

FY14 APIs

Active Pharmaceutical Ingredient Name	Manufacturing Firm	Tests Performed	Why Tested	Results
Albuterol Sulfate/Salbutamol Sulfate	Cambrex Profarmaco Milano Srl	Assay, impurities, loss on drying and identity	Concerns about economically motivated adulteration	Passed Test
Alprazolam	Cambrex Profarmaco Milano Srl	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Alprazolam	Malladi Drugs & Pharm Ltd	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Amoxicillin Trihydrate	Fersinsa Gb	Assay, organic impurities and water content	Concerns about economically motivated adulteration	Passed Test
Atorvastatin Calcium	Ranbaxy Laboratories Ltd	Assay, water content, organic impurities, and identity	Concerns about economically motivated adulteration	Passed Test
Atorvastatin Calcium	Pfizer Ireland Pharm	Assay, water content, organic impurities and identity	Concerns about economically motivated adulteration	Passed Test
Atorvastatin Calcium USP`	Mylan Labs Ltd	Assay, water content, organic impurities and identity	Concerns about economically motivated adulteration	Passed Test
Budesonide	Sicor De Mexico Sa De Cv	Assay, organic impurities and water content	Concerns about economically motivated adulteration	Passed Test
Budesonide	Aarti Industries Ltd	Assay, organic impurities and water content	Concerns about economically motivated adulteration	Passed Test
Budesonide	Aspen Oss B.V.	Assay, organic impurities and water content	Concerns about economically motivated adulteration	Passed Test

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Bupivacaine HCl	Moehs Catalana S.L.	Assay, impurities, water content and identity	Concerns about economically motivated adulteration	Passed Test
Celecoxib	Pfizer	poisons/toxins screening	Concerns about economically motivated adulteration	Passed Test
Ciprofloxacin Hydrochloride	Quimica Sintetica SA	Assay, organic impurities and water content	Concerns about economically motivated adulteration	Passed Test
Ciprofloxacin Hydrochloride	Neuland Laboratories Ltd	Assay, organic impurities and water content	Concerns about economically motivated adulteration	Passed Test
Ciprofloxacin Hydrochloride	Aarti Drugs Limited	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Ciprofloxacin USP	Dr. Reddy's Labs Ltd	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Clopidogrel Bisulphate USP	Dr. Reddys Labs Ltd	Assay, organic impurities and identity	Concerns about economically motivated adulteration	Passed Test
Esomeprazole Magnesium Trihydrate	Ranbaxy Labs Ltd (Toansa)	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Esomeprazole Magnesium Trihydrate	Minakem Dunkerque, S.A.S	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Fenofibrate	Labochim (Laboratorio Chimico Internazionale)	Assay, organic impurities and identity	Concerns about economically motivated adulteration	Passed Test
Fenofibrate USP Micronized	Labochim (Laboratorio Chimico Internazionale)	Assay, organic impurities and identity	Concerns about economically motivated adulteration	Passed Test

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Fluticasone Propionate	Farmabios S.P.A.	Assay, water content and impurities	Concerns about economically motivated adulteration	Passed Test
Fluticasone Propionate	Newchem S.P.A.	Assay, water content and impurities	Concerns about economically motivated adulteration	Passed Test
Fluticasone Propionate	Hovione FarmaCiencia SA	Assay, water content and impurities	Concerns about economically motivated adulteration	Passed Test
Fluticasone Propionate	Chemagis Ltd	Assay, water content and impurities	Concerns about economically motivated adulteration	Passed Test
Furosemide	F.I.S. Fabricca Italiana Sintetici S.p.A	Assay and loss on drying	Concerns about economically motivated adulteration	Passed Test
Furosemide	Ipca Labs Ltd	Assay, loss on drying, poison screening and impurities	Concerns about economically motivated adulteration	Passed Test
Furosemide	Assia Chemical Ind Ltd	Assay and loss on drying	Concerns about economically motivated adulteration	Passed Test
Gabapentin	Assia Chemical Ind Ltd	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Gabapentin	Zhejiang Chiral Medicine Chemicals Co	Assay, water content and impurities	Concerns about economically motivated adulteration	Passed Test
Gabapentin	Hikal Ltd	Assay, water content and impurities	Concerns about economically motivated adulteration	Passed Test
Heparin Sodium	Yantai Dongcheng	impurities and contamination screen	Concerns about economically motivated adulteration	Passed Test

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Heparin Sodium	NV Organon OSS	impurities and contamination screen	Concerns about economically motivated adulteration	Passed Test
Heparin Sodium	Bioiberica	impurities and contamination screen	Concerns about economically motivated adulteration	Passed Test
Heparin Sodium	NKF (Nanjing King-Friend)	impurities and contamination screen	Concerns about economically motivated adulteration	Passed Test
Heparin Sodium	Qingdao Juilong	impurities and contamination screen	Concerns about economically motivated adulteration	Passed Test
Heparin Sodium	Aspen OSS	impurities and contamination screen	Concerns about economically motivated adulteration	Passed Test
Heparin Sodium	Extrasul Extratos	impurities and contamination screen	Concerns about economically motivated adulteration	Passed Test
Hydrochlorothiazide USP	Suzhou Lixin Pharm	Assay, loss on drying, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Hydrochlorothiazide USP	Abic Ltd	Assay, impurities, physical appearance and identity	Concerns about economically motivated adulteration	Passed Test
Hydrochlorothiazide USP	Ipca Labs Ltd	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Ibuprofen	Shandong Xinhua Pharm	Assay, impurities, water content and identity	Concerns about economically motivated adulteration	Passed Test
Ibuprofen	Shasun Pharm Ltd	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test

