



MEDI-FLO[®]
ELASTOMERIC PUMP

Drug Stability Guide

Antibiotics, Chemotherapy
and Pain Management Infusions

Delivering Efficiency to Healthcare[®]

Distributed by: NDC Homecare, LLC
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MEDI-FLO® ELASTOMERIC PUMP

MEDI-FLO® Elastomeric Pumps provide a drug delivery system that is simple and safe to use for pharmacists, nurses and patients. These Guidelines for the administration of medications using the MEDI-FLO® Elastomeric Pump were developed as a result of testing performed by independent laboratories, review of various medical publications and manufacturers' product information, and available elastomeric infusion pump drug stability data.

Medication	Concentration	Diluent	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
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
CEFTRIAZONE 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			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			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	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 SU- CROSE	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

Medication	Concentration	Diluent	Room Temperature	Refrigerated	Reference No.
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		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	100,000 units/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
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

Laboratory Testing References:

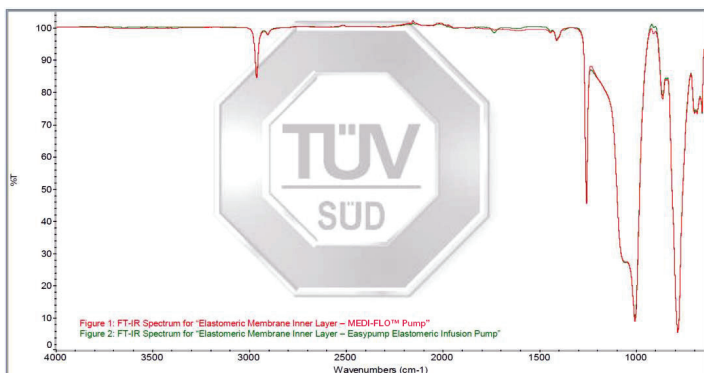
1. FTIR Analysis testing completed by TÜV SÜD PSB Pte. Ltd. Laboratory Services, Singapore, on MEDI-FLO®, SMARTeZ® and EasyPump® in 2015.
2. FTIR Analysis testing completed by TÜV SÜD PSB Pte. Ltd. Laboratory Services, Singapore, on MEDI-FLO®, SMARTeZ® and EasyPump® in 2015.
3. Testing completed by SGS 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 MEDI-FLO® 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.

Source Notes:

1. Data on File, Wolf Medical Supply, An NDC Company.
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.



Spectral overlay of the fluid path materials of the MEDI-FLO® and Easypump® elastomeric pumps.

Studies were conducted to compare the material composition of the fluid path (drug reservoir membrane, tubing and connectors) of the MEDI-FLO® pump to the Easypump® pump using ATR-FTIR spectral analysis^{1,2}. Spectral overlay analysis indicated identical fluid path composition when comparing MEDI-FLO® to the Easypump® elastomeric pumps. This validates the use of drug stability studies on Easypump® for MEDI-FLO®.

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

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