SMARTeZ® Pump

Drug Stability Data for SMARTeZ® Elastomeric Infusion Pumps

SMARTeZ® Pumps are portable single-use elastomeric infusion pumps intended for administration of antibiotics, chemotherapy, and pain management medications through intravenous, intra-arterial, subcutaneous, intramuscular, and epidural 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 from the results 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 EPIC Medical SMARTeZ® Pump 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.[a,b] These studies confirmed that the drug stability studies in these pumps would be unequivocally reproducible.

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

Medication	Concentration	Diluent	Refrigerated (Rf)	Room Temp (RTP)	Storage Condition	Reference
FLUOROURACIL (5-FU) *	5 mg/ml	D5W/NS	--	45 d	separate	1
	50 mg/ml	RTU	--	45 d	separate	1
	50 mg/mL	Undiluted	7 days	7 days	--	11
5-FU + SODIUM FOLINATE (ONCOFOLIC + RIBOFLUOR)	5 mg/ml + 2 mg/ml	NS	--	7 days	separate	1
	36 mg/ml + 8.8 mg/ml	NS	--	7 days	separate	1
ACYCLOVIR Na	10 mg/ml	NS	--	5 days	separate	6
AGALSIDASE BETA (FABRAZYME)	0.05 mg/ml	NS	--	24 hrs	separate	7
	0.7 mg/ml	NS	--	24 hrs	separate	7
AMIKACIN	10 mg/ml	NS	15 days	48 hrs	separate	7
	20 mg/ml	NS	15 days	48 hrs	separate	7
AMOXICILLINE	1 mg/ml	NS	6 hrs	2 hrs	combined	5
	40 mg/ml	NS	6 hrs	2 hrs	combined	5

Medication	Concentration	Diluent	Refrigerated (Rf)	Room Temp (RTP)	Storage Condition	Reference
AMOXICILLINE + CLAVULANATE	10 mg/ml + 2 mg/ml	NS	6 hrs	--	separate	6
	20 mg/ml + 4 mg/ml	NS	6 hrs	--	separate	6
AMPHOTERICIN B **	0.1 mg/ml	D5W	4 days	24 hrs	combined	1
	0.5 mg/ml	D5W	4 days	24 hrs	combined	1
	2 mg/ml	D5W	4 days	24 hrs	combined	1
AMPICILLIN Na	12 mg/ml	NS	4 days	6 hrs	combined	8
	20 mg/ml	NS	3 days	24 hrs	separate	5
AMPICILLIN Na + SULBACTAM Na	30 mg/ml + 15 mg/ml	NS	2 days	6 hrs	separate	5
AZITHROMYCIN	1 mg/ml	NS	7 days	24 hrs	separate	6
	2 mg/ml	NS	7 days	24 hrs	separate	6
AZTREONAM	10 mg/ml	NS	7 days	24 hrs	combined	4
	30 mg/ml	NS	7 days	24 hrs	combined	4
BUMETANIDE	0.016 mg/ml	D5W	--	24 hrs	separate	5
	0.16 mg/ml	D5W	--	24 hrs	separate	5
BUPIVACAINE	0.125 %	NS	--	30 day	separate	5
	0.75 %	NS	--	30 day	separate	5
BUPIVACAINE HCl	5 mg/ml	RTU	15 days	2 day	combined	1
	5 mg/mL	NS	14 days	2 days	--	Rf: 12; 12| RTP: 12
CASPOFUNGIN ACETATE	0.2 mg/ml	NS	14 day	60 hrs	separate	5
	0.5 mg/ml	NS	14 day	60 hrs	separate	5
CEFAZOLIN Na	16.7 mg/ml	NS	14 days	2 days	combined	1
CEFEPIME	20 mg/ml	NS	14 days	24 hrs	separate	6
CEFOTAXIME	10 mg/ml	NS	14 days	24 hrs	separate	8
	15 mg/ml	NS	14 days	24 hrs	separate	8
CEFOTAXIME Na	16.66 mg/ml	NS	3 days	24 hrs	separate	6
CEFOTIAM	20 mg/ml	NS/D5W	24 hrs	6 hrs	combined	5
CEFOXITIN	1 mg/ml	NS	7 days	48 hrs	separate	7
	10 mg/ml	NS	7 days	48 hrs	separate	7
CEFTAZIDIME	1 mg/ml	NS	2 days	24 hrs	combined	5
CEFTAZIDIME	40 mg/ml	NS	14 days	24 hrs	separate	3; 10
CEFTAZIDIME (INCL. PYRIDINE DETERMINATION)	9 mg/ml	NS	7 days	--	separate	8
	60 mg/ml	NS	5 days	--	separate	8
CEFTOLOZANE + TAZOBACTAM (ZERBAXA)	1 mg/ml + 0.5 mg/ml	NS	14 days	24 hrs	combined	7
	2 mg/ml + 1 mg/ml	NS	14 days	24 hrs	combined	7
	30 mg/ml + 15 mg/ml	NS	14 days	24 hrs	combined	7
CEFTRIAXONE **	10 mg/ml	NS	14 days	48 hrs	combined	7
	50 mg/ml	NS	14 days	48 hrs	combined	7
	10 mg/ml	D5W	6 days	24 hrs	combined	1
CEFTRIAXONE SODIUM	40 mg/mL	NS	14 days	24 hrs	--	12
CEFUROXIME	1 mg/ml	NS	3 days	24 hrs	combined	6
	30 mg/ml	NS	3 days	24 hrs	combined	6

