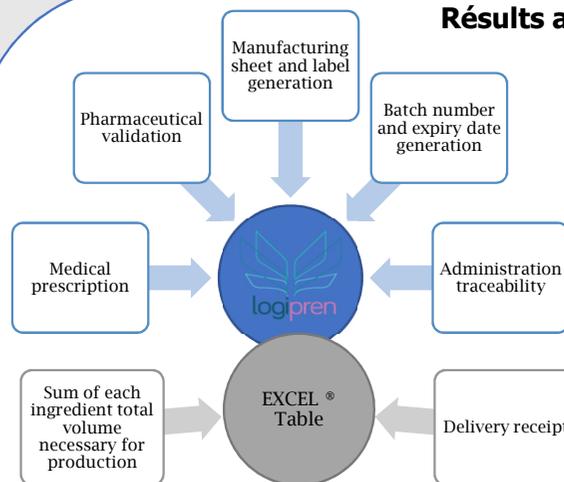
Nominative preparation allowing exact fit to newborn need.

Objective : To implement lipid-vitamins syringes production and control using LOGIPREN® software,

Méthod



Résultats and discussion



LOGIPREN® is easy to handle at each step,

We report one difficulty: to be in accordance with Fresenius compatibility data, Soluvit® powder must be firstly solubilized in Vitalipid®. LOGIPREN® software is not able to take into account the hidden contribution of Vitalipid® used to solubilize Soluvit®, this resulting in a slight overdose of Vitalipid®. Physicians approved this slight overdose.

Microbiological syringes stability

PVDF specific low binding membrane for oil and cream + adapted rinse steps with fluid K

Sterility assay

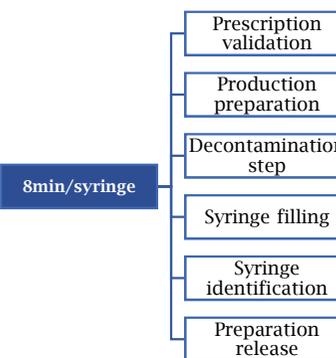
2.6.1 monograph of European Pharmacopeia 10th



Final syringe

Microbiological stability : 5 days in final packaging (3 parts PP Luer Lock syringe + stopper)

Production time assessment



Conclusion

After 4 months of use of LOGIPREN® software to produce lipids-vitamins parenteral mixtures, no significant problems were identified. Good coordination with neonatal NICU allows us to prepare syringes for the week-end by advance.