

FY13 APIs

Active Pharmaceutical Ingredient Name	Manufacturing Firm	Tests Performed	Why Tested	Results
Acetaminophen	Granules India Ltd	Assay, water determination, impurities and poison	Concerns about economically motivated adulteration	Passed Test
Acetaminophen (Rhodapap TM DC-90)	Novacyl Wuxi Pharm	Assay, water content and poisons/toxins screening	Concerns about economically motivated adulteration	Passed Test
Acetaminophen Raw DC-90	Zhejiang Kangle Pharm	Assay, water content and poisons/toxins screening	Concerns about economically motivated adulteration	Passed Test
Acetaminophen USP 34	Anqiu Lu'an Pharm	Assay, water content and poisons/toxins screening	Concerns about economically motivated adulteration	Passed Test
Albuterol Salbutamol Sulphate powder	Teva Pharm Fine	Assay, ID, impurities and poisons/toxins screening	Concerns about economically motivated adulteration	Passed Test
Albuterol Sulfate	Glaxo Wellcome Production	Assay, impurities, poisons/toxins screening and	Concerns about economically motivated adulteration	Passed Test
Albuterol Sulfate/Salbutamol Sulfate	Cambrex Profarmaco Milano Srl	Assay, impurities, poisons/toxins screening and	Concerns about economically motivated adulteration	Passed Test
Alprazolam	Cambrex Profarmaco Milano Srl	Assay, Organic Impurities and identity	Concerns about economically motivated adulteration	Passed Test
Amitriptyline HCl	Dipharma	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Amitriptyline HCl	Plantex Ltd	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Amitriptyline HCl	Dipharma Francis S.r.l	Assay and impurities	Concerns about economically motivated adulteration	Passed Test
Amlodipine Besylate USP	Moehs Catalana SI	impurities	Concerns about economically motivated adulteration	Passed Test
Amlopidine Besylate	Pfizer Pharmaceuticals LLC	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Aripiprazole	Otsuka Pharm Co	Assay, impurities, poisons/toxins screening and	Concerns about economically motivated adulteration	Passed Test
Atorvastatin Calcium	Pfizer	Assay, impurities, enantiomeric purity, water	Concerns about economically motivated adulteration	Passed Test
Atorvastatin Calcium USP	Ranbaxy Labs Ltd	Assay, water determination, enantiomeric purity and	Concerns about economically motivated adulteration	Passed Test
Azithromycin	Sandoz Industrial Products	Assay, water content and	Concerns about economically motivated adulteration	Passed Test
Azithromycin	Teva Pharmaceuticals	Assay, impurities, water	Concerns about economically motivated adulteration	Passed Test
Azithromycin monohydrate	Jubilant Life Sciences Ltd	Assay, water content,	Concerns about economically motivated adulteration	Passed Test
Benazepril HCl	Aarti Industries Ltd	Assay and toxins/poison	Concerns about economically motivated adulteration	Passed Test

