CONFIRMATION OF EQUIVALENT FLUID PATH MATERIALS

Studies were conducted to compare the material composition of the fluid path (drug reservoir membrane, tubing and connectors) of the SMARTeZ® pump to the AccuFlo™ and Easypump II™ pumps using ATR-FTIR spectral analysis[1,2] Spectral overlay analysis indicated equivalent fluid path composition when comparing SMARTeZ® to both the AccuFlo™ and the Easypump II™ elastomeric pumps. (Image 1 and 2)

The use of attenuated total reflectance technology (ATR) combining with Fourier transform infrared (FTIR) spectrophotometer enables high quality comparison of polymer materials.

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

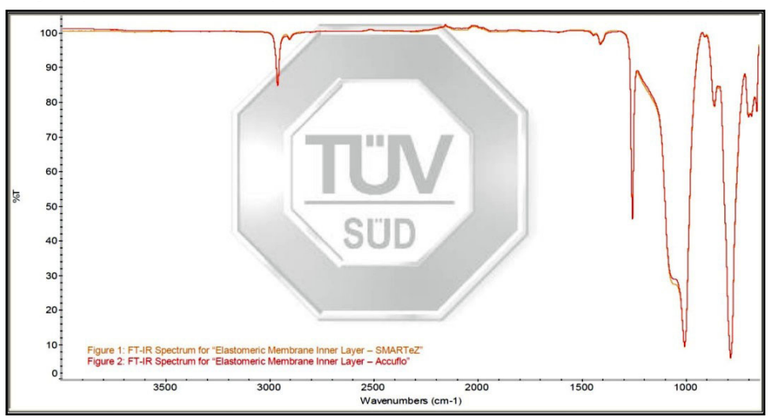
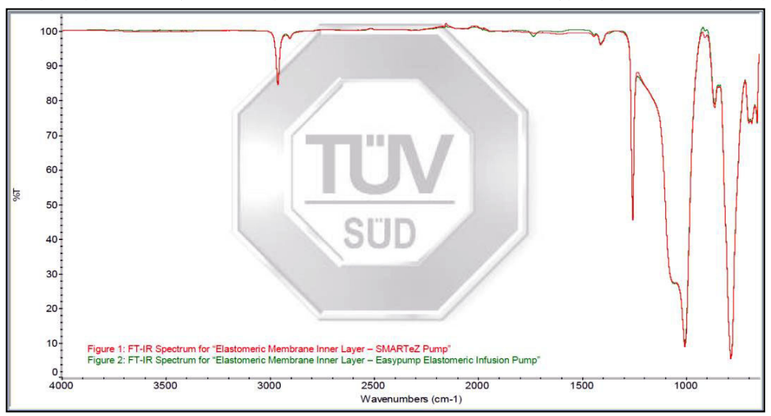


Image 2. Spectral overlay of the fluid path materials of the SMARTeZ® and Easypump II™ elastomeric pumps.



SMARTeZ®

SMARTeZ® Elastomeric Infusion Pump

STABILITY DATA FOR DRUGS USING ELASTOMERIC INFUSION PUMPS

SMARTeZ® disposable elastomeric pumps are intended for administration of antibiotics, chemotherapy and pain management.

The SMARTeZ® pump has a specially designed multi-layered balloon-like reservoir to be filled with the drug or fluid intended for infusion. It exerts mechanical pressure to administer the contents at a predetermined flow rate. The entire unit is sterile and is intended for single use only.

The stability data outlined in the table on pages 2 & 3 relate 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.

All stability data referenced on pages 2 & 3 were conducted in elastomeric pumps with an equivalent silicone drug reservoir. Studies were conducted to confirm equivalent fluid path material in the studied elastomeric pumps are outlined below. The medications listed in the shaded areas have been tested by independent laboratories to verify chemical stability in the SMARTeZ® pump.

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.

