

FY14 Drugs

Drug Name	Trade Name	Dosage Form	Firm	Tests Performed	Why Tested	Results
0.9% Sodium Chloride	Generic	Injection	Fresenius Medical Care	Microbiologic (bacterial endotoxin & visual exam; assay, identification (ID) & pH)	Reports of cloudiness	Passed Test
1.5% Dextrose Peritoneal Dialysis Solution	Delflex	Injection	Fresenius Medical Care	Microbiologic (bacterial endotoxin & visual exam; assay, ID & pH)	Reports of cloudiness	Passed Test
5% Dextrose Injection USP Mini Bag Plus	Generic	Injection	Baxter Healthcare Corp	Microbiologic (bacterial endotoxin, organisms & visual exam)	Reports of particulates and discoloration	Passed Test
Amino Acid	Premasol	Injection	Baxter Healthcare Corp	Microbiologic (bacterial endotoxin)	Reports of particulates and discoloration	Passed Test
Amino Acid	Travasol	Injection	Baxter Healthcare Corp	Microbiologic (bacterial endotoxin)	Reports of particulates and discoloration	Passed Test
Amino Acid	Clinisol	Injection	Baxter Healthcare Corp	Microbiologic (bacterial endotoxin)	Reports of particulates and discoloration	Passed Test
Amino Acid	Clinisol	Injection	Baxter Healthcare Corp	Microbiologic (bacterial endotoxin)	Reports of particulates and discoloration	Passed Test
Amino Acid	Clinimix	Injection	Baxter Healthcare Corp	Microbiologic (foreign material, bacteriostatic or fungistatic, bacterial endotoxin)	Reports of particulates and discoloration	Passed Test
Amino Acid	ProSol	Injection	Baxter Healthcare Corp	Microbiologic (bacteriostatic or fungistatic )	Reports of particulates and discoloration	Passed Test
Amino Acid	Clinimix E	Injection	Baxter Healthcare Corp	Microbiologic (bacteriostatic or fungistatic)	Reports of particulates and discoloration	Passed Test

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Amino Acid	Clinimix E	Injection	Baxter Healthcare Corp	Microbiologic (bacteriostatic or fungistatic )	Reports of particulates and discoloration	Passed Test
Amlodipine Besylate & Benazepril HCL	Generic	Capsules	Dr. Reddy's Laboratories Limited	Identitification (ID), Content Uniformity (CU), Dissolution, Impurities, weight variation (WV)	Response to cGMP inspection violations	Passed Test
Atorvastatin	Generic	Tablets	Greenstone	Dissolution, liquid chromatography-mass spectrometry (LC-MS)	Reports of Impurities	Passed Test
Atorvastatin	Generic	Tablets	KREMERS Urban Pharms	Dissolution, LC-MS	Reports of Impurities	Passed Test
Atorvastatin	Generic	Tablets	Mylan Pharmaceuticals	Dissolution, LC-MS	Reports of Impurities	Passed Test
Atorvastatin Calcium	Lipitor	Tablets	Parke-Davis Division of Pfizer	Dissolution, LC-MS	Reports of Impurities	Passed Test
Atorvastatin Calcium	Generic	Tablets	Apotex Corp.	Dissolution, LC-MS	Reports of Impurities	Passed Test
Atorvastatin Calcium	Generic	Tablets	Ranbaxy Pharmaceuticals	Dissolution, LC-MS	Reports of Impurities	Passed Test
Atorvastatin Calcium	Generic	Tablets	Dr. Reddy's Laboratories	Dissolution, LC-MS	Reports of Impurities	Passed Test
Atorvastatin Calcium	Generic	Tablets	Dr. Reddy's Laboratories	CU, Dissolution, Impurities, WV	Response to cGMP inspection violations	Passed Test
Atorvastatin Calcium	Generic	Tablets	Dr. Reddy's Laboratories	Assay, CU, Impurities, Dissolution, WV	Response to cGMP inspection violations	Passed Test
Atorvastatin Calcium	Generic	Tablets	Sandoz Inc.	Dissolution, LC-MS	Reports of Impurities	Passed Test
Azithromycin	Generic	Oral Suspension	Patheon	Assay, CU, viscosity, physical appearance	Stability Concerns	Failed Assay & CU – inspection initiated
Ciprofloxacin	Generic	Tablets	Dr. Reddy's Laboratories	Assay, CU, Dissoultion, ID, WV	Response to cGMP inspection violations	Passed Test
Citalopram	Generic	Tablets	Dr. Reddy's Laboratories	CU, Dissolution, Impurities, ID, WV	Response to cGMP inspection violations	Passed Test

