



MEDI-FLO®
ELASTOMERIC PUMP

Drug Stability Guide

Antibiotics, Chemotherapy
and Pain Management Infusions

Delivering Efficiency to Healthcare®

Distributed by: Wolf Medical Supply, An NDC Company
13951 NW 8th Street / Sunrise, FL 33325
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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 | |

Laboratory Testing References:

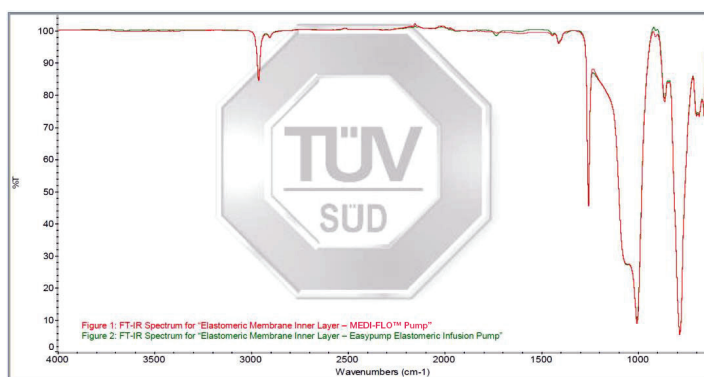
1. FT-IR Analysis testing completed by TÜV SÜD PSB Pte. Ltd. Laboratory Services, Singapore, on MEDI-FLO®, SMARTeZ® and Easypump® in 2015.
2. FT-IR Analysis testing completed by TÜV SÜD PSB Pte. Ltd. Laboratory Services, Singapore, on MEDI-FLO®, SMARTeZ® and Easypump® in 2015.
3. Testing completed by 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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REV03

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