

# LGC Standards - Newsletter

## Pharmaceutical reference substances and impurities Issue 1

### New Reference Standards and Impurities

This is the first newsletter since the publication of our new catalogue: "Pharmaceutical Reference Substances and Impurities 2009".

Further newsletters will follow over the course of the year. From LGC Germany there are 25 new impurity reference standards. From European Pharmacopoeia, USP and the British Pharmacopoeia, 98 more chemical reference substances (CRS) resp. reference standards (RS) have been released, which can be purchased from LGC Standards.

### The World of Reference Standards

The journal "Pharmaceutical Manufacturing & Packing Sourcer" (PMPS) published in its March 2009 issue the article "Reference Standards: Indispensable Tools for Product Quality". The author is our Global Product Manager Pharmaceutical, Dr. Christian Zeine.

Please use the following link to download a free copy of the article:

[www.lgcstandards.com/media/97366663.pdf](http://www.lgcstandards.com/media/97366663.pdf)

### Opportunities to meet representatives from LGC Standards this year:

7 – 9 September 2009	British Pharmaceutical Conference 2009
6 – 8 October 2009	BioTechnica, Hannover, Germany
13 – 15 October 2009	CPhI, Madrid, Spain
8 - 12 November 2009	AAPS 2009 Annual Meeting and Exposition, Los Angeles, USA (Exhibition takes place from 9 – 11 November 2009)

### To arrange a meeting or customer visit please contact:

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## LGC Standards News

## New reference standards

## New USP Standards

Code	Product	Unit	Price £
USP1000420	Abacavir Related Compound A [4-(2,6-diamino-9H-purin-9-yl)cyclopent-2-enyl]methanol	20 mg	514,00
USP1000441	Abacavir Related Compound B [4-(2,5-diamino-6-chloropyrimidin-4-ylamino)cyclopent-2-enyl]methanol	20 mg	514,00
USP1000452	Abacavir Related Compound C [(1S,4R)-4-(2-amino-6-chloro-9H-purin-9-yl)cyclopent-2-enyl]methanol HCl	20 mg	514,00
USP1012032	Actein	20 mg	793,00
USP1071268	Powdered Bilberry Extract	500 mg	274,00
USP1096790	(+)-Catechin	25 mg	190,00
USP1096848	Powdered Cat's Claw Extract	1 g	167,00
USP1140666	Cloprostenol Sodium	400 mg	2003,00
USP1151924	Cyanidin Chloride	25 mg	528,00
USP1171207	23-EPI-26-Deoxyactein	20 mg	793,00
USP1188560	Diclazuril	200 mg	167,00
USP1188571	Diclazuril System Suitability Mixture	50 mg	514,00
USP1226014	Doxycycline Related Compound A 6-epidoxycycline	10 mg	514,00
USP1231615	Ecamsule Related Compound A 1,4-Phenylenedimethanol	50 mg	514,00
USP1231626	Ecamsule Related Compound B 4-(hydroxymethyl)benzoic acid	50 mg	514,00
USP1231637	Ecamsule Related Compound C terephthalic acid	50 mg	514,00
USP1231648	Ecamsule Related Compound D ((1SR,4RS)-7,7-dimethyl-2-oxobicyclo[2.2.1]heptan-1-yl)methanesulfonic acid	50 mg	514,00
USP1231659	Ecamsule Related Compound E sodium ((1SR,4SR,E)-3-(4-(hydroxymethyl)benzylidene)-7,7-dimethyl-2-oxobicyclo[2.2.1]heptan-1-yl)methanesulfonate	25 mg	514,00
USP1231660	Ecamsule Related Compound F 4-((E)-((1SR,4SR)-7,7-dimethyl-3-oxo-4-(sulfomethyl)bicyclo[2.2.1]heptan-2-ylidene)methyl)benzoic acid	25 mg	514,00
USP1231681	Ecamsule Related Compound G 4-((E)-((1SR,4SR)-7,7-dimethyl-3-oxo-4-(sulfomethyl)bicyclo[2.2.1]heptan-2-ylidene)methyl)benzaldehyde, sodium salt	25 mg	514,00
USP1235911	Enrofloxacin Related Compound Mixture	50 mg	514,00
USP1250041	Estradiol Related Compound C 1,3,5(10)estratrien-3,17beta-diol-6-one	15 mg	554,00
USP1265526	2-Ethylhexan-1-ol	1.5 mL	167,00
USP1266802	N-Ethylpiperazine	0.5 mL	514,00
USP1269913	Fentanyl Related Compound A (2-bromoethyl)benzene	100 mg	514,00
USP1269924	Fentanyl Related Compound B 4-Anilino piperidine	10 mg	514,00
USP1269946	Fentanyl Related Compound D N-Phenyl-1-(phenylmethyl)-4-piperidinamine	10 mg	514,00
USP1269957	Fentanyl Related Compound E N-Phenyl-1-(2-phenylethyl)-4-piperidinamine	10 mg	514,00
USP1269979	Fentanyl Related Compound G Acetyl fentanyl	10 mg	514,00
USP1283324	Foscarnet Related Compound D O,O-diethyl ethoxycarbonylphosphonate	0.27 mL	514,00

