

SMARTeZ®

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	Room Temperature	Reference
5-FU + SODIUM FOLINATE (ONCOFOLIC + RIBOFLUOR)	5 mg/ml + 2 mg/ml	NS	--	7 days	1
	36 mg/ml + 8.8 mg/ml	NS	--	7 days	1
ACYCLOVIR Na	10 mg/ml	NS	--	5 days	6
AGALSIDASE BETA (FABRAZYME)	0.05 mg/ml	NS	--	24 hrs	7
	0.7 mg/ml	NS	--	24 hrs	7
AMIKACIN	10 mg/ml	NS	15 days	48 hrs	7
	20 mg/ml	NS	15 days	48 hrs	7
AMOXICILLINE	1 mg/ml	NS	6 hrs	2 hrs	5
	40 mg/ml	NS	6 hrs	2 hrs	5
AMOXICILLINE + CLAVULANATE	10 mg/ml + 2 mg/ml	NS	6 hrs	--	6
	20 mg/ml + 4 mg/ml	NS	6 hrs	--	6
AMPICILLIN Na	12 mg/ml	NS	4 days	6 hrs	8

Medication	Concentration	Diluent	Refrigerated	Room Temperature	Reference
AMPICILLIN Na	20 mg/ml	NS	3 days	24 hrs	5
AMPICILLIN Na + SULBACTAM Na	30 mg/ml + 15 mg/ml	NS	2 days	6 hrs	5
AMPHOTERICIN B **	0.1 mg/ml	D5W	4 days	24 hrs	1
	0.5 mg/ml	D5W	4 days	24 hrs	1
	2 mg/ml	D5W	4 days	24 hrs	1
AZITHROMYCIN	1 mg/ml	NS	7 days	24 hrs	6
	2 mg/ml	NS	7 days	24 hrs	6
AZTREONAM	10 mg/ml	NS	7 days	24 hrs	4
	30 mg/ml	NS	7 days	24 hrs	4
BUPIVACAINE HCl	5 mg/ml	RTU	15 days	2 day	1
BUPIVACAINE	0.125%	NS	--	30 day	5
	0.750%	NS	--	30 day	5
BUMETANIDE	0.016 mg/ml	D5W	--	24 hrs	5
	0.16 mg/ml	D5W	--	24 hrs	5
CASPOFUNGIN ACETATE	0.2 mg/ml	NS	14 day	60 hrs	5
	0.5 mg/ml	NS	14 day	60 hrs	5
CEFAZOLIN Na	16.7 mg/ml	NS	14 days	2 days	1
CEFEPIME	20 mg/ml	NS	14 days	24 hrs	6
CEFOTAXIME	10 mg/ml	NS	14 days	24 hrs	8
	15 mg/ml	NS	14 days	24 hrs	8
CEFOTAXIME Na	16.66 mg/ml	NS	3 days	24 hrs	6
CEFOTIAM	20 mg/ml	NS/D5W	24 hrs	6 hrs	5
CEFOXITIN	1 mg/ml	NS	7 days	48 hrs	7
	10 mg/ml	NS	7 days	48 hrs	7
CEFTAZIDIME	1 mg/ml	NS	2 days	24 hrs	5
	40 mg/ml [#]	NS	2 days	12 hrs	5
CEFTAZIDIME	40 mg/ml [^]	NS	14 days	24 hrs	3
CEFTAZIDIME (incl. PYRIDINE determination)	9 mg/ml	NS	7 days	--	8
	60 mg/ml	NS	5 days	--	8
CEFTOLOZANE + TAZOBACTAM (ZERBAXA)	1 mg/ml + 0.5 mg/ml	NS	14 days	24 hrs	7
	2 mg/ml + 1 mg/ml	NS	14 days	24 hrs	7
	30 mg/ml + 15 mg/ml	NS	14 days	24 hrs	7
CEFTRIAZONE **	10 mg/ml	NS	14 days	48 hrs	7
	50 mg/ml	NS	14 days	48 hrs	7
CEFTRIAZONE **	10 mg/ml	D5W	6 days	24 hrs	1
CEFUROXIME	1 mg/ml	NS	3 days	24 hrs	6
	30 mg/ml	NS	3 days	24 hrs	6
CEFUROXIME	1 mg/ml	D5W	3 days	12 hrs	6
	30 mg/ml	D5W	3 days	12 hrs	6

