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Study report number 222070803

23/02/2009

Study report

Title	Study of disinfectant efficacy by the microbe carrier test under simulated conditions of use
Test item	Cyber Clean ® with Benzalkonium Chloride + Didecyl dimethyl Ammonium Chloride CAS 7173 – 51 - 5
Batch number	KR08/004
Test facility	CONFARMA FRANCE SARL Zone Industrielle Rue du Canal d'Alsace F-68490 HOMBURG France
Sponsor	Joker AG Industriezone Postfach 69 CH 3210 Kerzers

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certified according to **GMP, cGMP (FDA), GLP**
FDA C. F. numbers 9614423 and 9615669
Etablissement pharmaceutique N° M 07/173
ISO 9001, ISO 17025, ISO 14001, OHSAS 18001

Study report number 222070803

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1. General information

1.1. Sponsor

Joker AG
Industriezone
Postfach 69
CH 3210 Kerzers

1.2. Study Monitor

Mr. René H. Dietrich
René H. Dietrich Consulting
Seewiesenstrasse 10
Postfach 18
CH- 8597 Landschlacht

1.3. Test facility

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This test facility is licensed to conduct animal trials in accordance with Order No. B 68-144-03 of the French Republic dated November 2nd 2004, for the testing of medicines under Number M 07/173 in accordance with the approval from the "Agence Française de Sécurité Sanitaire des Produits de Santé" dated September 20th 2007, and acknowledged as an "acceptable laboratory" by the FDA, C.F. numbers 9614423 and 9615669.

The test facility was classified to comply with the requirements of good laboratory practice, status A (in conformity with GLP) as declared by the certificate from the "Agence Française de Sécurité Sanitaire des Produits de Santé" dated May 6th 2008.

The test facility is certified for testing medical Products by the Agence Française de Sécurité Sanitaire des Produits de Santé and was classified to be compliant to the Good Manufacturing Practice as declared by the certificate number HPF/FR/210/2007 from the "Agence Française de Sécurité Sanitaire des Produits de Santé" dated October 1st 2007.

Furthermore CONFARMA is certified according to ISO 9001, ISO 17025, ISO 14001 and OHSAS 18001, i.e. the norms for Quality, Security, Hygiene and Environment as declared by the certificate number 2008/09/99 from the certification organism "Global Quality Cert - GQC" dated September 19th 2008.

1.4. Report number

The final report number, 222070803 was attributed according to the registration systems described in the corresponding CONFARMA procedures.

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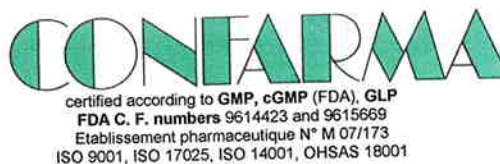
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1.5. Responsibilities

The study director was responsible for the test system, for the assays performed, the interpretation and the documentation of the results.

Study Director	J. De Geest, Biologist
Test facility Management	R. Holzinger, Microbiologist
Quality Assurance	K. Wechsler, Ph.D., Pharmacist / N. Weber, Microbiologist
Study personnel	R. Ringenbach, technician

1.6. Study methods

The study was conducted according to the indications in the USP, chapter <1072> « Disinfectants and antiseptics » [1] and according to the CONFARMA Protocol number 222070803 [8] which is based on the guideline of the German Society for Hygiene and Microbiology (DGHM) from 1991 [2] the norms EN 1040 « Chemical disinfectants and antiseptics Basic bactericidal activity Test method and requirements (phase 1) » [3] and EN 1275 « Chemical disinfectants and antiseptics : Basic fungicidal activity : test method and requirements (phase 1) » [4] as well as the norm EN 13697 « Chemical disinfectants and antiseptics — Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas — Test method and requirements without mechanical action (phase 2/step 2) » [5].

1.7. Objective of the study

The objective of the study was to determine the degree of disinfectant efficacy for the test item applied to **plastic surfaces** under simulated conditions of use in accordance with the USP, chapter <1072> [1], the guideline of the German Society for Hygiene and Microbiology (DGHM) [2] and the norms EN 1040 [3], EN 1275 [4] and EN 13697 [5].

Plastic surfaces were chosen in accordance with the sponsor in order to simulate the surfaces of electronic equipment such as computer keyboards or mobile phones for which the test item should allow an effective disinfection.

1.8. Dates

Study initiation date : August 4th 2008 (the date the study monitor signed the validation protocol)

Experimental starting date : August 18th 2008

Experimental completing date : December 18th 2008

Study completion date : December 19th 2008

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1.9. Archiving

The raw data and a copy of the report will be stored in the archives of CONFARMA France for a period of 11 years.

The originals of the final study report will be returned to the sponsor who has the full responsibility for archiving.

2. Summary

As an overall summary of the results obtained it can be concluded that the test item complies with the acceptance criteria of the norm EN 13697 [5] of superior or equal to 4 log₁₀ reduction with the action time of 1 minute and 5 minutes for living bacteria *Escherichia coli*, *Pseudomonas aeruginosa* and *Staphylococcus aureus*. In this context it has to be mentioned that the norms EN 1040 [3] and EN 13697 [5] recommend an action time of 5 minutes for living bacteria.

For the yeast *Candida albicans*, the test item fulfilled the acceptance criteria after 1 minute and 5 minutes of action time.

For the mould *Aspergillus niger*, which was used within the assay under the form of fungal spores, the test item did not comply with the acceptance criteria after 1 minute and after 5 minutes of action time.

The overall efficacy of the disinfectant is very satisfying for living bacteria as well as yeasts after the action time of 1 minute and 5 minutes, respectively.

For *Aspergillus niger* for which no significant reduction was observed, it can be postulated that this mould, used under the form of fungal spores disposes of a very effective resistance which allows survival even in the presence of the disinfectant.

Therefore the norms EN 1275 [4] and EN 13697 [5] both indicate an action time of 15 minutes in order to allow the disinfectant to be also effective against fungal spores.

3. Introduction

The present study allows to determine the degree of disinfectant efficacy for the disinfectant applied to surfaces under simulated conditions of use.

The method used in this study does not serve to prove the efficacy of wiping a surface with disinfectant as this "mechanical" disinfection technique would already eliminate the majority of the micro-organisms present on the microbe-carriers. Selected test organisms (only standard strains of official culture collections and no micro-organisms isolated in the production rooms during environmental monitoring) at a concentration of 10⁷ to 10⁸ micro-organisms per carrier are brought onto microbe carriers. The ready-made disinfectant solutions to be examined are then applied "in situ". After the prescribed periods of action, the test organisms are washed off from the microbe carriers using the appropriate inactivator solutions. The number of surviving micro-organisms is determined by the membrane filter technique and compared with the count of the untreated controls.

4. Test item

The test item Cyber Clean ® with Benzalkonium Chloride + Didecyl dimethyl Ammonium Chloride CAS 7173 – 51 - 5 arrived at the CONFARMA laboratories on July 22nd 2008 and got the analysis number 222070803 according to the registration systems.