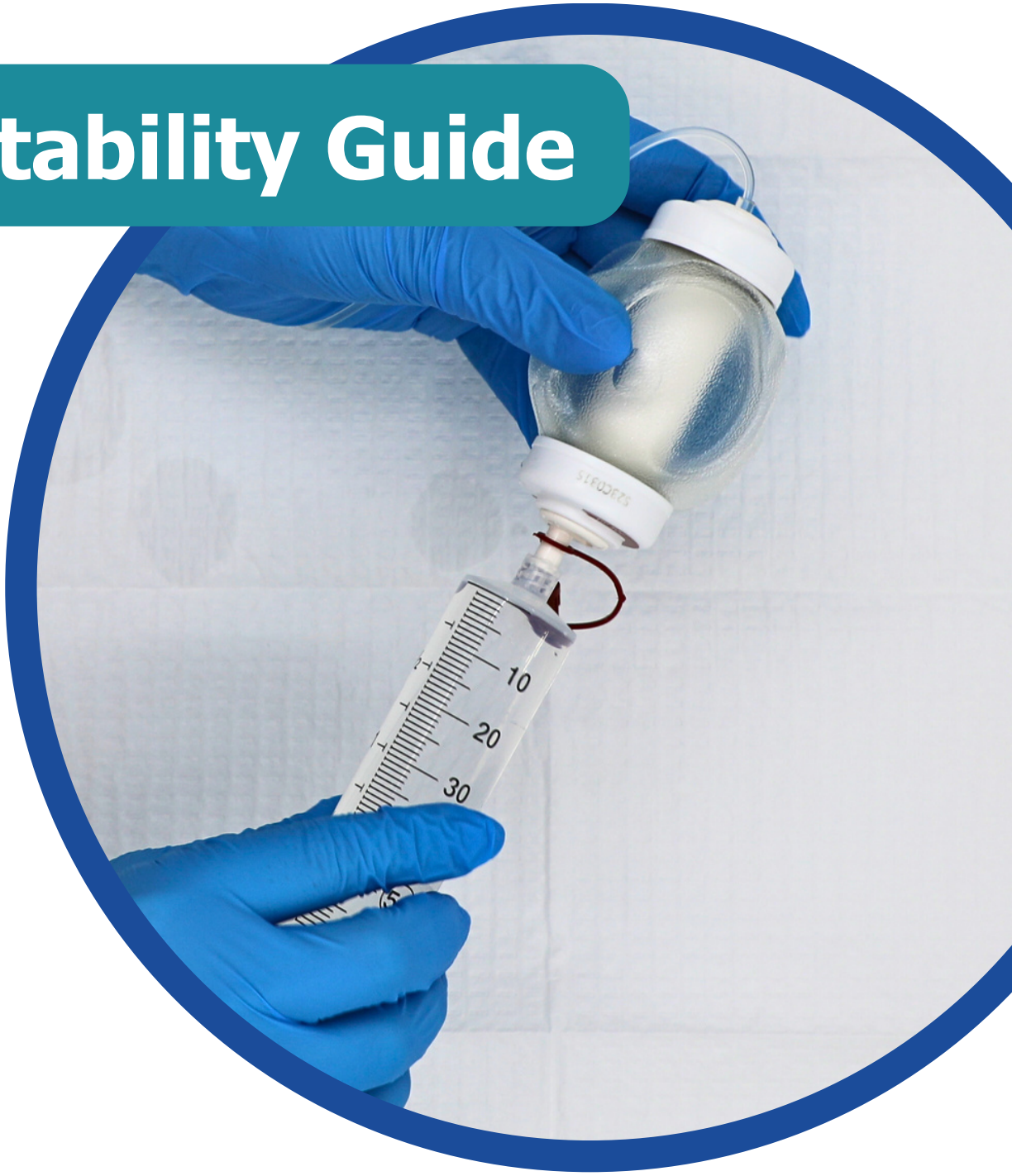
EZ FLOW™
ELASTOMERIC PUMP

IMed™ Products

Drug Stability Guide



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How Does the EZ-FLOW™ Elastomeric Pump Work?

Drug stability data is available on a wide range of medications. The drug stability guidelines for the administration of medications using the EZ-FLOW™ were developed as a result of testing performed by independent laboratories, a review of various medical publications, manufacturers' product information, and available elastomeric infusion pump drug stability data. The stability data relates to chemical stability of the drugs tested, not to sterility.

The pharmacist dispensing the drug is responsible for ensuring proper preparation using validated aseptic techniques to prevent microbiological contamination. For practice and quality standards, refer to USP 797 Pharmaceutical Compounding - Sterile Preparations and USP 800 Hazardous Drugs - Handling in a Healthcare Setting.