Medication	Concentration	Diluent	Refrigerated	Room Temperature	Reference
CIMETIDINE	1 mg/ml	NS	--	7 days	5
	6 mg/ml	NS	--	7 days	5
CIPROFLOXACIN	2 mg/ml	D5W	30 days	10 days	6
CISPLATIN *	0.2 mg/ml	NS	7 days	24 hrs	3
CISPLATIN *	0.1 mg/ml	NS	--	14 days	5
	0.5 mg/ml	NS	--	14 days	5
CLINDAMYCIN PO4	6 mg/ml	NS	30 days	3 days	6
	12 mg/ml	NS	30 days	3 days	6
COLISTIMETHATE SODIUM	3 mg/ml	NS	24 hrs	2 hrs	5
CLOXACILLIN	50 mg/ml	NS	7 days	24 hrs	3
CYCLOPHOSPHAMIDE	2 mg/ml	NS	14 days	2 days	5
	20 mg/ml	NS	7 days	2 days	5
DAPTOMYCIN (CUBICIN)	1 mg/ml	NS	10 days	1 day	7
	5 mg/ml	NS	10 days	1 day	7
	20 mg/ml	NS	10 days	1 day	1
DEFEROXAMINE	0.022 mg/ml	NS	14 days	2 days	3
DEFEROXAMINE MESYLATE	5 mg/ml	NS	14 days	2 days	1
	100 mg/ml	NS	14 days	2 days	1
DOXORUBICIN	2 mg/ml	NS	22 days	14 days	1
DOXYCYCLINE	1 mg/ml	NS/D5W	3 days	12 hrs	2
	1.5 mg/ml	NS/D5W	3 days	12 hrs	2
ERTAPENEM	5 mg/ml [#]	NS	24 hrs	6 hrs	6
	20 mg/ml [#]	NS	24 hrs	6 hrs	6
ERTAPENEM	5 mg/ml [^]	NS	7 days	--	1
	10 mg/ml [^]	NS	7 days	24 hrs	5
	20 mg/ml [^]	NS	5 days	24 hrs	5
ETOPOSIDE	0.2 mg/ml	NS	--	4 days	5
	0.4 mg/ml	NS	--	24 hrs	5
FERINJECT (IRON (III) SUCROSE COMPLEX)	2 mg/ml	NS	--	3 days	1
	5 mg/ml	NS	--	3 days	1
FLUCLOXACILLIN	10 mg/ml	NS	2 days	24 hrs	5
	70 mg/ml	NS	2 days	24 hrs	5
FLUCONAZOLE	2 mg/ml	RTU	7 days	2 days	1
FLUOROURACIL (5-FU) *	5 mg/ml	D5W/NS	--	45 days	1
	50 mg/ml	RTU	--	45 days	1
FLOXURIDINE	10 mg/ml	NS	14 days	1 day	9
FOLINIC ACID	4 mg/ml	NS	14 days	2 days	3
FOSCARNET Na	12 mg/ml	NS	14 days	7 days	10
	24 mg/ml	RTU	14 days	7 days	10