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Lactulose Concentrate USP	Laboratoires Abbott	Assay, impurities, and poisons/toxins screening	Concerns about economically motivated adulteration	Passed Test
Lactulose Concentrate USP	LACSA (PSY) Limited	Assay, poison screen and impurities	Concerns about economically motivated adulteration	Passed Test
L-Citrulline	Imported by Ningbo, China	Identity	Adverse event reports	Some lots of material found to be N-acetyl leucine rather than citrulline
Levetiracetam	Dr. Reddys Labs Ltd	Assay, organic impurities and water content	Concerns about economically motivated adulteration	Passed Test
Levetiracetam	Esteve Quimica, S.A.	Assay, water content, toxin/poison screening and impurities	Concerns about economically motivated adulteration	Passed Test
Levothyroxine Sodium	Sandoz GmbH	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Levothyroxine Sodium USP	Peptido GmbH	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Lidocaine Base	Societa Italiana Medicinali Scandicci	Assay, poison screening and impurities	Concerns about economically motivated adulteration	Passed Test
Lidocaine HCl	Moehs Catalana S.L.	Impurities and toxins/poisons	Concerns about economically motivated adulteration	Passed Test
Lidocaine HCl	Sims Srl	Assay, poison screening and impurities	Concerns about economically motivated adulteration	Passed Test

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Lidocaine HCl	Delta Synthetic Co Ltd	Assay, poison screening and impurities	Concerns about economically motivated adulteration	Passed Test
Lidocaine HCl	Cambrex Karlskoga AB	Assay, poison screening and impurities	Concerns about economically motivated adulteration	Passed Test
Lidocaine HCl	Fresenius Kabi USA, LLC	Assay, poison screening and impurities	Concerns about economically motivated adulteration	Passed Test
Lisinopril USP	Hetero Drugs Ltd	Assay, impurities, water content, and identity	Concerns about economically motivated adulteration	Passed Test
Metformin Hydrochloride	Farmhispania, S.A.	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Metformin Hydrochloride	USV Ltd	Assay, impurities, loss on drying and identity	Concerns about economically motivated adulteration	Passed Test
Metronidazole	Farchemia S.R.L	Assay, impurities, loss on drying and poison screen	Concerns about economically motivated adulteration	Passed Test
Metronidazole	Tianjin Zhongan Pharm Co Ltd	Assay, impurities, loss on drying and poison screen	Concerns about economically motivated adulteration	Passed Test
Montelukast	Teva API India Ltd	Assay, water content and impurities	Concerns about economically motivated adulteration	Passed Test
Montelukast Sodium	Mylan Labs Ltd	Assay, poison/toxin screening and water content	Concerns about economically motivated adulteration	Passed Test
Montelukast Sodium	MSD International GmbH	Assay, toxins/poisons, water content and impurities	Concerns about economically motivated adulteration	One lot failed water content; follow up with firm.

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Ondansetron HCl	Inke S.A.	Assay, impurities, water content and identity	Concerns about economically motivated adulteration	Passed Test
Ondansetron HCl USP	Ipca Labs Ltd	Assay, impurities, water content and identity	Concerns about economically motivated adulteration	Passed Test
Ondansetron	Teva Pharm Works Co Ltd	Assay, impurities, water content and identity	Concerns about economically motivated adulteration	Passed Test
Ondansetron HCl	Inke S.A.	Assay, impurities, water content and identity	Concerns about economically motivated adulteration	Passed Test
Pioglitazone HCl	Mylan Labs Ltd	Assay, organic impurities and toxin/poison screening	Concerns about economically motivated adulteration	Passed Test
Rosuvastatin Calcium	Astra Zeneca UK Ltd	Assay and Impurities	Concerns about economically motivated adulteration	Passed Test
Simvastatin	Biocon Ltd	Assay, impurities and identity	Concerns about economically motivated adulteration	Passed Test
Sitagliptin Phosphate	F.I.S. Fabbrica Italiana Sintetici S.p.A.	Assay, water content, poison screening and impurities	Concerns about economically motivated adulteration	Passed Test
Sitagliptin Phosphate	FIS-Fabbrica Italiana Sintetici	Assay, water content, poison screening and impurities	Concerns about economically motivated adulteration	Passed Test
Testosterone Cypionate USP	Avik Pharm Ltd	Assay, loss on drying and poison/toxic screening	Concerns about economically motivated adulteration	Passed Test
Tramadol Hydrochloride USP	Wanbury Ltd	Assay, water content, impurity profile and identity	Concerns about economically motivated adulteration	Passed Test

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Tramadol Hydrochloride	Proto Chemicals AG	Assay, water content, impurity profile and identity	Concerns about economically motivated adulteration	Passed Test
Tramadol Hydrochloride USP	Chemagis	Assay, loss on drying, impurity profile and identity	Concerns about economically motivated adulteration	Passed Test
Tramadol Hydrochloride USP	Inogen Labs Private Ltd	Assay, water content and impurities	Concerns about economically motivated adulteration	Passed Test
Valsartan USP	Mylan Labs Ltd	Assay, water content, impurities, enantiomeric purity and identity	Concerns about economically motivated adulteration	Passed Test