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 medical 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 sporidic 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

- October 2001: creation of an experts working group (WG) attended by hygienists, microbiologists and toxicologists
- First assessment of manufacturer’s documentation by the WG
- Choice of parameters to evaluate
- Implementation of a list of questions (items) for each parameter of the assessment
- List sent to manufacturers
- Responses analysis
- Requests for additional studies or information
- Presentation of the final results to manufacturers and discussion (contradictory period)
- May 2004: issue of the market survey report with the agreement of manufacturers

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

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

- Product
  - Type of product
  - Manufacturer
  - Testing strips
  - Life-time in routine use conditions
  - Problem detected

products evaluated and still on the French market

- Product
  - Type of product
  - Manufacturer
  - Testing strips
  - Life-time in routine use conditions
  - Use restriction

products still in the evaluation process

- Product
  - Manufacturer
  - Testing strips
  - Life-time in routine use conditions

Evaluation studies of healthcare workers respiratory exposition to the solution to be used (HP, PA, HP). Individual and collective issues for healthcare workers protection: need and characteristics of equipment

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 the packaging

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
- Stability tests performed in situ
- For existing strips pre-prepared: instructions for use, studies performed to demonstrate the specificity and colour changing range of the strips

ENVIROMENTAL TESTS

- Processing of waste generated by solutions and disinfection bath

COMPATIBILITY with materials

- List of materials compatible or not with the solution to be used

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
- Studies performed to demonstrate compatibility of the products with others products

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

Methodology

first list of items used for the assessment

<table>
<thead>
<tr>
<th>PRESENTATION</th>
<th>SCOPE</th>
<th>FORMULATION</th>
<th>PREPARATION</th>
<th>CE MARK</th>
<th>EFFICACY DATA</th>
<th>RINSING</th>
<th>SAFETY AND TOXICOLOGY DATA</th>
<th>STABILITY in packaging</th>
<th>STABILITY in routine use conditions</th>
<th>ENVIROMENTAL TESTS</th>
<th>COMPATIBILITY with materials</th>
<th>COMPATIBILITY with others products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid / powder / ready to use / to be mixed or diluted</td>
<td>Medical devices involved and not involved</td>
<td>Complete formulation of the different products and the solution to be used</td>
<td>Preparation protocol for the solution to be used</td>
<td>Certificate – Date of issue – Notify body – Class of the medical device</td>
<td>Contact times for high and intermediary levels disinfection (French definition)</td>
<td>Rinsing protocol and justification</td>
<td>Safety data sheet</td>
<td>Life-time of the products in packaging</td>
<td>Life-time of the products after opening the packaging</td>
<td>Storage conditions (temperature, light, humidity) before and after the packaging</td>
<td>Studies performed to demonstrate the stability of the products in limit storage conditions</td>
<td>Studies performed to demonstrate compatibility with metals, polymers, plastics, resin, glue, varnish, ...</td>
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<td>(Package - Active compounds concentration (PA, HP))</td>
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**REFERENCES**