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Cetirizine HCl	Dr. Reddy's Labs Ltd	Impurities	Concerns about economically	Passed Test
Cetirizine HCl	Dr. Reddy's Labs Ltd	Impurities	Concerns about economically	Passed Test
Cetirizine HCl	Perrigo (formerly Chemagis)	Impurities	Concerns about economically	Passed Test
Ciprofloxacin	Dr. Reddy's Labs Ltd	Assay	Concerns about economically	Passed Test
Clindamycin HCl	Alchymars ICM SM Private	Assay, water content,	Concerns about economically	Passed Test
Clindamycin HCl	Chongqing Carelife Pharm	Assay, impurities , water	Concerns about economically	Passed Test
Clindamycin HCl	Chongqing Carelife Pharm	Assay, impurities, water	Concerns about economically	Passed Test
Clindamycin Palmitate HCl	Zhejiang Hisoar Pharm	Assay, impurities and	Concerns about economically	Passed Test
Clindamycin Phosphate	Suzhou No. 4 Pharm Factory	Assay, impurities and identity	Concerns about economically	Passed Test
Clindamycin Phosphate	Zhejiang Hisoar Pharm	Assay, water content,	Concerns about economically	Passed Test
Clindamycin Phosphate	Suzhou No. 4 Pharm Factory	Assay, impurities and identity	Concerns about economically	Passed Test
Clindamycin Phosphate	Union Quimico Farmaceutica SA	Assay, water content, impurites and identity	Concerns about economically motivated adulteration	Passed Test
Clindamycin Phosphate USP	Trifarma S.p.A, Rozzano	Assay, impurities and identity	Concerns about economically	Passed Test
Clobetasol Propionate	Sicor SPA Societa Italiana	Assay, impurities, and loss on	Concerns about economically	Passed Test
Clobetasol Propionate	Avik Pharm Ltd	Assay, impurities, and loss on	Concerns about economically	Passed Test
Clopidogrel Bisulfate	Dr. Reddy's Labs	Assay, impurities, and loss on	Concerns about economically	Passed Test
Dexamethasone Sodium Phosphate USP	Tianjin Tianyao Pharm	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Dextromethorphan Hydrobromide USP	Wockhardt Ltd	Assay, water content, specific rotation, impurities and	Concerns about economically motivated adulteration	Passed Test
Dextromethorphan Hydrobromide USP	Divi's Labs Ltd	Assay, water content, specific rotation, impurities and	Concerns about economically motivated adulteration	Passed Test
Diazepam	Cambrex Profarmaco,	Assay, impurities, and loss on	Concerns about economically	Passed Test
Diphenhydramine HCl	Pharmatec Co Ltd	Assay, identity, and loss on	Concerns about economically	Passed Test
Diphenhydramine HCl USP	Qidong Dongyue Pharm	Assay, impurities and identity	Concerns about economically	Passed Test
Diphenhydramine HCl USP	S.S. Pharmachem	Assay, identity and loss on	Concerns about economically	Passed Test
Diphenhydramine HCl	Beijing Taiyang Pharm	Assay, identity and loss on	Concerns about economically	Passed Test
Diphenhydramine HCl USP	Kongo Chemical Co	Assay, identity and loss on	Concerns about economically	Passed Test
Docusate Sodium Powder	Vignesh Life Sciences Ptv Ltd	Assay	Concerns about economically motivated adulteration	Failed assay; material returned to firm for
Donepezil HCl	Ranbaxy Labs Ltd	Assay, organic impurities, water content, toxins/poisons	Concerns about economically motivated adulteration	Passed Test
Efavirenz	Lonza AG	Assay, impurities and identity	Concerns about economically	Passed Test

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Levetiracetam	Esteve Quimica	Assay, Loss on drying, chiral content, organic impurities	Concerns about economically motivated adulteration	Passed Test
Levetiracetam	Esteve Quimica S.A.	Assay, Loss on drying, chiral content, organic impurities	Concerns about economically motivated adulteration	Passed Test
Esomeprazole Magnesium	Ranbaxy Labs Ltd	Assay, impurities, water	Concerns about economically motivated adulteration	Passed Test
Ethinyl Estradiol USP	Schering AG	Assay and identity	Concerns about economically motivated adulteration	Passed Test
Famotidine	Chemical Works of Gedeon Richter PLC	Assay, impurities, toxins/poisons	Concerns about economically motivated adulteration	Passed Test
Famotidine	Ercros Industrial S.A.	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Famotidine	Quimica Sintetica SA	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Famotidine USP	Astellas	Assay, loss on drying,	Concerns about economically motivated adulteration	Passed Test
Fluconazole	Ipsa Labs Ltd	Toxins/poison screening	Concerns about economically motivated adulteration	Passed Test
Fluoxetine HCl	Olon Spa	Assay, content uniformity (CU), and poisons/toxins	Concerns about economically motivated adulteration	Passed Test
Fluoxetine HCl USP	Cadila Pharm Ltd	Assay, CU, water content, identity, related compounds, impurities, and	Concerns about economically motivated adulteration	Passed Test
Fluoxetine HCl USP	Cadila Pharm Ltd	Assay, CU, water content, identity, related compounds, impurities, and	Concerns about economically motivated adulteration	Passed Test
Fluticasone Propionate	Chemagis	Assay and impurities	Concerns about economically motivated adulteration	Passed Test
Furosemide	Fabbrica Italiana [sic Sintetio] Sintetici	Assay, CU, loss on drying and poisons/toxins screening	Concerns about economically motivated adulteration	Passed Test
Furosemide	Assia Chem Ind Ltd	Assay, loss on drying and	Concerns about economically motivated adulteration	Passed Test
Furosemide Micronized	Fabbrica Italiana Sintetici	Assay, loss on drying and	Concerns about economically motivated adulteration	Passed Test
Furosemide USP	Ipsa Labs Ltd	Toxins/poisons screening	Concerns about economically motivated adulteration	Passed Test
Gabapentin	Zach Zambon Chemicals	Assay, CU, related compounds, and	Concerns about economically motivated adulteration	Passed Test
Gabapentin	Assia Chemical Industries	Assay, CU, related compounds, and	Concerns about economically motivated adulteration	Passed Test
Gabapentin USP	Hikal Ltd	Assay, CU, related compounds, and	Concerns about economically motivated adulteration	Passed Test
Gabapentin USP	Divi's Labs Ltd	Assay, CU, related compounds, and	Concerns about economically motivated adulteration	Passed Test