Contact your Territory Manager at 800.755.3800, or refer to our website, integratedmedsys.com, for the most up-to-date drug stability information.

Choosing the Right Pump

The EZ-FLOW™ is easy to fill and is color-coded for quick and accurate device identification. A wide variety of sizes and flow rates are available, along with an extensive library of drug stability data. The range of SKUs available offers dosing flexibility to administer various infusion therapies. Please refer to the Fill Volume and Delivery Time Tables on pages 4-7, as well as the Drug Stability Guide to help determine which product is best suited for the needed therapy.

Fill Volumes and Delivery Times

Refer to the tables on the following pages to determine the appropriate pump model based on the fill volume and desired delivery time. Residual volume information is also included.

The EZ-FLOW™ nominal rates are based on sodium chloride (0.9%, 31° C/88° F) as reference. Use of 5% dextrose will result in 10% slower flow rate or correspondingly 10% longer delivery time.

Note:

1. Delivery times for partial or overfill volumes are approximate values.
2. Filling the pump more than the nominal fill volume results in a slower flow rate.
3. Filling the pump less than nominal fill volume results in a faster flow rate.
4. Do not fill the pump less than the minimal or more than the maximum fill volume specified on the chart.
5. It is recommended that the EZ-FLOW™ be filled with diluent before adding the drug/medication.

The EZ-FLOW™ Elastomeric Pumps offer a straightforward and secure drug delivery system suitable for pharmacists, nurses, and patients. These guidelines for utilizing the EZ-FLOW™ for medication administration were established based on assessments conducted by independent labs, examination of diverse medical literature, manufacturers' product details, and accessible data on drug stability pertaining to elastomeric infusion pumps.

Medication	Concentration	Dilutent	Room Temperature	Refrigerated	Reference No.
ACYCLOVIR Na	10 mg/ml	NS	5 days	--	3
AMIKACIN SO4	10 mg/ml	NS	1 day	28 days	4
AMPHOTERICIN B	0.1mg/ml, 0.5mg/ml, and 2 mg/ml	D5W	1 day	4 days	8
AMPICILLIN Na	12 mg/ml	NS	6 hours	4 days	15
	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
BUMETANIDE	0.016 mg/ml and 0.16 mg/ml	D5W	1 day	--	6
BUPIVACAINE HCl	0.5% (5 mg/ml)	NS	2 days	15 days	8
	0.125% (1.25 mg/ml) and 0.75% (7.5 mg/ml)	NS	30 days	--	6
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
CEFOXITIN Na	1 mg/ml and 10mg/ml	NS	2 days	7 days	16
CEFTAZIDIME	40 mg/ml	NS	1 day	14 days	4
CEFTOLOZANE/TAZOBACTAM	1 + 0.5 mg/ml and 10 + 5 mg/ml	NS	1 day	10 days	14
CEFTRIAXONE Na	40 mg/ml	NS	1 day	14 days	7
	10 mg/ml and 50 mg/ml	NS	2 days	14 days	16
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	14 days	4
	0.1 mg/ml and 0.5mg/ml	NS	14 days	--	6
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	0.022 mg/ml	NS	2 days	14 days	4
	95 mg/ml	NS	1 day	14 days	7
	5 mg/ml and 100 mg/ml	NS	2 days	14 days	8
DOXORUBICIN	2 mg/ml	NS	14 days	22 days	8
DOXYCYCLINE	1-1.5 mg/ml	NS/D5W	12 hours	3 days	9
ERAVACYCLINE	0.2 mg/ml and 0.6 mg/ml	NS	1 day	8 days	17

Studies were conducted to compare the material composition of the fluid path (drug reservoir membrane, tubing and connectors) of the EZ-FLOW™ Elastomeric Pump to the Easypump® pump using ATR-FTIR spectral analysis 1,2 Spectral overlay analysis indicated identical fluid path composition when comparing EZ-FLOW™ to the Easypump® elastomeric pumps. This validates the use of drug stability studies on Easypump® for EZ-FLOW™. The use of attenuated total reflectance technology (ATR) combining with Fourier transform infrared (FTIR) spectrophotometer enables high quality comparison of Spectral overlay of the fluid path materials of the EZ-FLOW™ polymer materials.

