MUCOSECTOMY : FEASIBILITY STUDY OF THE AUTOMATED PREPARATION OF A STERILE SOLUTION OF 5/10% FRUCTOSE GLYCEROL

A. BOCQUILLON[1], L. GUIHENEUC[1], S. ROBIN[1], E. CLAPEAU[1], E. OLIVIER[1], M. BOURGET[1], N. CORMIER[1].
[1]CENTRE HOSPITALO-UNIVERSITAIRE DE NANTES, PHARMACIE, NANTES, FRANCE.

V07- ALL OTHER NON-THERAPEUTIC PRODUCTS

Why was it done ?

The digestive endoscopy department sought the expertise of pharmacotechnology to develop a **sterile hospital preparation** aimed at **facilitating mucosectomies**. This **hyperosmolar solution** assists in separating digestive mucus and submucus layers, facilitating polyp removal during endoscopy.

What was done ?

- To assess **producing** a 5% fructose, 10% glycerol sterile solution.
- To **prepare and control** 30 bags of 100 mL.

How was it done ?

Literature review :
- European Pharmacopoeia evaluation
- Rennes Hospital Center procedure analysis
- Civil Hospices of Lyon stability study[1]

Controls :
- Osmolality by measuring the cryogenic point
- pH by pH meter
- Sodium concentration by inductively coupled plasma optical emission spectrometry
- Gravimetric checks
- Sterility testing by filtration assay

Production stages in isolator.

Protocols were drafted, followed by test productions

Aseptic processing

Safety cabinet
- **Concentrated solution**
  - 150 g fructose
  - 240 mL non-sterile glycerol
  - 250 mL sterile 0.9% sodium chloride (NaCl)

Transfer : sealed erlenmeyer flask

Isolator
- Filtered (0.22 µm) into an empty 3L bag
- 0.9% NaCl was added via **peristaltic pump**
- Distributed into 100 mL bags

What was achieved ?

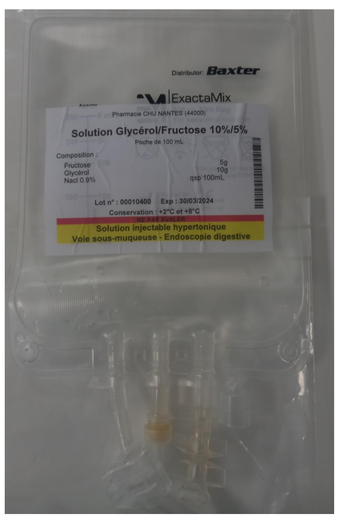
Solution feasibility ✓ Process efficacy ✓ Quality controls ✓

Osmolality (mOsmol/L)	pH	Sodium concentration (mmol/L)	Weight (g)	Density	Sterility test Day 14
1698.11 [±33.70]	5.64 [±0.11]	134.37 [±4.39]	103.42	1.06	✓

Conclusion and Relevance

Challenges :
- Non-sterile raw materials
- Peristaltic pump use in isolator
- Batch size, consumable volume
- Choice of suitable 0.22 µm filter reference
- Sodium measurements
- Difficulties in fructose and glycerol measurements

This study successfully demonstrated the **feasibility of producing** the hyperosmolar solution, outlined effective preparation processes, and established stringent quality controls for its **hospital-scale implementation**.



5% fructose / 10% glycerol 100 mL bag.

References

1. Tall ML, et al. Validation du procédé aseptique et étude de stabilité d'une préparation injectable de fructose (5 %)—glycérol (10 %) dans le cadre d'un programme hospitalier de recherche clinique portant sur le traitement curatif endoscopique

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