B BRAUN
SHARING EXPERTISE

Cyto-Set®

DOKUMENTACE PRO ZÁKAZNÍKY

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23.02.2015

Abstract

Evaluation of the microbial barrier performance of Cyto-Set® and Cyto-Set® Mix (NEW)

DMT 2014-195

Tested Products:	Cyto-Set® and Cyto-Set® Mix (NEW)
Manufacturer:	B. Braun AG D-34209 Melsungen
Objective:	Microbial tightness of the valve protected connections.
Test procedure:	The products were exposed to a microbial burden of *Bacillus subtilis* spores of 10^3 – 10^4 cfu per m^3 of air. This is 10^2 times higher than the bioburden in ambient air of operating rooms and intensive care units.
Results:	The valve protected connections of Cyto-Set® NEW and Cyto-Set® Mix NEW are an effective microbial barrier when exposed to a microbial burden of 10^3 cfu/ m^3 to 10^4 cfu/ m^3 *B. subtilis* spores. Detailed results, including a statistical evaluation, are shown in the Expert Report DMT 2014-195 from 9th December 2014.

Bonn, 23 February 2015

Prof. Dr. med. M. Exner
Head of Department

Dr. rer. nat. J. Gebel
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Quality Labs
BIOMATERIAL TESTING

DAkkS Deutsche Akkreditierungsstelle D-PL-13335-01-00

Anerkannt durch/Recognized by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
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Nuremberg, 01.09.2015

Abstract

Closed system test by means of Sodium Fluorescein –
Tightness of Cyto-Set® and Cyto-Set Mix® (NEW) valve-protected connections
Report 1816.3

Tested Products: Cyto-Set® and Cyto-Set® Mix (NEW)

Manufacturer: B.Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen

Objective: Chemical Tightness of Cyto-Set® and Cyto-Set® Mix (NEW) valve-protected connections.

Test Procedure: The products were tested with sodium fluorescein as a fluorescence tracer for the simulation of an administered drug substance and the quantitative determination of the chemical tightness of the valve-protected connections.

Results: The valve-protected connections of Cyto-Set® and Cyto-Set® Mix (NEW) release no chemical components during preparation and administration by use of fluorescein as a chemical tracer. The results confirm that the valve-protected connection of CytoSet® and CytoSet® Mix is a closed system according to NIOSH definition, as it prevents the escape of hazardous contaminants into the adjacent environment. Details of the test and the test results are shown in Report 1816.3 dated from June 20, 2014.

Nuremberg, September 01, 2015

Dr. rer. nat. J. Brünke
Managing Director

Institut für Energie- und
Umwelttechnik e.V.

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Datum: 20/03/2017

IUTA – Report of analysis No.

F 17/072

(Extract from the IUTA analysis report No. F 17/040 from 03/02/2017)

Investigations of the adsorption and desorption behaviour of the drip chamber of Cyto-Set® with AirStop against selected pharmaceutically active ingredients.

Abstract

Investigations of the adsorption and desorption behaviour of the drip chamber of Cyto-Set® with AirStop against selected pharmaceutically active ingredients

Tested Product: Drip chamber as a component of the Cyto-Set® with AirStop

Manufacturer: B.Braun Melsungen AG

Schwarzenberger Weg 21

34212 Melsungen

Objective: Investigation of the adsorption and desorption behaviour of the AirStop drip chamber filter of the Cyto-Set® against selected pharmaceutically active ingredients.

Test Procedure: The studies were carried out by simulated application of the cytostatics 5-fluorouracil, carboplatin, cyclophosphamide, docetaxel, etoposide and gemcitabine in comparison with and without the AirStop filter membrane. The cytostatic infusion solutions were pumped successively through the respective test pattern, each followed by a rinse step. The cytostatic concentration was determined in each of the application and rinse solutions. At the beginning and after completion of the simulated application, the flow rate was determined and the AirStop-function was checked. After completion of all experiments, the residual amounts of cytostatics remaining in the dripping chambers were determined.

Results: The flow rates determined after the described simulated application were within the specification. The AirStop-function of the tested drip chamber filters were unchanged before and after the simulated cytostatic applications. The cytotoxic agents adsorbed in the drip chambers with and without AirStop filter membrane were in all cases less than 0.0001% of the respectively applied amount of active ingredient. Overall, no critical influences of the AirStop filter membrane filter were observed.