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Guaifenesin	Delta Synthetic Co Ltd	Assay, CU, toxins/poisons screening, ultraviolet	Concerns about economically motivated adulteration	Passed Test
Heparin Sodium	Quindao Jiulang Biopharm	Impurities and contamination	Concerns about economically motivated adulteration	Passed Test
Heparin Sodium	Yantai Dongcheng Biochem	Impurities and contamination	Concerns about economically motivated adulteration	Passed Test
Heparin Sodium	Shenzhen Hepalink	Impurities and contamination	Concerns about economically motivated adulteration	Passed Test
Heparin Sodium	CELSUS	Impurities and contamination	Concerns about economically motivated adulteration	Passed Test
Heparin Sodium	Bioiberica	Impurities and contamination	Concerns about economically motivated adulteration	Passed Test
Heparin Sodium	Biopharmacotech	Microbiology, impurities and contamination screen	Concerns about economically motivated adulteration	Passed Test
Hydrochlorothiazide	Cambrex Profarmaco Milano Srl	Assay and poison/toxin screening	Concerns about economically motivated adulteration	Passed Test
Hydrochlorothiazide	Abic Ltd	Assay and poison/toxin screening	Concerns about economically motivated adulteration	Passed Test
Hydrocortisone Acetate	Yangzhou Pharm Co	Assay, loss on drying and poisons/toxins screening	Concerns about economically motivated adulteration	Passed Test
Hydroxyzine Pamoate	Cosma S.P.A.	Assay, water content, impurities and poison	Concerns about economically motivated adulteration	Passed Test
Ibuprofen USP	Shasun Pharm Ltd	Assay, impurities, poisons/toxins screening and	Concerns about economically motivated adulteration	Passed Test
Leuprolide Acetate	Bachem AG	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Levetiracetam	Dr. Reddy's Labs	Assay, loss on drying, chiral content, impurities and	Concerns about economically motivated adulteration	Passed Test
Levetiracetam	Esteve Quimica S.A.	Assay, loss on drying, chiral content, impurities and	Concerns about economically motivated adulteration	Passed Test
Levetiracetam	Esteve Quimica S.A.	Assay, loss on drying, chiral content, impurities and	Concerns about economically motivated adulteration	Passed Test
Levetiracetam	Divis Labs Ltd	Assay, loss on drying, chiral content, impurities and	Concerns about economically motivated adulteration	Passed Test
Levothyroxine Sodium	Peptido GmbH	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Levothyroxine Sodium	Sandoz GmbH	Assay, water content,	Concerns about economically motivated adulteration	Passed Test
Lidocaine	Moehs Catalana SI	Assay and poison/toxin	Concerns about economically motivated adulteration	Passed Test
Lidocaine HCl	Cambrex Karlskoga AB	Assay, water content, chromatographic purity and	Concerns about economically motivated adulteration	Passed Test
Lisinopril	Zhejiang Huahai Pharm	Assay	Concerns about economically motivated adulteration	Passed Test
Lisinopril USP	Hetero Drugs Ltd	Assay	Concerns about economically motivated adulteration	Passed Test