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Clopidogrel Bisulfate	Generic	Tablets	Dr. Reddy's Laboratories	Assay, ID, Impurities, Dissolution, CU, WV	Response to cGMP inspection violations	Passed Test
Decitabine	Generic	Injection	Dr. Reddy's Laboratories	Microbiologic (bacteriostatic or	Response to cGMP inspection violations	Passed Test
Desloratadine	Generic	Orally Disintegrating Tablets	Dr. Reddy's Laboratories Limited	Assay, CU, Dissolution, Impurities, ID, WV	Response to cGMP inspection violations	Passed Test
Divalproex Sodium	Generic	Extended-Release Tablets	Dr. Reddy's Laboratories Limited	Dissolution, Assay, CU, Impurities, WV	Response to cGMP inspection violations	Failed Dissolution – followup pending
Divalproex Sodium	Generic	Capsules	Dr. Reddy's Laboratories Limited	Dissolution, Assay, CU, Impurities, WV	Response to cGMP inspection violations	Failed Dissolution – follow up pending
Dobutamine HCl in 5% Dextrose	Generic	Injection	Baxter Healthcare Corp	Microbiologic (bacterial endotoxin)	Reports of particulates and discoloration	Passed test
Donepezil HCL	Generic	Tablets	Dr. Reddy's Laboratories	ID, Assay, CU, Related Substances, Dissolution,	Response to cGMP inspection violations	Passed Test
Dopamine HCl and 5% Dextrose	Generic	Injection	Baxter Healthcare Corp	Microbiologic (bacterial endotoxin)	Reports of particulates and discoloration	Passed Test
Dopamine HCl and 5% Dextrose	Generic	Injection	Baxter Healthcare Corp	Microbiologic (bacterial endotoxin)	Reports of particulates and discoloration	Passed Test
Fentanyl Transdermal System	Generic	Patch	LTS Lohmann Therapy Systems	CU, Degradation, ID, Adhesion Strength, Peel Strength, Adhesion Tack, Shear Force	Difficult to manufacture and past adhesion concerns	Passed Test
Fentanyl Transdermal System	Ionsys	Patch	Alza Corp	Cu, Degradation, assay, Adhesion & Release Force, Probe track	Difficult to manufacture and past adhesion concerns	Failed Probe Track – follow up inspection performed