Medication	Concentration	Diluent	Refrigerated (Rf)	Room Temp (RTP)	Storage Condition	Reference
	1 mg/ml	D5W	3 days	12 hrs	combined	6
	30 mg/ml	D5W	3 days	12 hrs	combined	6
CIMETIDINE	1 mg/ml	NS	--	7 days	separate	5
	6 mg/ml	NS	--	7 days	separate	5
CIPROFLOXACIN	2 mg/ml	D5W	30 days	10 days	separate	6
CISPLATIN *	0.1 mg/ml	NS	--	14 days	separate	5
	0.2 mg/ml	NS	7 days	24 hrs	separate	3; 10
	0.5 mg/ml	NS	--	14 days	separate	5
CLINDAMYCIN PO4	6 mg/ml	NS	30 days	3 days	separate	6
	12 mg/ml	NS	30 days	3 days	separate	6
CLOXACILLIN	50 mg/ml	NS	7 days	24 hrs	separate	3; 10
COLISTIMETHATE SODIUM	3 mg/ml	NS	24 hrs	2 hrs	combined	5
CYCLOPHOSPHAMID	2 mg/ml	NS	14 days	2 days	combined	5
	20 mg/ml	NS	7 days	2 days	combined	5
DAPTOMYCIN	5 mg/mL	NS	14 days	24 hrs	--	10
DAPTOMYCIN (CUBICIN)	1 mg/ml	NS	10 days	1 day	combined	7
	5 mg/ml	NS	10 days	1 day	combined	7
	20 mg/ml	NS	10 days	1 day	combined	1
DEFEROXAMINE	0.022 mg/ml	NS	14 days	2 days	separate	3; 10
DEFEROXAMINE MESYLATE	5 mg/ml	NS	14 days	2 days	combined	1
	100 mg/ml	NS	14 days	2 days	combined	1
	95 mg/mL	WFI	14 days	24 hrs	--	12
DORIPENEM	5 mg/mL	NS	3 days	2 hrs	--	10
DOXORUBICIN	2 mg/ml	NS	22 days	14 days	combined	1
DOXYCYCLINE	1 mg/ml	NS/D5W	3 days	12 hrs	combined	2
	1.5 mg/ml	NS/D5W	3 days	12 hrs	combined	2
ERTAPENEM	5 mg/ml	NS	7 days	6 hrs	Rf: separate; RTP: combined	Rf: 1 | RTP: 6
	10 mg/ml	NS	7 days	24 hrs	separate	5
	20 mg/ml	NS	5 days	24 hrs	separate	5
ETOPOSIDE	0.2 mg/ml	NS	--	4 days	separate	5
	0.4 mg/ml	NS	--	24 hrs	separate	5
FERINJECT (IRON (III) SUCROSE COMPLEX)	2 mg/ml	NS	--	3 days	separate	1
	5 mg/ml	NS	--	3 days	separate	1
FLOXURIDINE	10 mg/mL	NS	14 days	24 hrs	--	12
FLUCLOXACILLIN	10 mg/ml	NS	2 days	24 hrs	combined	5
	70 mg/ml	NS	2 days	24 hrs	combined	5
FLUCONAZOLE	2 mg/ml	RTU	7 days	2 days	combined	1
FOLINIC ACID	4 mg/ml	NS	14 days	2 days	separate	3; 10
FOSFOMYCIN DISODIUM	16.6 mg/ml	D5W	--	2 days	separate	1
	40 mg/ml	D5W	--	2 days	separate	1
FOSFOMYCIN SODIUM	20 mg/ml	NS	--	1h at 37°C	separate	1
	20 mg/ml	NS	--	24 hrs	separate	1

