

THE RISK MANAGEMENT OF THE PHARMACY PREPARATIONS IN THE HOSPITAL PHARMACIES



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What was done?

The quantitative risk assessment of the pharmacy preparations for stock in hospital pharmacies (HPs) in accordance with Resolution EDQM CM / Res (2016) 1;

- specify the decision criteria for the risk assessment;
- the risk management of the pharmacy preparations for stock in the country;
- to design a check list of the risk assessment for extempore preparations.

What has been achieved?

A total of 170 types of medicines are being prepared in HPs. One HP had the result of the risk \geq 100 when preparing ophthalmic medicines. Annex A is a check list designed to assess the risk of extempore preparations.

Table 3- part HP 2¹, HP 3², HP 6³

Why was it done?

The quality and safety standards of pharmacy preparations are not harmonised throughout Europe. They fall under the national competencies of individual European countries.

The impact of application of the Resolution EDQM CM / Res (2016) 1 in HPs vs. introduction of GMP.



How was it done?

Out of the total number of 53 hospital pharmacies contacted, 5 pharmacies sent a suitable file.

Preparation	API	Supply	Preparat. process	Dos. form	Pharmacolog. effect	Production volume	Result
Solutio iodi aquosa 100g ¹	1	1	2	1	3	1	6
Suppositoria metronidazoli 500,0 mg 100pcs ¹	1	1	2	3	3	1	18
Coll. tetracaini 0.05% ²	1	1	5	4	3	5	300
Supp. metronidazoli 500mg pro adultis							
(Massa A) ³	1	1	2	3	3	2	36

Annex A Request for individual preparation extempore

Request for individual preparation extempore

Part A: Essential informations Name and surname of patient:		of birth:
Ward:	Weight of patient:	
Pharmacist:	Sienature	Date:
Physician:	Specialisation:	Date:
Required medicine:		

Name/ API	Dosage form	Route of administration	Dose	Length of treatment	Inpatient/ outpatient	

Clinical evidence of use / therapeutic indication:

Part B: Decision about preparation

Is it available alternative dosage form?	YES / NO
Is it available medicine in different dosage form?	YES /NO
Is it available alternative registered medicine?	YES / NO
Is it available standard preparation procedure? (from literature / own)	YES / NO
Is it possible any alternative preparation procedure? (from tablets, injections p.o.)	YES / NO
Is the drug registered in this indication?	YES / NO
Do the substances (API/ auxiliary) have required quality?	YES / NO
Can the analysis or identity test of substances be done?	YES /NO
Can the preservition for individual preparation he changed for standard one? (nhe	maconosia proc

Table 1 - part List of preparations

	Preparation	Package (g/pc)	Pieces (year)	Venena/ Separanda / Inoxia	Sterility	No therap. effect	Supply (Int/ Ext)	HP 1	HP 2	HP 3	HP 4	HP 5	HP 6
1	Cremor cum acido lactico	60,5	20	Ι			Ι	X					
		100	50	Ι			Ι	X					
3	Pasta cum olei iecoris aselli	50	100	Ι			Ι				X		
		3000	15	Ι			Ι						x
8	Solutio argenti nitratis aquosa	10,1	10	S			Ι	X					
21	Coll. tetracaini 0.5%	10g	330	S	X		Ι		X				
60	Stylli phenobarbit. 0,01g	0,51	310	S			Ι		X				
80	Digoxini plv. 0,015mg	30	10	V			Ι				X		
152	Sol. formaldehydi 2%	1000	13	Ι		X				X			

YES / NO magistrales Comments:

Part C: Risk assessment

Use the matrix 1. Quality risk (formulation and stability)	v / middle / hieh
Notes:	, means , mpr
2. Clinical risk (safety and efficacy) lov	w / middle / high
Notes:	
3. Safety risk (hazardous substances) lov	v / middle / high
Notes:	
Overall risk assessment: low	/ middle / high
Part D: Approval	
Decision of preparation of medicine	. YES/NO
Signature:	Date:
Low and middle risk medicines approved by chief pharmacy assistant:	
N	lame
High risk medicines approved by pharmacist with specialisation in general pharmacy: .	Name





Table 2 - part Specified decision criteria for risk analysis

Figure 1 Algorythm of risk assessment and risk management

	yes	1			
Content of API	no	0			
1. Type of preparation/ dosage form		- I			
parenteralia					
inhalations, sterile dosage forms (ophtalmic preparations)					
enteral dosage forms					
topical preparations					
2. Volume of production per year (un	its)				
liquid dosage forms /kg, solid dosage (powders) /pcs of packages	forms > 2000	5			
oral solid dosage forms /pcs	> 120 000	5			
rectal dosage forms /pcs	> 40 000	5			
topical dosage forms /g	> 200 000	5			
ophtalmic dosage forms /g	> 200	5			
3. Pharmacological effect of API					
venena					
separanda					
inoxia					
4. Process of preparation					
aseptic filling					
final sterilisation					
dissolution, mixing (not reconstitution), dilution					
filling (nonsterile medicines)					
5. Supply					
Externally		5			
$I:E \approx 1:2$					
$I:E \approx 1:1$					
$I:E \approx 2:1$					
Internally					

System description and border determination **Risk identification** and possible consequences ſ **Risk estimation**







What next?

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The aim of using the document is to be a guideline for hospital pharmacies of the country. The management is and will be forced to consider its introduction or to use another model: hospital - GMP / outsourcing / central pharmacy preparing and distributing.







european association 25th EAHP Congress 2020, Gothenburg, Sweden

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