Medication	Concentration	Diluent	Refrigerated	Room Temperature	Reference
FOSFOMYCIN DISODIUM	16.6 mg/ml	D5W	--	2 days	1
	40 mg/ml	D5W	--	2 days	1
FOSFOMYCIN SODIUM	20 mg/ml	NS	--	24 hrs	1
	20 mg/ml	NS	--	1h at 37°C	1
FUROSEMIDE	10 mg/ml	NS	7 days	4 days	2
GANCICLOVIR *	1 mg/ml	NS	14 days	2 days	1
	10 mg/ml	NS	14 days	2 days	1
GANCICLOVIR *	1 mg/ml	D5W	14 days	2 days	5
	10 mg/ml	D5W	14 days	2 days	5
GENTAMYCIN SO4	0.5 mg/ml	NS	7 days	7 days	1
	5 mg/ml	NS	14 days	7 days	1
	10 mg/ml	NS	28 days	48 hrs	13
GRANISETRON	0.02 mg/ml	NS	7 days	2 days	5
	0.5 mg/ml	NS	7 days	2 days	5
GRANISETRON	0.02 mg/ml	D5W	3 days	6 hrs	5
	0.5 mg/ml	D5W	3 days	6 hrs	5
HUMAN PLASMA GLOBULIN (Hizentra)	200 mg/ml	RTU	--	7 days	1
IFOSFAMIDE	0.6 mg/ml [#]	NS/D5W	3 days	24 hrs	6
	40 mg/ml [#]	NS/D5W	3 days	24 hrs	6
IFOSFAMIDE	0.6 mg/ml [^]	D5W	--	7 days	1
	40 mg/ml [^]	D5W	--	3 days	1
IMIPENEM + CILASTATIN Na (PRIMAXIN)	5 mg/ml + 5 mg/ml	NS	3 days	24 hrs	5
KETAMINE	1 mg/ml	NS	--	2 days	5
	2 mg/ml	NS	--	2 days	5
LEVOBUPIVACAINE	0.125%	NS	--	30 days	5
	0.750%	NS	--	30 days	5
LEVOFLOXACIN	0.5 mg/ml	NS/D5W	14 days	7 days	6
	5 mg/ml	NS/D5W	14 days	7 days	6
LINCOMYCIN	1.2 mg/ml	NS	1 days	1 days	1
	10 mg/ml	NS/D5W	1 days	1 days	1
LIDOCAINE	0.50%	NS	--	30 days	5
	2%	NS	--	30 days	5
LINEZOLID	0.15 mg/ml	NS	13 days	24 hrs	1
	2 mg/ml	NS	13 days	24 hrs	1
MAGNESIUM SULFATE	20 mg/ml	NS	29 days	24 hrs	5
MEROPENEM	5 mg/ml [^]	NS	10 days	24 hrs	5,7
	10 mg/ml	NS	5 days	21 hrs	13
	20 mg/ml [^]	NS	4 days	24 hrs	5,6,7

Medication	Concentration	Diluent	Refrigerated	Room Temperature	Reference
MEROPENEM	2.5 mg/ml [#]	NS	24 hrs	6 hrs	6
	20 mg/ml [#]	NS	24 hrs	6 hrs	6
METHOTREXATE	0.3 mg/ml	NS	7 days	7 days	6
	25 mg/ml	NS	7 days	7 days	6
METHYLPREDNISOLONE	10 mg/ml	NS	7 days	2 hrs	2
METOCLOPRAMIDE	5 mg/ml	NS	2 days	2 days	8
METRONIDAZOLE	5 mg/ml	RTU	10 days	24 hrs	2
MICA FUNGIN	0.5 mg/ml	NS	4 days	24 hrs	1
	1.5 mg/ml	NS	9 days	-	12
	2 mg/ml	NS	4 days	24 hrs	1
MORPHINE SO ₄	1 mg/ml	NS	--	7 days	1
	20 mg/ml	NS	--	7 days	1
NAFCILLIN	5 mg/ml	NS	14 days	30 hrs	7
	50 mg/ml	NS	14 days	48 hrs	13
NEFOPAM	10 mg/ml	NS	1 days	1 days	5
NORMAL SALINE	0.9% NaCl	--	15 days	15 days	5
OFLOXACIN	0.4 mg/ml	NS	14 days	7 days	5
	2 mg/ml	NS	14 days	7 days	5
ONDANSETON HCL	0.03 mg/ml	NS/D5W	21 days	7 days	6
	0.7 mg/ml	NS/D5W	10 days	4 days	6
OXACILLIN	10 mg/ml	NS	8 days	4 days	6
	100 mg/ml	NS	8 days	4 days	6
PACLITAXEL	0.3 mg/ml	NS/D5W	7 days	24 hrs	1
	1.2 mg/ml	NS/D5W	7 days	24 hrs	1
PAMIDRONIC ACID SODIUM SALT	30 µg/ml	NS	27 days	2 days	1
	0.4 mg/ml	NS	27 days	2 days	1
	30 µg/ml	D5W	27 days	2 days	1
	30 µg/ml	NS	--	29 days	1
PENICILLIN G (K)	20,000 units/ml	NS	4 days	24 hrs	5
	20,000 units/ml	NS	14 days	24 hrs	14
	100,000 units/ml	NS	14 days	24 hrs	14
PENICILLIN G (Na)	2000 units/ml	NS	3 days	2 hrs	6
	100,000 units/ml [#]	NS	1 day	2 hrs	6
	100,000 units/ml [^]	NS	--	6 hrs	5
PIPERACILLIN	10 mg/ml	NS	14 days	3 days	5
	80 mg/ml	NS	5 days	24 hrs	5
PIPERACILLIN Na + TAZOBACTAM Na	10 mg/ml + 1.25 mg/ml [#]	NS	21 days	48 hrs	7
	80 mg/ml + 10 mg/ml [#]	NS	21 days	48 hrs	7