Institute of Energy and
Environmental Technology (IUTA e.V.)

Dr.-Ing. St. Haep
(CEO)

Dr.rer.nat. Jochen Türk
(Head of Department)

Remarks according DIN EN 17025:

1. The results are only valid for the described samples.
2. Extracts of this analytical report and the method description are not allowed to be forwarded to a third party without permission of IUTA.
3. Retained samples are stored for three months.

Institut für Energie- und
Umwelttechnik e.V.

Technical Report No. F 17/267 (brief form)

Customer:
B. Braun Melsungen AG
Hospital Care Division
Schwarzenberger Weg 21
D-34212 Melsungen
Germany

Test subject: Tubing connection with clamp as a part of the CytoSet® Mix

Purpose: Investigation of the leakage behaviour in the tubing connection closed with a clamp against selected pharmaceutically active ingredients.

Test specifications: The study was carried out by preparing applications of the cytostatics carbo-platin, cyclophosphamide, gemcitabine, doxorubicine and paclitaxel with the CytoSet® Mix with n = 5 and storing the applications for 8, 24 and 48 hours, respectively. The concentrations of the prepared applications were tested in the beginning and after finishing each test. A clamp separated the solution in the tubing connection from the cytostatic solution. The solution in the end of the tubing was tested for the respective cytostatic concentration after the specified storage period.

Test result: The concentrations of the prepared applications remained within the specifications during the experiments. The clamp of the tubing connection showed good sealing properties without any visible fluid passing through. All liquid samples taken from the end of the tubing were below the limit of quantification. Overall, no critical aspects in handling the CytoSet® Mix were observed.

Duisburg, 18th of September 2017

Dr.-Ing. St. Haep
(CEO)

Dr.rer.nat. Jochen Türk
(Head of Department)

Remarks according DIN EN 17025:
1. The results are only valid for the described samples / materials.
2. Extracts of this report and the method description are not allowed to be forwarded to a third party without permission of IUTA.
3. Retained samples are stored for three months.

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Date: November 20, 2018

To whom it may concern

CONFIRMATION

This is to confirm that the valve-protected connections of our medical devices of the product groups

Cyto-Set® Infusion
Cyto-Set® Infusomat® Space
Cyto-Set® Infusomat® plus
Cyto-Set® Mix

are closed systems referring to NIOSH 2004 definition, as it prevents the escape of hazardous contaminants into the adjacent environment. Corresponded tests were conducted by external laboratories.

Please note, that the above-mentioned medical devices are only tested for the first connection and therefore, are not subject to a disconnection.

For and on behalf of

B. Braun Melsungen AG

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IUTA – Technical report No.

F 19/600

(Extract from the IUTA analysis report No. F 19/599 from 10/12/2019)

Product resistance test

Abstract

Customer: B. Braun Melsungen AG
Hospital Care Division
Schwarzenberger Weg 21
D-34212 Melsungen
Germany

Test subject:

Cyto-Set® Infusomat® Space 835414SP
Cyto-Set® Infusomat® Space 835817SP
Cyto-Set® Mix A2903N
Cyto-Set® Mix A2900N
Cyto-Set® Mix A2906N

Purpose: Product resistance test

Test specifications: For the product resistance tests a storage test and following compatibility tests: flow rate test, air tightness test, vacuum tightness, liquid tightness and tensile tightness have been carried out. The test subjects were investigated with solutions of the cytostatics 5-fluorouracil, vincristine, cyclophosphamide, doxorubicin, carboplatin, gemcitabine, paclitaxel and etoposid. The cytostatic infusion solutions were stored 7 days in different Cyto-Set® Mix pattern. After this the cytostatic solutions were pumped successively through the respective test pattern, each followed by a rinse step. This was followed by the compatibility tests. After each investigation the sets were checked for visible damages (visible changes of the original shape or surface).

Test results: No visible damages could be detected after the storage test, all components that came in contact with cytostatic drugs passed the investigation and the compatibility tests without visible damages.

Duisburg, 11th of December 2019

Dr.-Ing. St. Haep
(CEO)

Dr.rer.nat. Jochen Türk
(Head of Department)

Remarks according DIN EN ISO/IEC 17025:2018 (general criteria for the operation of analytical laboratories)
1. The results are only valid for the described samples / materials.
2. Extracts of this report and the method description are not allowed to be forwarded to a third party without permission of IUTA.
3. Retained samples are stored for three months.

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