Medication	Concentration	Dilutent	Room Temperature	Refrigerated	Reference No.
ERTAPENEM	10 mg/ml	NS	1 day	7 days	6
	20 mg/ml	NS	1 day	5 days	
ETOPOSIDE	0.2 mg/ml	NS	4 days	--	6
	0.4 mg/ml	NS	1 day	--	
FLOXURIDINE	10 mg/ml	NS	1 day	14 days	7
FLUCONAZOLE	2 mg/ml	RTU	2 days	7 days	8
FLUOROURACIL (5FU)	5 mg/ml and 50 mg/ml	NS	45 days	--	8
	50 mg/ml	NS	45 days	45 days	4
FOLINIC ACID	4 mg/ml	NS	2 days	14 days	4
FOSFOMYCIN Na	16.6 mg/ml and 40 mg/ml	D5W	2 days	--	8
FUROSEMIDE	10 mg/ml	NS	4 days	7 days	9
GANCICLOVIR	1 mg/ml and 10 mg/ml	NS	2 days	14 days	8
GENTAMICIN	0.5 mg/ml	NS	7 days	7 days	8
	5 mg/ml	NS	7 days	14 days	
	10 mg/ml	NS	2 days	28 days	7
GRANISETRON	0.02 mg/ml and 0.5 mg/ml	NS	2 days	7 days	6
IFOSFAMIDE	0.06 mg/ml and 40 mg/ml	NS/D5W	1 day	3 days	6
IMIPENEM-CILASTATIN Na	5 mg/ml	NS	1 day	3 days	6
IRON (III) HYDROXIDE SUCROSE	1 mg/ml	NS	1 day	1 day	8
	2 mg/ml and 5 mg/ml	NS	3 days	--	
KETAMINE	1 mg/ml and 2 mg/ml	NS	2 days	--	6
LEVOFLOXACIN	0.5 mg/ml and 5 mg/ml	NS/D5W	7 days	14 days	3
LIDOCAINE	0.5%, 2%	NS	30 days	--	6
LINCOMYCIN	1.2 mg/ml	NS	1 day	1 day	8
	10 mg/ml	NS/D5W	1 day	1 day	
LINEZOLID	0.15 mg/ml and 2 mg/ml	NS	1 day	13 days	8
MAGNESIUM SULFATE	20 mg/ml	NS	1 day	29 Days	6
MEROPENEM	5 mg/ml	NS	1 day	10 days	6,15
	10 mg/ml	NS	21 hours	10 days	7
	20 mg/ml	NS	1 day	4 days	3, 6, 15
METHOTREXATE	0.3 mg/ml and 25 mg/ml	NS	7 days	7 days	3
METHYLPREDNISOLONE Na	10 mg/ml	NS	2 hours	7 days	9
METOCLOPRAMIDE	5 mg/ml	NS	2 days	2 days	15
METRONIDAZOLE	5 mg/ml	NS/RTU	1 day	10 days	9
MICAFUNGIN	0.5mg/ml and 2 mg/ml	NS	1 day	9 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

Medication	Concentration	Dilutent	Room Temperature	Refrigerated	Reference No.
NORMAL SALINE	0.9% NaCl	NS	15 days	15 days	6
OMADACYCLINE	1 mg/ml and 2 mg/ml	NS/D5W	--	9 days	18
ONDANSETRON HCL	0.03 - 0.3 mg/ml	NS/D5W	7 days	21 days	3
	0.7 mg/ml	N5/D5W	4 days	10 days	
OXACILLIN	10 mg/ml and 100 mg/ml	NS	4 days	8 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 IU/ml	NS	1 day	14 days	6
	100,000 IU/ml	NS	1 day	14 days	4
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
	0.5% (5mg/ml)	NS	1 day	14 days	
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
VINCRISTINE	1 mg/ml	NS	21 days	--	6

Laboratory Testing References:

1. FT-IR Analysis testing completed by TÜV SÜD PSB Pte. Ltd. Laboratory Services, Singapore, on EZ-FLOW™, SMARTeZ® and EasyPump® in 2015.
2. FT-IR Analysis testing completed by TÜV SÜD PSB Pte. Ltd. Laboratory Services, Singapore, on EZ-FLOW™, 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 EZ-FLOW™ and 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.
14. Terracciano, J., Rhee, E.G., & Walsh, J. (2017). Chemical Stability of Ceftolozane/Tazobactam in Polyvinychloride Bags and Elastomeric Pumps. Current Therapeutic Research, Clincal and Experimental, Vol. 84, Pages 22-25.
15. Testing Completed by Selvita S.A., Kraków, Poland
16.Testing completed by Nelson Labs, Leuven, Belgium
17.Data on file at Tetraphase Pharmaceuticals

Source Notes:

1. Data on File, Integrated Medical Systems, Inc. (IMS).
2. Stability Data for Drugs Using B. Braun's AccuFlo™ Elastomeric Infusion System B.Braun Medical Inc. April 2015.
3. Drug Stability for Easypump® 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.

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