15 à 44

To monitor

Acceptable

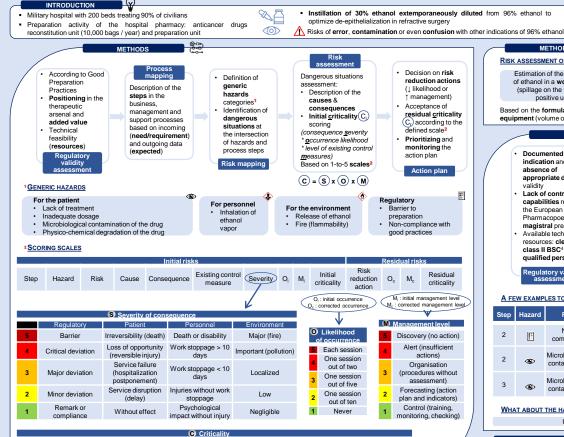
Technical and regulatory feasibility of a new sterile preparation posing health and environmental risk:

the case of 30% ethanol eye drops



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Risk situations not acceptable as they stand → Analysis and treatment actions

Lower risk situations → Identification and monitoring actions

Low-risk situations acceptable as they stand

OBJECTIVES ☐ To ensure medication management safety, this study aimed to evaluate the technical and regulatory

feasibility of preparing 30% ethanol eve drops within the hospital pharmacy, considering the sterility requirement of ophthalmic preparations and the safe handling of concentrated ethanol **METHODS**

RISK ASSESSMENT OF CONCENTRATED ETHANOL HANDLING

Estimation of the evaporation rate of ethanol in a worst case situation (spillage on the work surface and positive uncertainty)

Estimation of ethanol concentration in the working atmosphere Estimation of ethanol volumetric percentage in the working atmosphere

Compared to occupational exposure Compared to lower flammability limit

· 14 actions including

Distribution of the initial criticality

of risk situation

Distribution of the residual

criticality of risk situations

8 priorities

To be treated . To monitor

Based on the formulas issued by the French National Institute for Research and Safety (ED 5068), the qualification data for the premises and equipment (volume of the room, air change rate, work surface, etc.) and the toxicological data sheets for ethanol

RESULTS Documented medical

- indication and absence of appropriate dosage → validity Lack of control
- capabilities required by the European Pharmacopoeia > magistral preparation
- Available technical resources: cleanroom3. class II BSC4 and
- qualified personnel Regulatory validity assessment

situations identified for the 29 substeps and 9 aeneric

hazards

Risk mapping

54 risk

- preparation 4. Production 5. Packaging
- 6. Quality control Storage

· 7 steps:

1. Prescription

production

resources

3. Production

2. Control of

29 sub-steps

cleanroom: supplied with filtered air 4BSC : biosafety cabinet

42 situations

- analyzed (others having overlapping causes or hazards)
- 14 situations considered
- unacceptable and to be addressed

To be treated . To monitor . Acceptable

Action plan

A FEW EXAMPLES TO HELP YOU SEE THINGS MORE CLEARLY?

compliance No preparation file of the file	itep	C,	Н	p Hazard	Hazard	Hazard Risk	Cause	0	Consequence	S	Existing control measure	M	Ci	Risk reduction action	C,
2 wind contamination primary packaging contamination materials primary packagin materials wind	2	tion 6		F	¥F	Non- compliance	No preparation file	O _i 5 O _c 1	Major deviation	3			60	Drafting a preparation file	6
Microbiological BSC cleaning not U.5 Non-sterile product	2			●	●		primary packaging			4			100	Supply of sterile primary packaging materials	8
	3	8		■	●					4	(BSC not used, so no		100	Microbiological validation of equipment cleaning	8

WHAT ABOUT THE HANDLING OF CONCENTRATED ETHANOL?

Use under defined working conditions \rightarrow No risk to personnel or the environment

DISCUSSION & CONCLUSION

- √ Implementation of a new magistral sterile preparation with √ It could be further enhanced by a self-assessment of good controlled risk for patients, personnel and the environment
- ✓ Medication management safety ensured

practices compliance and direct atmospheric monitoring of ethanol concentrations in the working area