SimplFusor™

SimplFusor™ Pumps are intended for administration of antibiotics, chemotherapy, and pain management medications through intravenous, intra-arterial and subcutaneous infusion.

The stability data outlined in the table below relates to chemical stability of the drugs tested and not to sterility. This reference guide was developed as a result of testing performed by independent ISO/ IEC 17025 certified laboratories and review of various medical publications including manufacturers' product information and available elastomeric infusion pump drug stability data.

Equivalency studies have been conducted on the fluid path materials in the SimplFusor™ Pumps and B.Braun Medical Inc. AccuFlo™ and Easypump II™ elastomeric pumps. Spectral analysis using FTIR spectrometry have shown that all fluid path materials (drug reservoir membrane, tubing and connectors) are identical.[1,2] These studies confirm that drug stability studies in these pumps would be unequivocally reproducible.

The pharmacist or medical personnel dispensing the medication is responsible for ensuring proper preparation using validated aseptic techniques to prevent microbiological contamination and ensuring that the medication is prepared and administered in accordance with the drug manufacturer's package insert.

Chemical Stability of Drugs Using Elastomeric Infusion Pumps

Medication	Concentration	Diluent	Room Temperature	Refrigerated	Laboratory Testing Reference Number
ACYCLOVIR Na	10 mg/ml	NS	5 days	--	3[a]
AMIKACIN SO_4	10 mg/ml	NS	1 day	7 days	4[a]
AMOXICILLIN	1 mg/ml	NS	4 hours	--	5[a]
	40 mg/ml	NS	2 hours	--	5[a]
AMPICILLIN Na	20 mg/ml	NS	1 day	3 days	6[a]
AMPICILLIN Na-SULBACTAM Na	30+15 mg/ml	NS	6 hours	4 days	6[a]
AZITHROMYCIN	1-2 mg/ml	NS	1 day	7 days	3[a]
AZTREONAM	10-30 mg/ml	NS	1 day	7 days	5[a]
BUPIVACAINE HCl	5mg/ml	NS	1 day	14 days	7
CASPOFUNGIN Acetate	0.2-0.5 mg/ml	NS	60 hours	14 days	6[a]
CEFAZOLIN Na	16.7 mg/ml	NS	2 days	14 days	8[a]
CEFEPIME	20 mg/ml	NS	1 day	14 days	9[a]
CEFOTAXIME Na	16.66 mg/ml	NS	1 day	3 days	3[a]
CEFTAZIDIME	40 mg/ml	NS	1 day	14 days	9[a]
CEFTRIAXONE Na	40 mg/ml	NS	1 day	14 days	7
CIPROFLOXACIN	2 mg/ml	D5W	10 days	30 days	3[a]

CISPLATIN	0.2 mg/ml	NS	1 day	14 days	4[a]
CLINDAMYCIN PO4	6-12 mg/ml	NS	3 days	10 days	3[a]
CLOXACILLIN	50 mg/ml	NS	1 day	7 days	4[a]
COLISTIMETHATE Na	3 mg/ml	NS	2 hours	1 day	6[a]
CYCLOPHOSPHAMIDE	4.5 mg/ml	NS	7 days	7 days	10[b]
DAPTOMYCIN	20mg/ml	NS	1 day	10 days	8[a]
DEFEROXAMINE MESYLATE	5 mg/ml	NS	2 days	14 days	8[a]
	22 mg/ml	NS	2 days	14 days	4[a]
	100 mg/ml	NS	2 days	14 days	8[a]
DOXORUBICIN	2 mg/ml	NS	1 day	14 days	4[a]
DOXYCYCLINE	1-1.5 mg/ml	NS/D5W	12 hours	3 days	9[a]
	1-1.5 mg/ml	NS	12 hours	3 days	9[a]
ERTAPENEM	10 mg/ml	NS	1 day	7 days	6[a]
	20 mg/ml	NS	1 day	5 days	6[a]
ETOPOSIDE	0.1-0.4 mg/ml	NS	9 days	--	11[b]
FLOXURIDINE	10 mg/ml	NS	1 day	14 days	7
FLUCONAZOLE	2 mg/ml	RTU	2 days	7 days	8[a]
FLUOROURACIL	5-50 mg/ml	NS	--	45 days	8[a]
FOLINIC ACID	4 mg/ml	NS	2 days	14 days	4[a]
FOSCARNET Na	12 mg/ml	NS	7 days	14 days	12[b]
	24 mg/ml	RTU	7 days	14 days	12[b]
FOSFOMYCIN Na	20 mg/ml	NS	1 day	--	8[a]
	20 mg/ml	NS	1 h @ 37°C	--	8[a]
FUROSEMIDE	10 mg/ml	NS	4 days	7 days	9[a]
GANCICLOVIR	1 mg/ml	NS	2 days	14 days	8[a]
	10 mg/ml	NS	2 days	14 days	8[a]
GENTAMYCIN	1 mg/ml	NS	2 days	14 days	4[a]
IMIPENEM-CILASTATIN Na (PRIMAXIN)	5 mg/ml	NS	1 day	3 days	6[a]
IRON (III) HYDROXIDE SUCROSE	1 mg/ml	NS	1 day	1 day	8[a]
MEROPENEM	5 mg/ml	NS	21 hours	5 days	6[a]
METHYLPREDNISOLONE Na	10 mg/ml	NS	2 hours	7 days	9[a]
METRONIDAZOLE	5 mg/ml	NS	1 day	10 days	9[a]
MORPHINE SO_4	1 mg/ml	NS	7 days	--	8[a]
	20 mg/ml	NS	7 days	--	8[a]
NAFCILLIN Na	5-50 mg/ml	NS	1 day	3 days	3[a]
NORMAL SALINE	0.9% NaCl	NS	15 days	15 days	6[a]
ONDANSETRON HCL	0.03-0.3 mg/ml	NS/D5W	--	14 days	13[b]
OXACILLIN	10-100 mg/ml	NS	4 days	10 days	3[a]
PACLITAXEL	1.2 mg/ml	NS	1 day	7 days	5[a]
	1.2 mg/ml	D5W	1 day	7 days	5[a]

