POST CE MARKING MARKET SURVEY : the French experience on peracetic acid products used for medical devices manual disinfection

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Introduction

- Medical devices market survey is one of the main tasks of a dedicated unit within the French competent authority (Afssaps) : this kind of survey is mainly triggered on the request of the French Ministry of Health.
- The French regulation, related to prion transmission prevention, issued in march 2001 (“circulaire n° 138 du 14 mars 2001”) recommends the cessation of use of glutaraldehyde disinfectants due to the fixative properties of this compound on proteins. As a matter of consequence, a market survey has started end of 2001 on peracetic acid manual disinfectants, the only alternative currently on the French market.

Purposes

- identify CE marked peracetic acid products intended to the thermosensible medical devices disinfection,
- evaluate these products against a defined list of parameters in comparison with standards when these do exist :
  - **efficacy** : European standards have been used for bactericidal, fungicidal and mycobactericidal activities, French standards for virucidal, bactericidal in clean conditions and sporicidal activities,
  - **stability** : this parameter has been strongly focused due to the well known instability of peracetic acid solutions ; lack of standardisation
  - **compatibility** with medical devices, especially endoscopes ; lack of standardisation
  - **toxicity** of the products and issues for healthcare workers protection ; standards do exist

Methodology

chronology of the market survey

1. october 2001 : creation of an experts working group (WG) attended by hygienists, microbiologists and toxicologists
2. first assessment of manufacturer’s documentation by the WG
3. choice of parameters to evaluate
4. implementation of a list of questions (items) for each parameter of the assessment
5. list sent to manufacturers
6. responses analysis
7. requests for additional studies or information
8. presentation of the final results to manufacturers and discussion (contradictory period)
9. may 2004 : issue of the market survey report with the agreement of manufacturers

first list of items used for the assessment

PRESENTATION	Liquid / powder / ready to use / to be mixed or diluted - With or without testing strips - Packaging - Active compounds concentration (PA, HP)
SCOPE	Medical devices involved and not involved
FORMULATION	Complete formulation of the different products and the solution to be used
PREPARATION	Preparation protocol for the solution to be used
CE MARK	Certificate – Date of issue – Notify body – Class of the medical device
EFFICACY DATA	Contact times for high and intermediary levels disinfection (French definition)
	Tests performed to demonstrate antimicrobial activity at the defined contact time and for routine use concentration
	Minimal effective concentration of the product
RINSING	Rinsing protocol and justification
SAFETY AND TOXICOLOGY DATA	Safety data sheet
	Individual and collective issues for healthcare workers protection : need and characteristics of this equipment
	Tests OCDE performed to evaluate the toxicity of products and the solution to be used (primary skin irritation, ocular irritation, skin sensibilisation, ingestion)
	Evaluation studies of healthcare workers respiratory exposition to the solution to be used (HP, PA, AA, ...) with measures of limit values
STABILITY in packaging	Life-time of the products in packaging
	Life-time of the products after opening the packaging
	Storage conditions (temperature, light, humidity) before and after opening the packaging
	Studies performed to demonstrate the stability of the products in limit storage conditions
STABILITY in routine use conditions	Life-time of the solution to be used in the disinfection bath
	Maximum number of endoscopes for one disinfection bath
	Studies performed to demonstrate the stability of the solution to be used taking into account of the different interfering factors (temperature, aeration, water, proteins, ...)
	Stability tests performed *in situ*
	If testing strips are proposed : instructions for use, studies performed to demonstrate the specificity and colour changing range of the strips
ENVIRONNEMENT	Processing of waste generated by solutions and disinfection bath
COMPATIBILITY with materials	List of materials compatible or not with the solution to be used
	Tests performed to evaluate the compatibility with metals, polymers, plastics, resin, glue, varnish,...
COMPATIBILITY with medical devices	Studies performed by endoscopes manufacturers (scope : new endoscopes, existing endoscopes initially processed with glutaraldehyde)
	Studies performed to evaluate the consequences of a full disinfection process using the disinfectant solution
COMPATIBILITY with others products	List of non compatible products and justification : disinfectants or detergents used in the pre-process phase, rinsing water, ...
	Studies performed to demonstrate compatibility of the solution with others products

PA : peracetic acid HP : hydrogen peroxide AA : acetic acid

Results

products evaluated and not anymore on the French market
(by decision of manufacturers)

Product	Hydraseptic®	Peralkan®	Perasafe®
Manufacturer	Hydrex	Alkapharm	Biocordis
Type of product	Liquid ready to use	Liquid ready to use	Powder to be diluted
Testing strips	yes	yes	not known
Life-time in routine use conditions	7 days	7 days	24 hours
Problem detected	Inadequate testing strips Peracetic acid concentration not tested in the final product	Productor subcontractor not properly evaluated	Informations requested not transmitted

products evaluated and still on the French market

Product	Dynacide PA®	Nu Cidex®	Anioxyde® 1000	Bioxal® M
Manufacturer	Rivadis	J & J Medical	Anios	Seppic
Type of product	Powder to be diluted	Liquids to be mixed	Liquids to be mixed	Liquid ready to use
Life-time in routine use conditions*	10 hours	24 hours	7 days	7 days
Use restriction (Afssaps)	4h/10 endoscopes	8h/20 endoscopes	50 endoscopes	50 endoscopes
Testing strips	no	no	yes	yes
Frequency of strip testing (Afssaps recommendation)	NA	NA	Every four hours	Every four hours

* Manufacturer claim

products still in the evaluation process

Product	Anioxy® Twin	Endocide®	Sekusept Aktiv®
Manufacturer	Anios	Prodene Klint	Paragerm/Ecolab
Type of product	Liquids to be mixed and diluted	Liquid ready to use	Powder to be diluted
Testing strips	yes	yes	yes
Life-time in routine use conditions	24 hours	7 days	24 hours

Discussion

- Confirmation of the criticality of the stability aspects of the disinfectants, particularly in routine use conditions.
- Responsibility of the manufacturer : they shall better demonstrate how to maintain efficacy of such instable products (for example, by assessing the influence of different interfering parameters such as temperature, number of endoscopes, aeration, ...).
- Responsibility of notify bodies : need to be aware of the specific requirements for medical devices disinfectants and to take them into account in their conformity evaluation procedures.

Conclusion

- Need to consider validation of performance of medical devices disinfectants
- Lack of adequate standards to evaluate some of the characteristics of disinfectants

>>> Afssaps has recently developed a methodology for the stability assessment of medical devices disinfectants in routine use conditions : the protocol is in the process of being tested on the selected products and may lead to standardisation in the future.

In preparation :

- for the short term period, continue of the market survey on new peracetic acid disinfectants,
- for the long term period, issue of the list of requirements and items used for the survey : for the attention of manufacturers (who intend to market new products) and notify bodies (for the purpose of CE mark delivery).

The report of this market survey is available on the Afssaps web site : **http//: www.afssaps.sante.fr.**