Medication	Concentration	Diluent	Refrigerated	Room Temperature	Reference
PIPERACILLIN Na + TAZOBACTAM Na	10 mg/ml + 1.25 mg/ml [^]	NS	28 days	24 hrs	5
	80 mg/ml + 10 mg/ml [^]	NS	28 days	24 hrs	5
RANITIDINE	0.5 ml/ml	NS	21 days	2 days	1
	2 mg/ml	NS	21 days	7 days	1
RANITIDINE	0.5 ml/ml	D5W	21 days	2 days	1
	2 mg/ml	D5W	21 days	7 days	1
RIBODRONAT (PAMIDRONIC ACID SODIUM SALT)	30 µg/ml	NS/D5W	27 days	2 days	1
	0.4 mg/ml	NS	27 days	2 days	1
	30 µg/ml	NS	--	29 days	1
RIFAMPICIN	0.5 ml/ml	NS	6 days	24 hrs	1
	3 mg/ml	NS	6 days	24 hrs	1
ROPIVACAINE	0.2 mg/ml	NS	14 days	24 hrs	1
	5 mg/ml	NS	14 days	24 hrs	1
ROPIVACAINE	0.10%	NS	--	30 days	5
	0.75%	NS	--	30 days	5
TEICOPLANIN	1 mg/ml	NS	7 days	24 hrs	5
	20 mg/ml	NS	7 days	24 hrs	5
TEMOCILLIN	10 mg/ml [#]	NS	14 days	24 hrs	5
	20 mg/ml [#]	NS	14 days	24 hrs	5
TEMOCILLIN	10 mg/ml [^]	NS	-	24 hrs	1
	80 mg/ml [^]	NS	-	24 hrs	1
TICARCILLIN Disodium CLAVULANATE K	31 mg/ml	NS	7 days	1 day	11
TIGECYCLINE	0.5 mg/ml	NS	2 days	24 hrs	1
	1 mg/ml	NS	2 days	24 hrs	1
TOBRAMYCIN	0.2 mg/ml	NS	14 days	24 hrs	1
	10 mg/ml	NS	14 days	24 hrs	1
VANCOMYCIN	4 mg/ml [#]	NS/D5W	21 days	4 days	6
	15 mg/ml [#]	NS/D5W	14 days	2 days	6
VANCOMYCIN	15 mg/ml [^]	NS	30 days	2 days	6
VINCRISTINE	1 mg/ml	NS	--	21 days	5
VENOFER (IRON (III) HYDROXIDE SUCROSE)	1 mg/ml	NS	24 hrs	24 hrs	1

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

combined – tested refrigerated + room temperature

[^] separate – tested only refrigerated and only room temperature

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 - FTIR 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-FTIR 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 8). 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.