PAMIDRONIC ACID SODIUM SALT	30 µg/ml	NS	2 days	27 days	8[a]
	0.4 mg/ml	NS	2 days	27 days	8[a]
	30 µg/ml	D5W	2 days	27 days	8[a]
	30 µg/ml	NS	29 days	--	8[a]
PENICILLIN G Potassium	20,000 units/ml	NS	1 day	4 days	6[a]
PIPERACILLIN Na /TAZOBACTAM Na	10+1.25 mg/ml - 80+10 mg/ml	NS	1 day	28 days	6[a]
RIFAMPICIN (RIFAMPIN)	0.5 mg/ml	NS	1 day	6 days	8[a]
	3 mg/ml	NS	1 day	6 days	8[a]
TICARCILLIN Disodium CLAVULANATE K	31 mg/ml	NS	1 day	7 days	14[b]
TOBRAMYCIN	0.2 mg/ml	NS	1 day	7 days	13[a]
	0.8 mg/ml	NS	1 day	14 days	12[a],14[a]
VANCOMYCIN HYDROCHLORIDE	5 mg/ml	NS	1 day	14 days	4[a]

NS: Normal Saline D5W: Glucose 5% Dextrose in Water RTU: Ready to Use W: Water

Confirmation of Fluid Path Materials

To support the use of drug studies already conducted on competitive elastomeric pumps, spectral analysis of the fluid path materials of the SimplFusor ™ pump using ATR - FTIR spectrometry have been investigated.

The use of attenuated total reflectance technology (ATR) combining with Fourier transform infrared spectrophotometer enables high quality comparison of polymer materials without the need for tedious sample preparation. The fluid path materials in an elastomeric pump are principally the drug reservoir membrane, tubing and connectors.

The fluid path materials in the SimplFusor ™ were compared to the fluid path materials in AccuFlo® and Easypump II® (B Braun) using ATR-FTIR spectrometry.[1,2] The spectral overlay of the fluid path materials in the SimplFusor ™ Pump are identical to the spectral overlay of the fluid path materials in the AccuFlo® and Easypump II® elastomeric pumps. See Image 1 (below) and Image 2 (page 4). This confirms the notion that drug stability studies for AccuFlo® would be unequivocally reproducible in SimplFusor™ elastomeric pumps.

Image 1. Spectral overlay of the fluid path materials of the SimplFusor ™ pump and AccuFlo® elastomeric pumps.