Medication	Concentration	Diluent	Refrigerated (Rf)	Room Temp (RTP)	Storage Condition	Reference
FOSFOMYCIN SODIUM (FOSMICIN)	26.7 mg/mL	NS	-	7 days	--	11
FUROSEMIDE	10 mg/ml	NS	7 days	4 days	combined	2
GANCICLOVIR *	1 mg/ml	NS	14 days	2 days	combined	1
	10 mg/ml	NS	14 days	2 days	combined	1
	1 mg/ml	D5W	14 days	2 days	combined	5
	10 mg/ml	D5W	14 days	2 days	combined	5
GENTAMYCIN	1 mg/ml	NS	14 days	2 day	--	Rf: 9; 10 | RTP: 9
	10 mg/mL	NS	28 days	48 hrs	--	12
GENTAMYCIN SO4	0.5 mg/ml	NS	7 days	7 days	combined	1
	5 mg/ml	NS	14 days	7 days	combined	1
GRANISETRON	0.02 mg/ml	NS	7 days	2 days	combined	5
	0.5 mg/ml	NS	7 days	2 days	combined	5
	0.02 mg/ml	D5W	3 days	6 hrs	combined	5
	0.5 mg/ml	D5W	3 days	6 hrs	combined	5
HUMAN PLASMAGLOBULIN (HIZENTRA) ***	200 mg/ml	RTU	--	7 days	separate	1
IFOSFAMIDE	0.6 mg/ml	D5W	--	7 days	separate	1
	40 mg/ml	D5W	--	3 days	separate	1
	0.6 mg/ml	NS/D5W	3 days	24 hrs	combined	6
	40 mg/ml	NS/D5W	3 days	24 hrs	combined	6
IMIPENEM	5 mg/mL	NS	7 days	24 hrs	--	10
IMIPENEM + CILASTATIN Na (PRIMAXIN)	5 mg/ml + 5 mg/ml	NS	3 days	24 hrs	separate	5
KETAMINE	1 mg/ml	NS	--	2 days	separate	5
	2 mg/ml	NS	--	2 days	separate	5
LEVOBUPIVACAINE	0.125 %	NS	--	30 days	separate	5
	0.75 %	NS	--	30 days	separate	5
LEVOFLOXACIN	0.5 mg/ml	NS/D5W	14 days	7 days	combined	6
	5 mg/ml	NS/D5W	14 days	7 days	combined	6
LIDOCAINE	0.5 %	NS	--	30 days	separate	5
	2 %	NS	--	30 days	separate	5
LINCOMYCIN	1.2 mg/ml	NS	1 days	1 days	combined	1
	10 mg/ml	NS/D5W	1 days	1 days	combined	1
LINEZOLID	0.15 mg/ml	NS	13 days	24 hrs	combined	1
	2 mg/ml	NS	13 days	24 hrs	combined	1
MAGNESIUM SULFATE	20 mg/ml	NS	29 days	24 hrs	combined	5
MEROPENEM	2.5 mg/ml	NS	24 hrs	6 hrs	combined	6
	5 mg/ml	NS	10 days	24 hrs	separate	5; 7
	10 mg/mL	NS	5 days	21 hrs	--	12
	20 mg/ml	NS	4 days	24 hrs	separate	5; 6; 7
METHOTREXATE	0.3 mg/ml	NS	7 days	7 days	combined	6
	25 mg/ml	NS	7 days	7 days	combined	6
METHYLPREDNISOLONE	10 mg/ml	NS	7 days	2 hrs	combined	2
METOCLOPRAMIDE	5 mg/ml	NS	2 days	2 days	combined	8
METRONIDAZOLE	5 mg/ml	RTU	10 days	24 hrs	combined	2
MICAFUNGIN	0.5 mg/ml	NS	4 days	24 hrs	combined	1
	1.5 mg/mL	NS	9 days	-		12
	2 mg/ml	NS	4 days	24 hrs	combined	1
MORPHINE SO4	1 mg/ml	NS	--	7 days	separate	1