## New reference standards

Code	Product	Unit	Price £
USP1288339	Ganciclovir Mono-N-methyl Valinate 2-(RS)-[(guanin-9-yl)methoxy]-3-hydroxypropyl N-methyl-L-valinate hydrochloride	10 mg	514,00
USP1298139	Granisetron Related Compound C N-[(1R,3r,5S)-9-azabicyclo[3.3.1]non-3-yl]-1-methyl-1H-indazole- 3-carboxamide HCl	15 mg	528,00
USP1298140	Granisetron Related Compound D 1-methyl-1H-indazole-3-carboxylic acid	15 mg	528,00
USP1302156	Guanine	100 mg	167,00
USP1302203	Purified Guggul Extract	500 mg	274,00
USP1302214	Guggulsterone Z	25 mg	472,00
USP1359437	Levetiracetam Related Compound B (S)-2-aminobutanamide HCl	20 mg	514,00
USP1362602	Levonorgestrel	200 mg	167,00
USP1392807	Mesna	200 mg	167,00
USP1414025	Methotrexate Related Compound B (S)-2-{4-[2,4-diaminopteridin-6yl)methylamino]benzoamido}pentanedioic acid	75 mg	608,00
USP1414036	Methotrexate Related Compound C (S)-2-{4-[(2-amino-4-oxo-1,4-dihydropteridin- 6-yl)methyl](methyl)amino}benzamido}pentanedioic acid	50 mg	514,00
USP1414058	Methotrexate Related Compound E 4-[[[(2,4-Diaminopteridin-6-yl)methyl](methyl)amino]benzoic acid, hemihydrochloride	50 mg	514,00
USP1438205	Methyl Tricosanoate	200 mg	185,00
USP1443602	Midazolam HCl (AS) <b>Controlled Substance CI</b>	200 mg	245,00
USP1443759	Mifepristone	200 mg	263,00
USP1448027	Morphine Sulfate Related Compound B CII (Pseudomorphine) <b>Controlled Substance</b>	20 mg	514,00
USP1448606	Moxifloxacin HCl	200 mg	455,00
USP1448617	Moxifloxacin Related Compound A 1-cyclopropyl-6,8-difluoro-7-[(4aS,7aS)-octahydro-6H-pyrrolo[3,4-b]pyridin- 6-yl]-4-oxo-1,4-dihydroquinoline-3-carboxylic acid	25 mg	514,00
USP1457607	Nateglinide	200 mg	167,00
USP1481215	Oxaliplatin Related Compound A Oxalic acid dihydrate	100 mg	167,00
USP1481226	Oxaliplatin Related Compound B [SP-4-2-(1R-trans-)]-(1,2-cyclohexanediamine-N,N')dinitratoplatinum (II)	15 mg	514,00
USP1481237	Oxaliplatin Related Compound C [1R-trans-(1,2-cyclohexanediamine-N,N')]-trans-dihydroxido-[oxalato(2-)- O,O']platinum (IV)	20 mg	514,00
USP1481248	Oxaliplatin Related Compound D cis[(1S,2S)-1,2-cyclohexanediamine-N,N']-[oxalato(2-)-O,O']platinum	10 mg	514,00
USP1485227	Oxycodone Related Compound B Oxycodone N-oxide <b>Controlled Substance CII</b>	15 mg	608,00
USP1570326	Propafenone Related Compound B (2E)-1-[2-[(2RS)-2-hydroxy-3-(propylamino)propoxy]phenyl]-3-phenylprop- 2-en-1-one	50 mg	514,00
USP1604905	Rocuronium Bromide	250 mg	167,00
USP1612528	Sertraline HCl Related Compound A 1:1 mixture of (1R, 4S) and (1S, 4R)-4-(3,4-dichlorophenyl)-N-methyl- 1,2,3,4-tetrahydro-1-naphthylamine hydrochloride	25 mg	528,00
USP1643260	Tamsulosin HCl	200 mg	POA
USP1643281	Racemic Tamsulosin HCl	50 mg	POA
USP1672756	Tranexamic Acid Related Compound C (RS)-4-(aminomethyl)cyclohex-1-enecarboxylic acid	15 mg	630,00
USP1673001	Travoprost	3 mL	167,00