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STABILITY DATA FOR DRUGS USING ELASTOMERIC INFUSION PUMPS

Medication	Concentration	Diluent	Room Temperature	Refrigerated	Reference Number
ACYCLOVIR Na	10 mg/ml	NS	5 days	--	3
AMIKACIN SO4	10 mg/ml	NS	1 day	28 days	4
AMOXICILLIN	1 mg/ml and 40 mg/ml	NS	2 hours	6 hours	6
AMPICILLIN Na	20 mg/ml	NS	1 day	3 days	6
AMPICILLIN Na-SULBACTAM Na	30+15 mg/ml	NS	6 hours	4 days	6
AZITHROMYCIN	1-2 mg/ml	NS	1 day	7 days	3
AZTREONAM	10-30 mg/ml	NS	1 day	7 days	5
BUPIVACAINE HCl	5mg/ml	NS	1 day	14 days	7
CASPOFUNGIN Acetate	0.2-0.5 mg/ml	NS	60 hours	14 days	6
CEFAZOLIN Na	16.7 mg/ml	NS	2 days	14 days	8
CEFEPIME	20 mg/ml	NS	1 day	14 days	9
CEFOTAXIME Na	20 mg/ml	NS	1 day	14 days	7
CEFTAZIDIME	40 mg/ml	NS	1 day	14 days	4 & 7
CEFTRIAXONE Na	40 mg/ml	NS	1 day	14 days	7
CEFUROXIME	1 mg/ml and 30 mg/ml	NS	1 day	3 days	3
CIPROFLOXACIN	2 mg/ml	D5W	10 days	30 days	3
CISPLATIN	0.2 mg/ml	NS	1 day	7 days	4 & 7
CLINDAMYCIN PO4	6-12 mg/ml	NS	3 days	30 days	3
CLOXACILLIN	50 mg/ml	NS	1 day	7 days	4
COLISTIMETHATE Na	3 mg/ml	NS	2 hours	1 day	6
CYCLOPHOSPHAMIDE	2 mg/ml	NS	2 days	14 days	6
	20 mg/ml	NS	2 days	7 days	
DAPTOMYCIN	20mg/ml	NS	1 day	10 days	8
DEFEROXAMINE MESYLATE	95mg/ml	NS	1 day	14 days	7
DOXORUBICIN	2 mg/ml	NS	1 day	14 days	4
DOXYCYCLINE	1-1.5 mg/ml	NS/D5W	12 hours	3 days	9
ERTAPENEM	10 mg/ml	NS	1 day	7 days	6
	20 mg/ml	NS	1 day	5 days	
FLOXURIDINE	10 mg/ml	NS	1 day	14 days	7
FLUCONAZOLE	2 mg/ml	RTU	2 days	7 days	8
FLUOROURACIL	5-50 mg/ml	NS	--	45 days	8
FOLINIC ACID	4 mg/ml	NS	1 day	14 days	4
FOSFOMYCIN Na	20 mg/ml	NS	1 day	--	8
FUROSEMIDE	10 mg/ml	NS	4 days	7 days	9
GANCICLOVIR	1-10 mg/ml	NS	2 days	14 days	8
GENTAMYCIN	10 mg/ml	NS	2 days	28 days	7
IMIPENEM-CILASTATIN Na (PRIMAXIN)	5 mg/ml	NS	1 day	3 days	6
IRON (III) HYDROXIDE SUCROSE	1 mg/ml	NS	1 day	1 day	8
LEVOBUPIVACAINE	0.75%	NS	30 days		6
LEVOFLOXACIN	5 mg/ml	NS/D5W	7 days	14 days	3
LIDOCAINE	0.5 % and 2%	NS	30 days	--	6
LINEZOLID	0.15 mg/ml and 2 mg/ml	NS	1 day	13 days	8
MEROPENEM	10 mg/ml	NS	21 hours	10 days	7
METHYLPREDNISOLONE Na	10 mg/ml	NS	2 hours	7 days	9
METRONIDAZOLE	5 mg/ml	NS	1 day	10 days	9
MICAFUNGIN	0.5mg/ml and 2 mg/ml	NS	1 day	4 days	8
MORPHINE SO4	1 mg/ml and 20 mg/ml	NS	7 days	--	8
NAFCILLIN Na	50 mg/ml	NS	2 days	14 days	7
NORMAL SALINE	0.9% NaCl	NS	15 days	15 days	6
OFLOXACIN	0.4 mg/ml and 2 mg/ml	NS	7 days	14 days	6
ONDANSETRON HCL	0.03-0.3 mg/ml	NS/D5W	7 days	21 days	3
	0.7 mg/ml	NS/D5W	4 days	10 days	
OXACILLIN	10-100 mg/ml	NS	4 days	10 days	3
PACLITAXEL	0.3 mg/ml and 1.2 mg/ml	NS/D5W	1 day	7 days	8
PAMIDRONIC ACID SODIUM SALT	30 µg/ml and 0.4 mg/ml	NS/D5W	2 days	27 days	8
PENICILLIN G Potassium	20,000 units/ml	NS	1 day	4 days	6
PIPERACILLIN Na / TAZOBACTAM Na	10+1.25 mg/ml - 80+10 mg/ml	NS	1 day	28 days	6
RIFAMPICIN (RIFAMPIN)	0.5 mg/ml and 3 mg/ml	NS	1 day	6 days	8
ROPIVACAINE	0.1 % and 0.75%	NS	30 days	--	8
TIGECYCLINE	0.5 mg/ml and 1 mg/ml	NS	1 day	2 days	8
TOBRAMYCIN	0.2 mg/ml and 10 mg/ml	NS	1 day	14 days	8
VANCOMYCIN HYDROCHLORIDE	5 mg/ml	NS	1 day	14 days	4
	15 mg/ml	NS	2 days	30 days	3

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

REFERENCES

Laboratory Testing References:

1. FT-IR Analysis testing completed by TÜV SÜD PSB Pte. Ltd. Laboratory Services, Singapore, on SMARTeZ® and AccuFlo™ in 2015.
2. FT-IR Analysis testing completed by TÜV SÜD PSB Pte. Ltd. Laboratory Services, Singapore, on SMARTeZ® 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 SMARTeZ® Pumps.
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. Testing completed by Pyramid Laboratories, U.S.A.

Source Notes:

1. Data on File, EPIC Medical.
2. Stability Data for Drugs Using B. Braun's AccuFlo™ Elastomeric Infusion System B.Braun Medical Inc. April 2015.
3. Drug Stability for Easypump II™ B.Braun Medical Inc. February 2017.

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 Non-clinical Laboratory Studies).
6. ISO/IEC 17025 General Requirements for The Competence of Testing and Calibration Laboratories.