

SUMMARY OF TEST RESULTS

ENDOHIGH[®] PAA IN VITRO TEST

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Title : EndoHigh[®] PAA Summary of the disinfectant performance
Laboratory : Chemische Fabrik Dr. Weigert GmbH & Co KG by Dr. Johannes Lenz

1. Introduction

EndoHigh[®] PAA is a liquid high-level disinfectant based on peracetic acid used for machine-based reprocessing of flexible endoscopes. **EndoHigh[®] PAA** has a bactericidal, fungicidal mycobactericidal virucidal and sporicidal activity.

EndoHigh[®] PAA also has the potential to kill bacterial spores. The disinfecting activity was proven and confirmed according to DIN EN 14885. **EndoHigh[®] PAA** conforms to the requirements of disinfectants for flexible endoscopes according to DIN EN ISO 15883 part 4.

2. Methods

The disinfecting activity can be proven with the European Standards of CEN/TC 216 „Chemical Disinfectants and Antiseptics“, which are harmonized in Europe. The application is described in the European Standard EN 14885.

According to EN 14885 the bactericidal, fungicidal, mycobactericidal, virucidal and sporicidal activity was confirmed by the following methods:

bactericidal:	EN 13727, EN 14561
fungicidal:	EN 13624, EN 14562
mycobactericidal:	EN 14348, EN 14563
virucidal:	EN 14476
sporicidal:	EN 13704

As **EndoHigh[®] PAA** is used as disinfectant for cleaned medical devices, all microbiological tests were made under clean conditions.

3. Results

According to EN 14885 **EndoHigh[®] PAA** was proven on bactericidal, fungicidal, mycobactericidal, virucidal and sporicidal activity under clean conditions, a temperature of 35°C and 5 minutes time of action.

The effective concentrations of the different tests are shown in the following table.

Activity (35°C, 5 min)	Method	Effective concentration	Expert opinion
bactericidal	EN 13727	0,25%	Dr. Pitten, 21/10/15
	EN 14561	0,10%	
fungicidal	EN 13624	0,10%	
	EN 14562	0,75%	
mycobactericidal	EN 14348	0,75%	
	EN 14563	0,10%	
virucidal	EN 14476	1,30%	Dr. Steinmann, 20/10/15
sporicidal	EN 13704	1,00%	Dr. Pitten, 23/10/15

4. Summary and evaluation

According to the present results, the disinfectant **EndoHigh® PAA** fulfils the criteria of the requirement of EN 14885 with a bactericidal, fungicidal, mycobactericidal, virucidal and sporicidal activity under the recommended conditions of use:

temperature: 35°C time of action: 5 min concent ration: 1,3% (13 ml/l)

References

Microbiological expert opinions

1. Bactericidal activity according to EN 13727 and EN 14561, Dr. Pitten
2. Fungicidal activity according to EN 13624 and EN 14562, Dr. Pitten
3. Mycobactericidal activity according to EN 14348 and EN 14653, Dr. Pitten
4. Virucidal activity according to EN 14476, Dr. Jochen Steinmann
5. Sporocidal activity according to EN 13704, Dr. Pitten

Literature

- DIN EN ISO 15883 part 4, Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
- EN 14885, Chemical disinfectants and antiseptics - Application of European - Standards for chemical disinfectants and antiseptics
- DIN EN 13727, Chemical disinfectants and antiseptics– Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area– Test method and requirements (phase2, step1)
- EN 14561, Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area – Test method and requirements (phase 2, step 2)
- DIN EN 13624, Chemical disinfectants and antiseptics– Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area– Test method and requirements (phase2, step1)
- EN 14562, Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area – Test method and requirements (phase 2, step 2)
- DIN EN 14348, Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants – Test methods and requirements (phase 2, step 1)
- EN 14563, Chemical disinfectants - Quantitative carrier test for evaluation of mycobactericidal activity of chemical disinfectants for instruments used in medical area – Test method and requirements (phase 2, step 2)
- EN 14476, Chemical disinfectants and antiseptics - Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine. Test method and requirements (phase 2/step 1)
- EN 13704 „Chemical disinfectants and antiseptics – sporocidal activity – Test methods and requirements (Phase 1 / Step 1)“