Medication	Concentration	Diluent	Refrigerated (Rf)	Room Temp (RTP)	Storage Condition	Reference
	20 mg/ml	NS	--	7 days	separate	1
NAFCILLIN	5 mg/ml	NS	14 days	30 hrs	separate	7
	50 mg/ml	NS	14 days	48 hrs	separate	Rf: 7; 12 | RTP: 12
NEFOPAM	10 mg/ml	NS	1 days	1 days	combined	5
NORMAL SALINE	0.9% NaCl	--	15 days	15 days	combined	5
OFLOXACIN	0.4 mg/ml	NS	14 days	7 days	combined	5
	2 mg/ml	NS	14 days	7 days	combined	5
ONDANSETRON HCl	0.03 mg/ml	NS/D5W	21 days	7 days	combined	6
	0.7 mg/ml	NS/D5W	10 days	4 days	combined	6
OXACILLIN	10 mg/ml	NS	8 days	4 days	separate	6
	100 mg/ml	NS	8 days	4 days	separate	6
PACLITAXEL (EBETAXEL)	6 mg/mL	NS	7 days	7 days	--	11
PACLITAXEL	0.3 mg/ml	NS/D5W	7 days	24 hrs	combined	1
	1.2 mg/ml	NS/D5W	7 days	24 hrs	combined	1
RIBODRONAT (PAMIDRONIC ACID SODIUM SALT)	0.4 mg/ml	NS	27 days	2 days	combined	1
	30 µg/ml	NS	--	29 days	separate	1
	30 µg/ml	NS/D5W	27 days	2 days	combined	1
PENICILLIN G (K)	20.000 units/ml	NS	4 days	24 hrs	separate	5
PENICILLIN G (Na)	100.000 units/ml	NS	1 day	6 hrs	Rf: combined; RTP: separate	Rf: 6 | RTP: 5
	2000 units/ml	NS	3 days	2 hrs	combined	6
PIPERACILLIN	0.8 mg/mL	NS	7 days	24 hrs	--	10
	10 mg/ml	NS	14 days	3 days	combined	5
	80 mg/ml	NS	5 days	24 hrs	combined	5
PIPERACILLIN Na + TAZOBACTAM Na	10 mg/ml + 1.25 mg/ml	NS	28 days	48 hrs	Rf: separate; RTP: combined	Rf: 5 | RTP: 7
	80 mg/ml + 10 mg/ml	NS	28 days	48 hrs	Rf: separate; RTP: combined	Rf: 5 | RTP: 7
RANITIDINE	0.5 ml/ml	NS	21 days	2 days	combined	1
	2 mg/ml	NS	21 days	7 days	combined	1
	0.5 ml/ml	D5W	21 days	2 days	combined	1
	2 mg/ml	D5W	21 days	7 days	combined	1
RIFAMPICIN	0.5 ml/ml	NS	6 days	24 hrs	combined	1
	0.75 mg/mL	NS	14 days	24 hrs	--	10
	3 mg/ml	NS	6 days	24 hrs	combined	1
ROPIVACAINE	0.1 %	NS	--	30 days	separate	5
	0.2 mg/ml	NS	14 days	24 hrs	combined	1
	0.75 %	NS	--	30 days	separate	5
	5 mg/ml	NS	14 days	24 hrs	combined	1
TEICOPLANIN	1 mg/ml	NS	7 days	24 hrs	combined	5
	20 mg/ml	NS	7 days	24 hrs	combined	5

Medication	Concentration	Diluent	Refrigerated (Rf)	Room Temp (RTP)	Storage Condition	Reference
TEMOCILLIN	10 mg/ml	NS	14 days	24 hrs	Rf: combined; RTP: combined, separate	Rf: 5 | RTP: 5; 1
	20 mg/ml	NS	14 days	24 hrs	combined	5
	80 mg/ml	NS	-	24 hrs	separate	1
TIGECYCLINE	0.5 mg/ml	NS	2 days	24 hrs	combined	1
	1 mg/ml	NS	2 days	24 hrs	combined	1
TOBRAMYCIN	0.2 mg/ml	NS	14 days	24 hrs	combined	1
	0.75 mg/ml	NS	14 days	1 day	--	9; 10
	5 mg/mL	NS	14 days	7 days	--	11
	10 mg/ml	NS	14 days	24 hrs	combined	1
VANCOMYCIN	5 mg/ml	NS	14 days	1 day	--	9; 10
	15 mg/ml	NS	30 days	2 days	separate	6
	4 mg/ml	NS/D5W	21 days	4 days	combined	6
	15 mg/ml	NS/D5W	14 days	2 days	combined	6
VANCOMYCIN HYDROCHLORIDE	5 mg/mL	NS	14 days	24 hrs	--	12
VENOFER (IRON (III) HYDROXIDE SUCROSE)	1 mg/ml	NS	24 hrs	24 hrs	combined	1
VINCRISTINE	1 mg/ml	NS	--	21 days	separate	5

NS: Normal Saline *D5W: Glucose 5% Dextrose in Water*
RTU: Ready to Use *WFI: Water for Injection*

** Attention must be paid to the drug's potential for precipitation which may occur depending on preparation, storage conditions, concentration, pH and diluents.*

*** Susceptible to crystallization when refrigerated.*

Confirmation of Fluid Path Materials

To support the use of drug studies already conducted on competitor elastomeric pumps, spectral analysis of the fluid path materials of the SMARTeZ® pump using ATR FT-IR spectrometry has 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 SMARTeZ® Pump (Epic Medical) were compared to the fluid path materials in AccuFlo™ and Easypump®II (B Braun) using ATR FT-IR spectrometry[a,b]. The spectral overlay of the fluid path materials in the SMARTeZ® 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 9). This confirmed that the drug stability studies for Easypump®II and AccuFlo™ would be unequivocally reproducible in SMARTeZ® elastomeric pumps.