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Fentanyl Transdermal System	Generic	Patch	AVEVA Drug Delivery Systems	Assay, CU, Impurities, Adhesion Strength, Peel Strength, Adhesion Tack, Shear Force	Difficult to manufacture and past adhesion concerns	Passed Test
Fentanyl Transdermal System	Generic	Patch	Mylan Pharmaceuticals Inc.	Assay, CU, impurities, Adhesion Strength, Peel Strength, Adhesion Tack, Shear Force	Difficult to manufacture and past adhesion concerns	Passed Test
Fentanyl Transdermal System	Generic	Patch	Corium International Inc.	Assay, CU, impurities, ID, Adhesion Strength, Release Linear Force, Probe Tack, Shear	Difficult to manufacture and past adhesion concerns	Passed Test
Finasteride	Generic	Tablets	Dr. Reddy's Laboratories Limited	CU, Dissolution, Related Substances, Weight Uniformity, ID	Response to cGMP inspection violations	Passed Test
Fluconazole USP	Generic	Injection	Baxter Healthcare Corp	Microbiologic (bacterial endotoxin)	Reports of particulates and discoloration	Passed Test
Fluoxetine	Generic	Capsules	Dr. Reddy's Laboratories	CU, Dissolution, Chrom Purity, ID, WV	Response to cGMP inspection violations	Passed Test
Fluoxetine	Generic	Delayed-Release Capsules	Dr. Reddy's Laboratories Limited	CU, Dissolution, Chrom Purity, ID, WV	Response to cGMP inspection violations	Passed Test
Gabapentin	Generic	Tablets	Patheon	Assay, CU, Dissolution, ID, related compounds	Dissolution concerns	Passed Test
Gentamicin Sulfate in 0.9% Sodium Chloride	Generic	Injection	Baxter Healthcare Corp	Microbiologic (bacterial endotoxin)	Reports of particulates and discoloration	Passed Test
Glimepiride	Generic	Tablets	Dr. Reddy's Laboratories	Assay, CU, Dissolution, Related Substances, ID,	Response to cGMP inspection violations	Passed Test

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Heparin Sodium		Injection	Aurobindo	Contamination	Large percentage of crude, API and finished dose heparin products are tested for contamination as a result of the 2008 heparin crisis.	Passed Test
Heparin Sodium	Generic	Injection	Gland	Contamination	Large percentage of crude, API and finished dose heparin products are tested for contamination as a result of the 2008 heparin crisis.	Passed Test
Heparin Sodium and 0.9% Sodium Chloride	Generic	Injection	Baxter Healthcare Corp	Microbiologic (no viable organisms or bacteriostatic or	Reports of particulates and discoloration	Passed test
Lamotrigine	Generic	Extended Release Tablets	Dr. Reddy's Laboratories Limited	CU, Dissolution, Related Substances, ID, WV	Response to cGMP inspection violations	Passed Test
Lamotrigine	Generic	Extended Release Tablets	Dr. Reddy's Laboratories Limited	CU, Dissolution, Related Substances, ID, WV, Assay	Response to cGMP inspection violations	Passed Test
Lansoprazole	Generic	Delayed-Release Capsules	Dr. Reddy's Laboratories Limited	CU, Dissolution, Related Substances, ID, CU, WV	Response to cGMP inspection violations	Passed Test
Levofloxacin	Generic	Tablets	Dr. Reddy's Laboratories	ID, Assay, CU, Related Substances, Dissolution,	Response to cGMP inspection violations	Passed Test
Levothyroxine Sodium	Generic	Tablets	Jerome Stevens	Dissolution, identification (ID), WV, impurities, CU	Stability history and new USP assay acceptance criteria	Passed Test