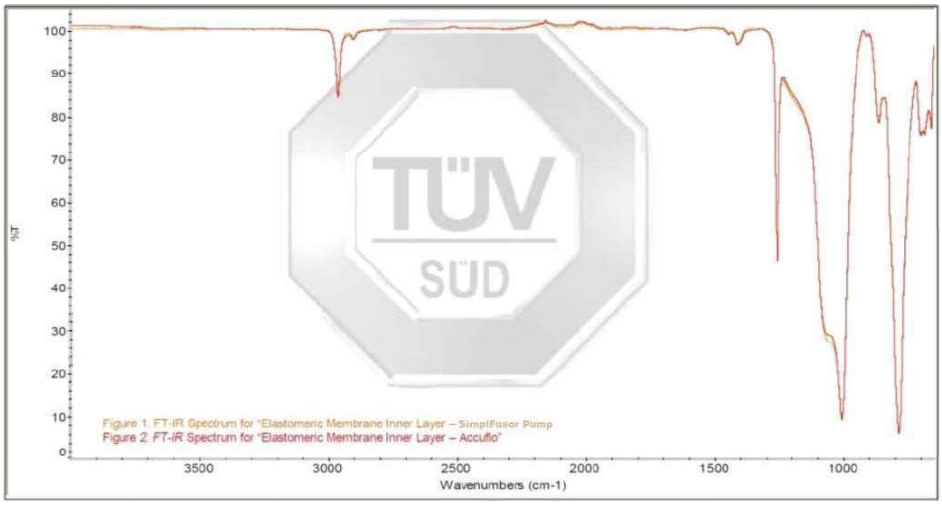
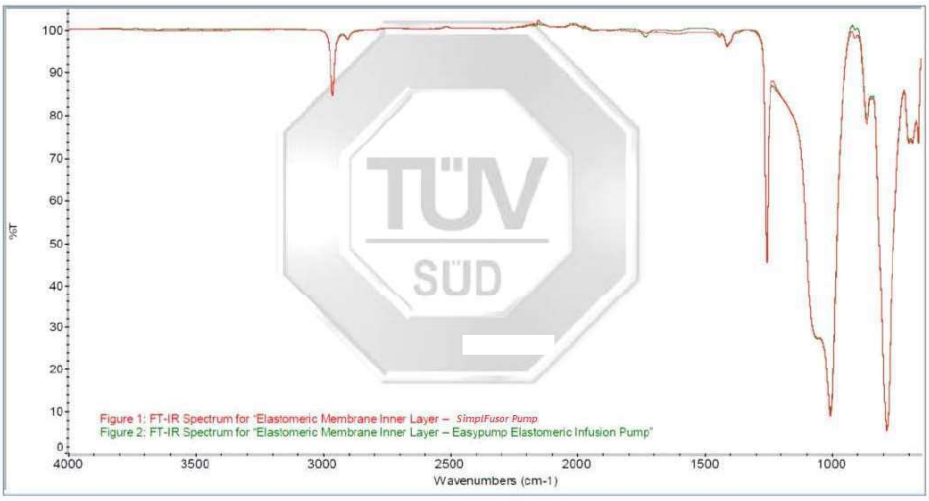


Image 2. Spectral overlay of the fluid path materials of the SimplFusor™ andEasypump II® elastomeric pump



References

Laboratory Testing References

1. FT-IR Analysis testing completed by TÜV SÜD PSB Pte. Ltd. Laboratory Services, Singapore, on SimplFusor™ and AccuFlo™ in 2015.
2. FT-IR Analysis testing completed by TÜV SÜD PSB Pte. Ltd. Laboratory Services, Singapore, on SimplFusor™ and EasyPump™ in 2015.
3. Testing completed by SGS Life Science Services, Lincolnshire, IL, USA.
4. Testing completed by PHV Analytic, Laboratory Faculte de Medecine et Pharmacie, France.
5. Testing completed by Philips Innovation Services, Eindhoven, The Netherlands.
6. Testing completed by Toxikon Europe nv, Leuven, Belgium.
7. Testing completed by TÜV SÜD PSB Pte. Ltd. Laboratory Services, Singapore, on SimplFusor™ Pumps in 2015.
8. Testing completed by ECOTOX Testing Service, Oldenburg, Germany.
9. Testing completed by Henkel AG & Co., KGaA, Dusseldorf, Germany.
10. Testing completed by Centre Antoine Lacassagne, France.
11. Testing completed by Karolinska Hospital, Dept. of Clinical Pharmacology, Sweden.
12. Testing completed by Beckman Industrial Corp., U.S.A.
13. Jhee SS et al. Stability of ondansetron hydrochloride in a disposabel elastomeric infusion device at 4°C. Am J Hosp Pharm. 1993 ;50 :1918-20.
14. Testing completed by Pyramid Laboratories, U.S.A.

Source Notes

a. *Stability Data for Drugs Using B. Braun's AccuFlo® Elastomeric Infusion System.* B.Braun Medical Inc. April 2015.
b. Stability Data for Drugs Using Homepump Eclipse and Homepump C-Series Disposable Ambulatory Infusion System. Halyard Health. March 2015.

Guidelines

1. ICH (International Conference of Harmonization) Guidance on Drug Stability Study.
2. USP chapter on stability studies and good chromatographic practices.
3. Drug manufacturer product information.
4. PDR (Physicians' Desk Reference), 60th edition, Medical Economics Company, Oradell, NJ 2003, USA.
5. US FDA 21 CFR Part 58 (Good Laboratory Practice for Nonclinical Laboratory Studies).
6. ISO/IEC 17025 General Requirements for The Competence of Testing and Calibration Laboratories.