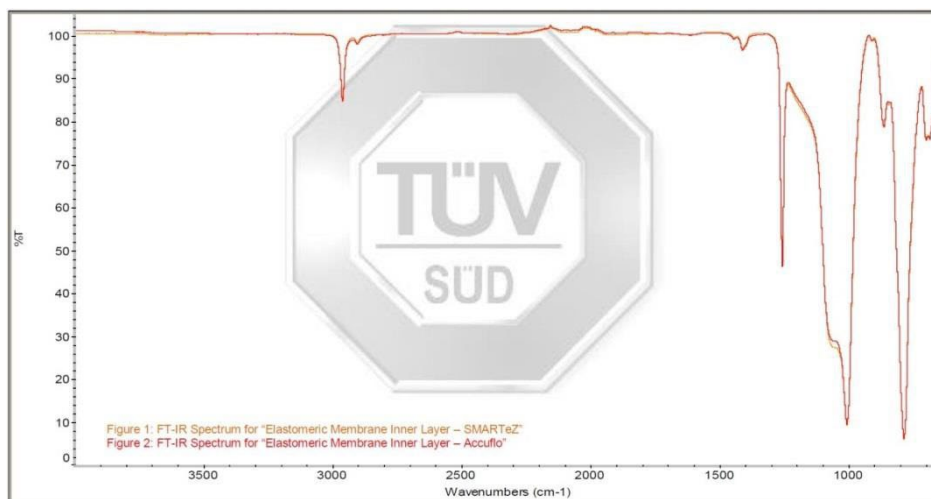
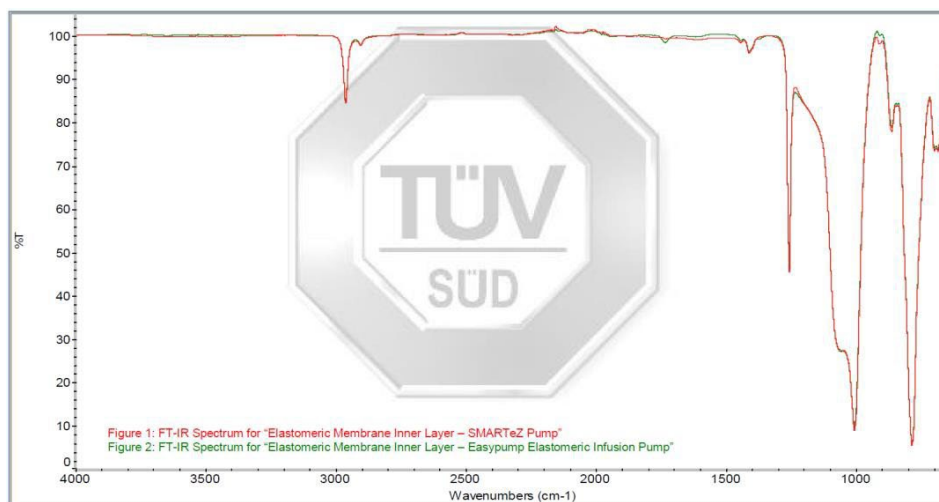


Image 2. Spectral overlay of the fluid path materials of the SMARTeZ® and Easypump II® elastomeric pump



Note

* 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.

Laboratory Testing References

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
 9. Testing completed by TÜV SÜD PSB Pte. Ltd. Laboratory Services, Singapore, on SMARTeZ Pumps in 2015.
 10. Testing completed by Beckman Industrial Corp., U.S.A.
 11. Testing completed by Pyramid Laboratories, U.S.A.
 12. Testing completed by TÜV SÜD PSB Pte. Ltd. Laboratory Services, Singapore in 2023.
 13. Testing completed by TÜV SÜD PSB Pte. Ltd. Laboratory Services, Singapore in 2017
- a. FT-IR Analysis testing completed by TÜV SÜD PSB Pte. Ltd. Laboratory Services, Singapore, on SMARTeZ® and AccuFloTM in 2015.

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

14. ASHP (American Society of Health-System Pharmacists), Extended Stability for Parenteral Drugs, 7th Edition

Source Notes

Drug Stability List for EasyPump II. B.Braun Medical Inc. June 2020

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.