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Levothyroxine Sodium	Generic	Tablets	Mylan Pharmaceuticals Inc.	Dissolution, identification (ID), impurities, assay, CU	Stability history and new USP assay acceptance criteria	Passed Test
Levothyroxine Sodium	Tirosent	Capsules	Institut Biochimique	Dissolution, identification (ID), WV, impurities, assay, CU	Stability history and new USP assay acceptance criteria	Passed Test
Levothyroxine Sodium	Generic	Tablets	King Legacy, subsidiary of Pfizer	Dissolution, identification (ID), WV, impurities, assay, UDU	Stability history and new USP assay acceptance criteria	Passed Test
Levothyroxine Sodium	Unithroid	Tablets	Jerome Stevens	Dissolution, identification (ID), impurities, assay, CU	Stability history and new USP assay acceptance criteria	Passed Test
Levothyroxine Sodium	Synthroid	Tablets	Knoll/LLC/ dba Abbott Labs	Dissolution, identification (ID), impurities, assay, CU	Stability history and new USP assay acceptance criteria	Passed Test
Levothyroxine Sodium	Generic	Tablets	Patheon	Assay, CU, Dissolution, ID, Impurities, Poison/Toxin Screening	Stability history and new USP assay acceptance criteria	Passed Test
Lidocaine HCL and 5% Dextrose	Generic	Injection	Baxter Healthcare Corp	Microbiologic (bacterial endotoxin & no growth observed)	Reports of particulates and discoloration	Passed Test
Loperamide HCl	Imodium A-D	Capsules	McNeil PPC	Assay, CU, Dissolution, ID, Degradation	Dissolution	Passed Test
Methotrexate	Generic	Tablets	Mylan Pharmaceuticals	Dissolution, identification (ID), impurities, assay, CU	Consumer complaints	Passed Test
Methotrexate	Generic	Tablets	Mylan Pharmaceuticals	Dissolution, identification (ID), impurities, assay, CU	Consumer complaints	Passed Test
Metoprolol Succinate	Generic	Extended Release Tablets	Dr. Reddy's Laboratories Limited	CU, Dissolution, Impurities, Tablet Weight, WV, Assay	Response to cGMP inspection violations	Passed Test
Metronidazole USP	Generic	Injection	Baxter Healthcare Corp	Microbiologic (bacterial endotoxin) and visual exam	Reports of particulates and discoloration	Passed Test

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Metronidazole USP	Generic	Injection	Baxter Healthcare Corp	Microbiologic (bacterial endotoxin) and visual exam	Reports of particulates and discoloration	Passed Test
Milrinone Lactate and 5% Dextrose	Generic	Injection	Baxter Healthcare Corp	Microbiologic (bacterial endotoxin); method suitability	Reports of particulates and discoloration	Passed Test
Montelukast Sodium	Generic	Chewable Tablets	Dr. Reddy's Laboratories	CU, Dissolution, Related Substances, ID, WV	Response to cGMP inspection violations	Passed Test
Montelukast Sodium	Generic	Oral Granules	Dr. Reddy's Laboratories	CU, Dissolution, Related Substances, ID, WV	Response to cGMP inspection violations	Passed Test
Montelukast Sodium	Generic	Tablets	Dr. Reddy's Laboratories	CU, Dissolution, Related Substances, ID, WV	Response to cGMP inspection violations	Passed Test
Nateglinide	Generic	Tablets	Dr. Reddy's Laboratories	CU, Dissolution, Impurities, ID, CU, WV	Response to cGMP inspection violations	Passed Test
Nizatidine	Generic	Capsules	Dr. Reddy's Laboratories	Assay, Dissolution, CU, Impurities, ID, WV	Response to cGMP inspection violations	Passed Test
Olanzapine	Generic	Orally Disintegrating Tablets	Dr. Reddy's Laboratories Limited	CU, Dissolution, Related Substances, ID, WV	Response to cGMP inspection violations	Passed Test
Olanzapine	Generic	Tablets	Dr. Reddy's Laboratories	Assay, CU, Dissolution, impurities, WV, ID	Response to cGMP inspection violations	Passed Test
Omeprazole	Generic	Delayed Release Capsules	Dr. Reddy's Laboratories Limited	CU, Dissolution, Impurities, WV	Response to cGMP inspection violations	Passed Test
Ondansetron HCL	Generic	Tablets	Dr. Reddy's Laboratories	CU, Dissolution, ID, Organic Impurities, WV	Response to cGMP inspection violations	Passed Test
Oxaprozin	Generic	Tablets	Dr. Reddy's Laboratories	CU, Dissolution, Appearance, WV	Response to cGMP inspection violations	Passed Test
Pantoprazole Sodium	Generic	Delayed Release Tablets	Dr. Reddy's Laboratories Limited	ID, WV, Drug Release, Impurities, Related Substances, CU	Response to cGMP inspection violations	Passed Test
Pantoprazole Sodium	Generic	Tablets	Dr. Reddy's Laboratories Limited	ID, WV, CU, Drug Release, Impurities, Related Substances, CU	Response to cGMP inspection violations	Passed Test