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Lorazepam	F.I.S. Fabbrica Italiana Sintetici SPA	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Lorazepam	Cambrex Pharmaco	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Methylprednisolone Acetate	Crystal Pharma S.A.U.	Assay, impurities and loss on	Concerns about economically motivated adulteration	Passed Test
Metoprolol Succinate	Teva API Division	Assay, impurities and	Concerns about economically motivated adulteration	Passed Test
Metronidazole	Farchemia S.r.l.	Assay, impurities and poisons/toxins	Concerns about economically motivated adulteration	One portion slightly below limits (b)(4)% ((b)(4)-(b)(4)%). Contacting USP about system suitability for assay being inconsistent with acceptance criteria.
Montelukast Sodium	Unimark Remedies Ltd	Assay, toxins/poisons screening, water content,	Concerns about economically motivated adulteration	Passed Test
Montelukast Sodium	Unimark Remedies Ltd	Assay, toxins/poisons	Concerns about economically motivated adulteration	Passed Test
Montelukast Sodium	Merck Sharp Dohme Ireland Ltd	Assay, water content, impurities and enantiomeric	Concerns about economically motivated adulteration	Passed Test
Montelukast Sodium	Mylan Labs Ltd	Toxins/poisons, impurities and water content	Concerns about economically motivated adulteration	High water content; may be a sampling issue or incorrect packaging for this hygroscopic material.
Montelukast Sodium (Levetiracetam)	Teva API India Ltd	Assay, poisons and loss on drying	Concerns about economically motivated adulteration	Slightly below assay; firm data to be examined during 2015 GMP inspection.
Naproxen Sodium	Divi's Labs Ltd	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Naproxen Sodium	Dr. Reddy's Labs	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test

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Naproxen USP	Divi's Labs Ltd	Assay, impurities and identity	Concerns about economically	Passed Test
Olanzapine	Teva API India Ltd	Assay, poison screening, water content and impurities	Concerns about economically motivated adulteration	Passed Test
Prednisolone Sodium	Sanofi Chimie	Assay, loss on drying,	Concerns about economically	Passed Test
Promethazine HCl	Egis PLC	Assay, loss on drying,	Concerns about economically	Passed Test
Propranolol HCl	Cosma S.P.A.	Assay, impurities and	Concerns about economically	Passed Test
Quetiapine Fumarate	Fermion OY	Assay	Concerns about economically	Passed Test
Quetiapine Fumarate	Ajinomoto Omnicem Nv	Assay and toxins/poisons	Concerns about economically	Passed Test
Quetiapine Fumarate	Ajinomoto Omnicem Nv	Assay	Concerns about economically	Passed Test
Ranitidine HCl USP	Shasun Pharm Ltd	Assay, impurities and	Concerns about economically	Passed Test
Risperidone	Dr. Reddy's Lab Ltd	Assay, Loss on Drying and poisons/toxins screening	Concerns about economically motivated adulteration	Passed Test
Risperidone	Mylan Labs Ltd	Assay, Loss on Drying and poisons/toxins screening	Concerns about economically motivated adulteration	Passed Test
Rosuvastatin Calcium	Astra Zeneca UK Ltd	Assay, impurities, water content, toxins/poisons	Concerns about economically motivated adulteration	Passed Test
Simvastatin	Biocon Ltd	Assay, impurities and identity	Concerns about economically	Passed Test
Tramadol HCl	Sun Pharm Ind	Assay, water content,	Concerns about economically	Passed Test
Tramadol HCl	Jubilant Life Sciences Ltd	Assay and impurities	Concerns about economically	Passed Test
Tramadol HCl	Wanbury Ltd	Assay, impurity, water	Concerns about economically	Passed Test
Tramadol HCl	Chem Agis Ltd	Assay, water	Concerns about economically	Passed Test
Triamcinolone Acetonide	Crystal Pharma S.A.U.	Assay and toxins/poisons	Concerns about economically	Passed Test
Triamcinolone Acetonide	Sicor S.R.L.	Toxins/poisons screening	Concerns about economically	Passed Test
Valsartan	Mylan Labs	Assay and impurities	Concerns about economically	Passed Test