Quality review of sterile hospital preparations

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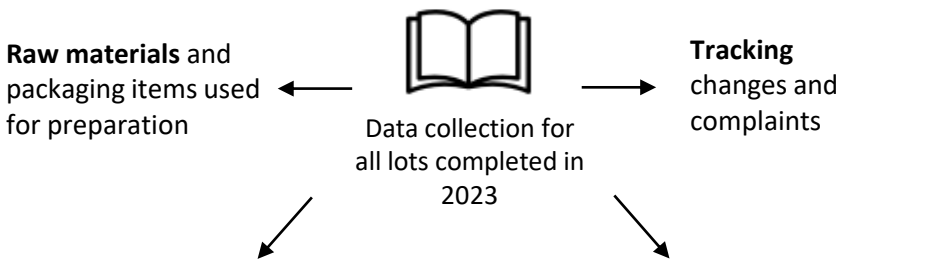
BACKGROUND AND OBJECTIVES

Good preparation practices recommend quality reviews. Quality reviews of sterile pharmaceutical preparations were conducted on an injectable neonatal rehydration solution, designated "AP ISO," produced via a sterile preparation process under laminar flow in a 50 mL autoclavable bottle, and on a sterile solution of fructose (5%) 12.5 g and glycerol (10%) 25 g and 250 mL produced via a sterile preparation process under laminar flow.

These reviews help us to identify product and process improvements.

MATERIALS AND METHODS



RESULTS

In 2023, 14 batches of AP ISO neonatal rehydration solution were produced, of which 2 were destroyed. Out of 4600 units planned, 4483 units were produced (97.5%) and 3212 units were released (69.8%).
For the sterile solution of fructose (5%) 12.5 g - glycerol (10%) 25 g - 250 mL, 13 batches were produced in 2023, of which 1 batch was destroyed. Out of 1560 units planned, 1560 units were produced (100.0%) and 1080 units were released (69.2%).

The deviations found on these preparations are presented in Table 1. All other parameters analyzed showed no deviation.

Preparation	AP ISO	Fructose glycérol
Deviation 1 / Deviation rating	Non-compliant autoclaving cycle Major deviation, non compliant	Non-compliant osmolality for batch 20230613-A Major deviation, non compliant
Deviation 2 / Deviation rating	Broken glass found at candling Major deviation, non compliant	Non-compliant sodium content in batch 20230613-A Major deviation, non compliant
Deviation 3 / Deviation rating	Broken bottles impacting production output Deviation to be declared but not blocking	Glycerol content for 5 non-compliant batches (outsourced dosage) Deviation to be reported but not blockin

Table 1: Reported batch deviations of sterile AP ISO and fructose glycerol solutions in 2023.

DISCUSSION AND CONCLUSION

These RQPPs led to the definition of improvement actions: (i) rearrangement of vials during the depyrogenation and sterilization stages to avoid broken vials, (ii) decision to remove the entire container of vials from production in the event of broken vials found in production, (iii) internalization of glycerol quantification (iv), acrolein quantification, an aldehyde produced by thermal degradation of glycerol, to be added to the controls of the sterile solution of fructose (5%) 12.5 g - glycerol (10%) 25 g - 250 mL.