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Potassium Chloride	Generic	Injection	Baxter Healthcare Corp	Microbiologic	Reports of particulates and discoloration	Passed Test
Potassium Chloride	Generic	Injection	Baxter Healthcare Corp	Microbiologic	Reports of particulates and discoloration	Passed Test
Potassium Chloride	Generic	Injection	Baxter Healthcare Corp	Microbiologic (bacterial endotoxin)	Reports of particulates and discoloration	Passed Test
Potassium Chloride	Generic	Injection	Baxter Healthcare Corp	Microbiologic (bacterial endotoxin) and visual exam	Reports of particulates and discoloration	Passed Test
Potassium Chloride 0.09% Sodium Chloride Mini Bag	Generic	Injection	Baxter Healthcare Corp	Microbiologic (bacterial endotoxin) and visual exam	Reports of particulates and discoloration	Passed Test
Quetiapine Fumarate	Generic	Tablets	Dr. Reddy's Laboratories	CU, Dissolution, Related Substances, ID, WV	Response to cGMP inspection violations	Passed Test
Ranitidine HCL	Generic	Capsules	Dr. Reddy's Laboratories	CU, Dissolution, Related Substances, ID, WV	Response to cGMP inspection violations	Passed Test
Risperidone	Generic	Orally Disintegrating Tablets	Dr. Reddy's Laboratories Limited	Assay, CU, Dissolution, Related Substances, ID, WV	Response to cGMP inspection violations	Passed Test
Rivastigmine	Generic	Capsules	Dr. Reddy's Laboratories	Assay, CU, Dissolution, Impurities, ID, WV	Response to cGMP inspection violations	Passed Test
Ropinirole	Generic	Extended Release Tablets	Dr. Reddy's Laboratories Limited	Assay, CU, Dissolution, Related Substances, ID, WV	Response to cGMP inspection violations	Passed Test
Sildenafil	Generic	Tablets	Dr. Reddy's Laboratories	Assay, CU, Dissolution, Organic Impurities, ID, WV	Response to cGMP inspection violations	Passed Test
Simvastatin	Generic	Tablets	Dr. Reddy's Laboratories	Assay, CU, Dissolution, Impurities, ID, WV	Response to cGMP inspection violations	Passed Test



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Simvastatin	Generic	Tablets	Dr. Reddy's Laboratories Limited	Assay, CU, Dissolution, Impurities, ID, WV	Response to cGMP inspection violations	Failed CU – follow up testing planned
Simvastatin	Generic	Tablets	Dr. Reddy's Laboratories	Assay, CU, Dissolution, Impurities, WV	Response to cGMP inspection violations	Passed Test
Sumatriptan Succinate	Generic	Tablets	Dr. Reddy's Laboratories	CU, Dissolution, Related Substances, ID, WV	Response to cGMP inspection violations	Passed Test
Tacrolimus	Generic	Capsules	Dr. Reddy's Laboratories	ID, CU, Dissolution, Impurities, WV	Response to cGMP inspection violations	Passed Test
Terbinafine	Generic	Tablets	Dr. Reddy's Laboratories	Assay, CU, Dissolution, Related Substances, ID,	Response to cGMP inspection violations	Passed Test
Tizanidine	Generic	Tablets	Dr. Reddy's Laboratories	Assay, CU, Dissolution, Impurities, ID, WV	Response to cGMP inspection violations	Passed Test
Valacyclovir	Generic	Tablets	Dr. Reddy's Laboratories	Assay, CU, Dissolution, Impurities, WV	Response to cGMP inspection violations	Passed Test
Zafirlukast	Generic	Tablets	Dr. Reddy's Laboratories	Assay, CU, Dissolution, Impurities, ID, WV	Response to cGMP inspection violations	Passed Test
Ziprasidone HCL	Generic	Capsules	Dr. Reddy's Laboratories	Assay, CU, Dissolution, Impurities, WV	Response to cGMP inspection violations	Passed Test