Impurity/Degradation Product Test Standards available from Stability Testing and Impurity Profiling Laboratories at NIPER

Drug	Impurity/Degradation Products	Price within India (Rs)		Export price† (US $)	
		50 mg*	100 mg*	50 mg*	100 mg*
Amoxycillin	Sodium salt of amoxicilloic acid (BP Impurity D)	10,000	15,000	300	500
	Diketopiperazine of amoxycillin ((BP Impurity C)	10,000	15,000	300	500
Ampicillin	Sodium salt of ampicilloic acid (BP Impurity D)	10,000	15,000	300	500
	Diketopiperazine of ampicillin (BP Impurity C)	10,000	15,000	300	500
Candesartan cilexetil	1-(Cyclohexyloxycarbonyloxy)ethyl 1-((2'-(1H-tetrazol-5-yl)biphenyl-4-yl)methyl)-2-hydroxy-1H-benzo[d]imidazole-7-carboxylate	10,000	15,000	300	500
Captopril	Captopril disulfide (BP Impurity A; USP RS)	10,000	15,000	300	500
Clarithromycin	Clarithromycin N-oxide	20,000	30,000	600	1,000
	N-Desmethyl clarithromycin (EP Impurity D)	20,000	30,000	600	1,000
	N-Desmethyl erythromycin A	20,000	30,000	600	1,000
	N-Formyl clarithromycin (EP Impurity H)	20,000	30,000	600	1,000
Clonazepam	2-Amino-2'-chloro-5-nitrobenzophenone (BP Impurity A; USP related compound B)	10,000	15,000	300	500
Cloxacillin	Penicilloic acid of cloxacillin (BP Impurity A)	10,000	15,000	300	500
	N-Acetylated cloxacilloic acid	50,000	75,000	1,500	2,500
Diazepam	2-Amino methyl-5-chlorobenzophenone (USP related compound A)	10,000	15,000	300	500
Dexamethasone	(9-Fluoro-11-hydroxy-10,13,16-trimethyl-3-oxo-3,6,7,8,9,10, 11,12,13,14, 15,16-dodecahydrocyclopenta[a]-phenanthren-17-ylidene)-hydoxyacetaldehyde	20,000	30,000	600	1,000
Dicloxacillin	Penicilloic acid of dicloxacillin (BP Impurity A)	10,000	15,000	300	500
	N-Acetylated dicloxacilloic acid	50,000	75,000	1,500	2,500
Doxorubicin	Doxorubicin aglycone (BP Impurity D)	20,000	30,000	600	1,000

Famotidine	3-[2-(Diaminomethyleneamino)-1,3-thiazol-4-yl methylthio]-N-sulphamoyl propionamide (BP Impurity)	10,000	15,000	300	500
	3-[2-(Diaminomethyleneamino)-1,3-thiazol-4-yl methylthio] propionamide (BP Impurity)	10,000	15,000	300	500
	3-[2-(Diaminomethyleneamino)-1,3-thiazol-4-yl methylthio]propionic acid	10,000	15,000	300	500
	Sodium salt of 3-[2-(Diaminomethyleneamino)-4-thiazolylmethyl] thiol	15,000	25,000	500	800
Flucloxacillin	Penicilloic acid of flucloxacillin (BP Impurity A)	10,000	15,000	300	500
	N-Acetylated flucloxacilloic acid	50,000	75,000	1,500	2,500
Glibenclamide	5-Chloro-2- methoxy-N- [2(4- sulphamoyl phenyl) ethyl] benzamide (BP Impurity A)	15,000	25,000	500	800
Gliclazide	4-Methylbenzene sulphonamide (BP Impurity A)	15,000	25,000	500	800
Glimepride	5-Chloro-2oxy-N-[2(4-sulphamoylphenyl)ethyl]benzamide	15,000	25,000	500	800
Glipizide	5-Methyl-N-[2 (4-sulphamoylphenyl) ethyl] pyrazine-2-carboxamide (BP Impurity A)	15,000	25,000	500	800
Mebendazole	(2-Amino-1H-benzoimidazol-5-yl)-phenyl-methanone (BP Impurity A)	10,000	15,000	300	500
Nifedipine	Nitrophenylpyridine analogue	10,000	15,000	300	500
	Nitrosophenylpyridine analogue				
Nimesulide	Dihydrate sodium salt of 4-nitro-2-phenoxy phenol (Impurity G, Pharmeuropa, December 1998)	15,000	25,000	500	800
Ornidazole	Ornidazole diol	10,000	15,000	300	500
	Ornidazole epoxide	10,000	15,000	300	500
Ranitidine	5-[(2-Aminoethyl)thiomethyl]furfuryl(dimethyl)amine (BP Impurity B)	10,000	15,000	300	500
	5-[(Dimethylamino)methyl]-furan-2-methanol (BP Impurity)	15,000	25,000	500	800
	5,6-Dihydro-3-methylamino-1,4-thiazin-2(2H)-one oxime (BP Impurity)	15,000	25,000	500	800
	N-[2-[[[5-[(Dimethylamino)methyl]-2-uranyl]methyl]sulphinyl]ethyl]-N'-methyl-2-nitro-1,1-ethenediamine (USP related compound C)	15,000	25,000	500	800
Rifampicin	Isonicotinyl hydrazone of rifampicin and isoniazid	20,000	30,000	600	1,000
	Rifampicin quinone	20,000	30,000	600	1,000
	3-Formyl rifamycin SV	15,000	25,000	500	800
Tinidazole	1-[2-(Ethyl sulphonyl) ethyl] – 2-methyl-4-nitro-1H-imidazole (BP Impurity B)	10,000	15,000	300	500

