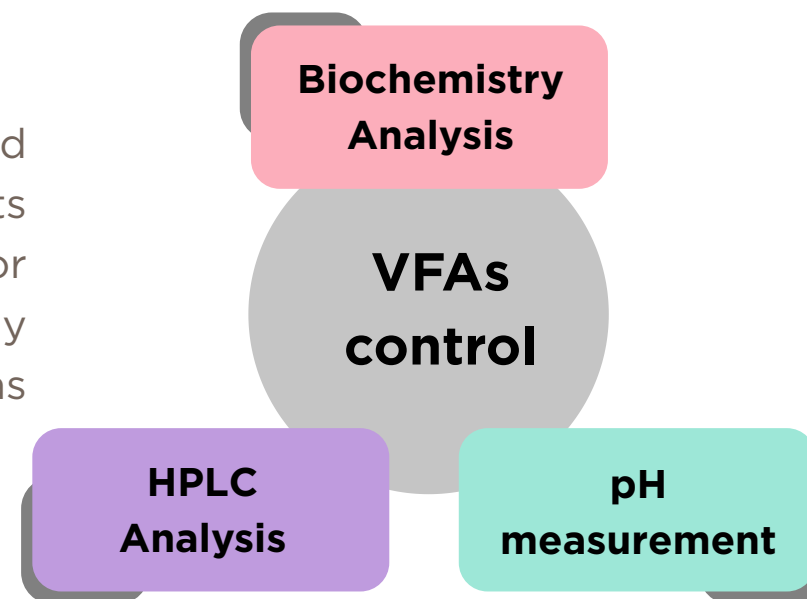
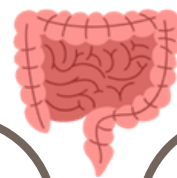


RISK MAPPING IN QUALITY CONTROL OF VOLATILE FATTY ACID SOLUTIONS: AN FMEA STUDY

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Volatile fatty acids (VFAs)—acetate, propionate, and butyrate—are molecular activators produced by colic fermentation and are essential for the survival and function of colonocytes. In patients with a stoma, this physiological supply is interrupted, VFA administration aims to compensate for this deficiency. As this is a non-sterile liquid preparation, the quality of patient care is directly based on the reliability of its analytical testing. A new multi-step quality control method was recently implemented to verify the concentrations of the three active ingredients in the solution.



OBJECTIVES

- Map the risks associated with the control of hospital preparations of VFA solutions
- Identify the critical stages of the process
- Assess the criticality of each situation
- Implement corrective measures

MATERIALS & METHODS

FMEA method (Failure Modes and Effects Analysis) to analyse the risks:

- Defining the stages of the control process
- Identifying the associated critical risk situation
- Defining the severity (1–5), frequency (1–5) and criticality (1–3) scales
- Rating each risk situation according to the scales
- Drawing up a criticality matrix (C1–C3)
- Implementation of corrective actions for level 3 scenarios

CONCLUSION

HPLC analysis is the control stage posing the greatest risk, accounting for 8 of the 22 risk situations (36.4 %), including 3 classified as criticality 3. The implementation of the proposed corrective measures must be followed by a reassessment of criticality, in order to validate their effectiveness and adjust them if necessary.

RESULTS

Process in 6 main stages:

Criticality matrix

	1	2	3	4	5
5					
4	1				
3	3			2	
2		4	2	3	
1		1		5	1

Criticality ranking.

C1	In acceptable state	No action required
C2	Tolerable when managed	A risk management monitoring system must be put in place
C3	Unacceptable	The situation must be rejected and risk-reduction measures must be taken; otherwise, the activity must be rejected

22 risk situations identified:

Criticality 1 - **5** RS
Criticality 2 - **14** RS
Criticality 3 - **3** RS

The 3 RSs with criticality level 3 correspond to the HPLC analysis stage

- **Air in HPLC lines** - Corrective action: systematic checks when changing mobile phase solutions
- **Incorrect computer recording of the sample in HPLC program** - detailed procedure for computerised sample recording
- **Use of a used HPLC column** - creation of a digital logbook to track analyses carried out using the column, to ensure traceability of its use