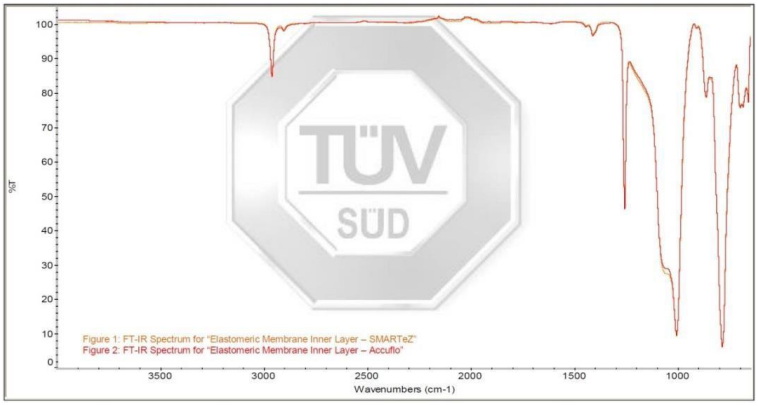

Image 1. Spectral overlay of the fluid path materials of the SMARTeZ® and AccuFlo™ elastomeric pumps.

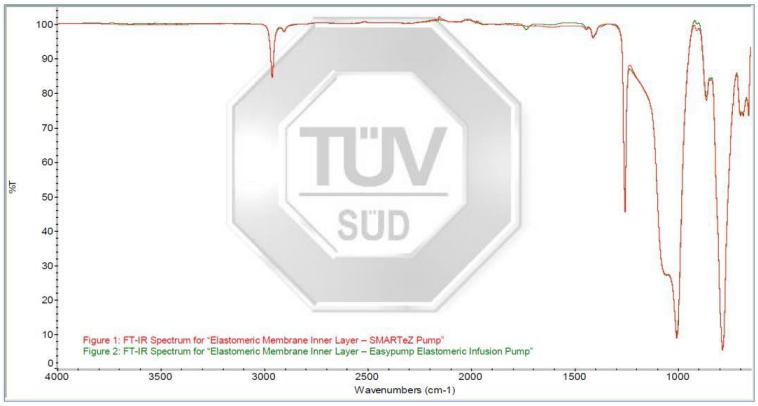

Image 2. Spectral overlay of the fluid path materials of the SMARTeZ® and Easypump®II elastomeric pump

Laboratory Testing References

FT-IR Testing

a. FT-IR Analysis testing completed by TÜV SÜD PSB Pte. Ltd. Laboratory Services, Singapore, on SMARTeZ® and AccuFlo™ in 2015.

b. FT-IR Analysis testing completed by TÜV SÜD PSB Pte. Ltd. Laboratory Services, Singapore, on SMARTeZ® and Easypump®II in 2015.

Easypump®II (*Drug Stability List for Easypump®II.* B.Braun Medical Inc. June 2020)

1. Testing completed by ECOTOX Testing Service, Oldenburg, Germany
2. Testing completed by Henkel AG & Co. KGaA, Düsseldorf, Germany
3. Testing completed by Laboratory Faculte de Medecine et Pharmacie, France
4. Testing completed by Philips Innovation Service, Eindhoven, Netherland
5. Testing completed by Toxikon Europe NV, Leuven, Belgium
6. Testing completed by SGS Life Science Services, Lincolnshire IL, USA
7. Testing completed by Nelson Labs, Leuven, Belgium
8. Testing completed by Selvita S.A., Kraków, Poland

AccuFlo™ (Stability Data for Drugs Using B.Braun's AccuFlo™ Elastomeric Infusion System)

9. Testing completed by PHV Analytic, Laboratory Faculte de Medecine et Pharmacie, France
10. Testing completed by PHV Analytic, Laboratory Faculte de Medecine et Pharmacie, France in 2005
11. Testing completed by SGS Limited, Thailand in 2010

Various SMARTeZ® Tests

12. Testing completed by TUV SUD PSB Pte Ltd, Singapore in 2015, 2017, 2019, 2022, 2023

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.