† Additional US $ 20 as postal charge ✲ Only available pack sizes

List of Clients for Impurities

Local	Overseas
Medopharm, Mumbai	*Morvek Biochemicals, USA*
Mecleods Pharmaceuticals, Mumbai	*Shiono Chemical Co. Ltd., Japan*
Lincoln Pharmaceutical Ltd., Ahmedabad	*HFL Ltd., UK*
Windlas Biotech Ltd., Dehradun	*Aldo International Ltd., Canada*
Fortune Overseas Company Pvt. Ltd., New Delhi.	*Phapros Tbk, Indonesia*
Ind-Swift Ltd., Dera Bassi	*Stiefel Research Institute, USA*
DSM Anti-Infectives Ltd., Toansa	*Mapichem AG, Switzerland, Russia*
Protech Biosystems Pvt. Ltd., New Delhi	*Zentiva a.s. Czech Republic*
Ranbaxy Laboratories, Mohali	*Sigma Pharmaceuticals, Australia*
Elder Pharmaceutical Ltd, Mumbai	
Suchem Lab., Ahemdabad	
Bharat Serums and Vaccines Ltd., Mumbai	
Cadila Pharmaceuticals, Ahmedabad	
Microlabs Ltd., Bangalore	
Enem Nostrum Remedies Pvt. Ltd., Mumbai	
Flamingo Pharmaceutical Ltd., Mumbai	
Strides Acrobal Ltd, Bangalore	
Pharmasolve Specialities, Mumbai	
Apex Drugs & intermediate, Hyderabad	
Medreich Ltd., Bangalore	
Calyx Ltd., Thane	
Martina Biogenics, Kolkata	
Innovassynth Technologies, Mumbai	

Industry Projects Handled by Stability Testing and Impurity Profiling Laboratories at NIPER	
Establishment of percentage of impurities in bulk drug samples	**Themis Ltd., Bombay**
Stability- indicating analysis procedures of drugs	**Panacea Biotec Ltd., Lalru**
Establishment of stability test facilities	**Panacea Biotec Ltd., Lalru**
Validation of the method for establishment of percentage of impurities in cephems	**Orchid Chemicals and Pharmaceuticals Ltd., Chennai**
Isolation and characterization of unknown impurities in cephems	**Orchid Chemicals and Pharmaceuticals Ltd., Chennai**
Isolation and characterization of unknown impurity in a sample of drug	**Medicorp Technologies, Hyderabad**
Synthesis/Isolation and characterization of unknown impurities in a sample of drug	**Lupin Laboratories Ltd., Mandideep**
Isolation and characterization of an impurity in a sample of drug	**Medicorp Technologies, Hyderabad**
Isolation and characterization of impurities of an antituberculosis drug	**Lupin Laboratories Ltd., Mandideep**
Development of stability-indicating analytical method of a drug	**Panacea Biotec Ltd., Lalru**
Stress decomposition studies on a drug	**Atul Ltd., Gujarat**
Testing of clinical trial samples for potential adulteration	**Pfizer Ltd., Mumbai**
Development of stability-indicating assays for certain drugs	**Panacea Biotec Ltd., Lalru**
Analytical studies on doxorubicin and daunorubicin	**RPG Life Sciences, Mumbai,**
LS-MS/MS studies on doxorubicin impurity	**RPG Life Sciences, Mumbai,**
Study on physical and chemical instability of anti-tuberculosis FDC products	**Panacea Biotec Ltd., Lalru**
Characterization of an impurity in a sample of an API	**DSM Anti- infectives, Toansa**
Stress studies and stability-indicating method development of a new drug	**Ind-Swift Ltd., Dera Bassi**

Synthesis and characterization of an impurity	**Ind-Swift Ltd., Dera Bassi**
Stress studies, stability indicating assay method development and characterization of degradation products of a new drug	**Ind-Swift Ltd., Dera Bassi**
Identification of impurities	**Malladi Drugs and Pharmaceuticals Ltd., Chennai**
Identification and characterization of unknown impurity of an API	**DSM Anti- infectives, Toansa**
Development of stability-indicating methods for multi ingredient eye drops	**Promed Exports Pvt. Ltd., New Delhi**
Identification and characterization of known impurity of cloxacillin	**DSM Anti-Infectives, Toansa**
Analytical, LC-MS and LC-MS/MS study for an impurity in sample of loratadine	**Morepen Labs, Baddi**
Literature survey of caffiene, etophylline, theophylline and related compounds	**Kudos Chemie Ltd., Derabassi**
Analytical and LC-MS/TOF studies for characterization of a degradation product of cloxacillin sodium	**DSM Anti-Infectives, Toansa**
Isolation and characterization an unknown impurity	**FDC, Mumbai**
Stability studies on polypill	**Dr Reddy's Lab., Hyderabad**
Characterization of unknown impurities in a sample of amphotericin B	**Asence Pharma, Vadodara**
Analysis and quantitation of some batches of amphotericin B as per EP monograph	**Asence Pharma, Vadodara**
Synthesis of acetyl degradation product of dicloxacillin sodium	**DSM Anti-infectives, Toansa**
Characterization of flucloxacillin amide in flucloxacillin sodium	**DSM Anti-infectives, Toansa**
Synthesis of acetyl derivative of flucloxacillin sodium	**DSM Anti-infectives, Toansa**
Characterization of dicloxacillin amide in dicloxacillin sodium	**DSM Anti-infectives, Toansa**
Analytical and LC-MS/TOF studies for the characterization of an impurity of cyclobenzaprine. HCl	**Polpharma, Poland**

List of Clients for LC-MS & LC-NMR Technical Services
Panacea Biotec, Lalru
Cipla, Mumbai
Indswift Ltd., Mohali
Torrent Research Centre, Amhedabad
DSM Anti-infectives, Ropar
Abbott India Ltd, Goa
Wockhardt Research Centre, Aurangabad
Matrix Lab India, Hyderabad
Pharmaffiliates Analytics & Synthetics., Panchkula
Dhanuka Lab Ltd., Gurgaon
Chemical Resources., Panchkula
Dabur Ltd., Sahibabad

Facilities Available in Stability Testing and Impurity Profiling Laboratory at NIPER	
LC-NMR 500 Mhz	**Shimadzu/Jeol-Oxford**
LC-MS/TOF	**Agilent/Bruker**
HPLC with Corona CAD Detector	**Agilent/ESA**
HPLC Systems with UV Detection- 3	**Shimadzu**
HPLC Systems with PDA Detection- 3	**Waters/Shimadzu**
MPLC – 1	**Buchi**
Preparative HPLC	**Shimadzu**
Stability Chambers Including Photostability Chamber	**Binder**
Rotary Film Evaporators – 3	**Buchi**
Precision Water Baths - 6	**Julabo**
Multi Reactor	**Radley**

Supporting Facilities Available in Central Instrumentation Laboratory at NIPER for Characterization of Impurities	
LC-MS^n	**Finnigan**
GC-MS	**Shimadzu**
FT-NMR (400 MHz)	**Bruker**
FT-NMR (300 MHz)	**Bruker**
FT-IR –2	**Nicolet and Perkin Elmer**
CHNS analyzer	**Elementar**
GC with head space	**Shimadzu**
Freeze Dryer	**Heto**

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Also write for:

1. **Problems related to drug stability or impurity profiling**
2. **On-site training programs on drug stability testing and impurity profiling**