## New EP Standarads

Code	Product	Unit	Price £
USP1673012	Travoprost Related Compound A (5Z,13E)-(9S,11R,15R)-9,11,15-trihydroxy-16-(m-trifluoromethylphenoxy)- 17-,18,19,20-tetranor-5,13-prostadienoic acid	1.5 mL	514,00
USP1680018	Triamterene Related Compound A 2,4,6-triamino-5-nitrosopyrimidine	50 mg	514,00
USP1680030	Triamterene Related Compound C 2,4,diamino-7-hydroxy-6-phenylpteridine	50 mg	630,00
USP1708730	Valrubicin	100 mg	514,00

## New EP Standarads

Code	Product	Unit	Price £
EPY0001117	Amikacin for impurity A identification	120 mg	87,00
EPY0001067	Amlodipine for peak identification	10 mg	87,00
EPY0001068	Amlodipine impurity A 3-ethyl 5-methyl (4RS)-4-(2-chlorophenyl)-2-[[[2-(1,3-dioxo-1,3-dihydro-2H- isoindol-2-yl)ethoxy]methyl]-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate	10 mg	87,00
EPY0001069	Amlodipine impurity B 3-ethyl 5-methyl (4RS)-4-(2-chlorophenyl)-6-methyl- 2-[[[2-(methylcarbamoyl)benzoyl]amino]ethoxy]methyl]- 1,4-dihydropyridine-3,5-dicarboxylate	10 mg	87,00
EPY0001070	Amlodipine impurity G dimethyl 4-(2-chlorophenyl)-2,6-dimethyl-1,4-dihydropyridine- 3,5-dicarboxylate	10 mg	87,00
EPY0001122	Buprenorphine for system suitability Controlled Substance	10 mg	87,00
EPY0001141	Diltiazem for system suitability	10 mg	87,00
EPY0001105	Drospirenone	60 mg	87,00
EPY0001115	Drospirenone impurity E 3-oxo-6 $\alpha$ ,7 $\alpha$ ,15 $\alpha$ ,16 $\alpha$ -tetrahydro-3'H,3''H- dicyclopropa[6,7:15,16]pregn-4-ene-21,17- carbolactone (17-epidrospirenone)	0.06 mg	87,00
EPY0001112	Gestodene	100 mg	87,00
EPY0001092	Hydrocortisone for peak identification	5 mg	87,00
EPY0001106	Medronic acid impurity B Tetrakis(1-methylethyl)methylenediphosphonate	40 $\mu$ l	87,00
EPY0001114	Tenoxicam impurity mixture	0.0042 mg	87,00
EPY0001123	Tolnaftate for system suitability	10 mg	87,00
EPY0000799	Tributyl acetylcitrate for peak identification	25 mg	87,00
EPY0001118	Vedaprofen impurity mixture	0.006 mg	87,00

## New BP Standards

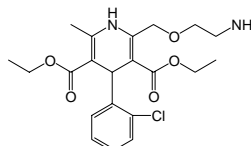
Code	Product	Unit	Price £
BP 813	2-Amino-5-chloropyridine	25 mg	130,00
BP 785	Anhydrous Ampicillin Assay Standard	250 mg	190,00
BP 047	Bisacodyl Assay Standard	100 mg	190,00
BP 833	Clarithromycin Assay Standard	100 mg	190,00
BP 789	Demeclocycline hydrochloride Assay Standard	100 mg	190,00
BP 811	Dexamethasone impurity standard	25 mg	130,00
BP 781	Erythromycin	50 mg	130,00
BP 795	Erythromycin B Assay Standard	50 mg	190,00
BP 796	Erythromycin C Assay Standard	50 mg	190,00
BP 790	Erythromycin estolate	100 mg	130,00
BP 798	Erythromycin ethyl succinate	50 mg	130,00
BP 797	Fluoxetine hydrochloride Assay Standard	250 mg	190,00
BP 206	Isosorbide dinitrate	300 mg	190,00

Code	Product	Unit	Price £
BP 762	Mercaptopurine impurity standard	25 mg	130,00
BP 805	Ondansetron for TLC system suitability	25 mg	130,00
BP 806	Ondansetron impurity standard	25 mg	130,00
BP 480	Tetracycline hydrochloride Assay Standard	100 mg	190,00

## New LGC Impurity Standards

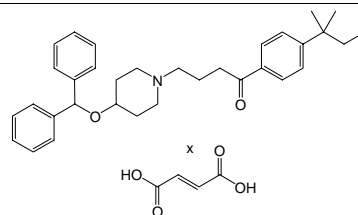
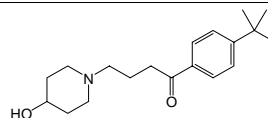
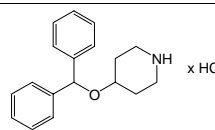
### Amlodipine Besilate

Code	Product	Unit	Price £
MM 0383.10	<b>Imp. E</b> (EP): Diethyl (4 <i>RS</i> )-2-[(2-Aminoethoxy)methyl]-4-(2-chlorophenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate	100 mg	1080,00



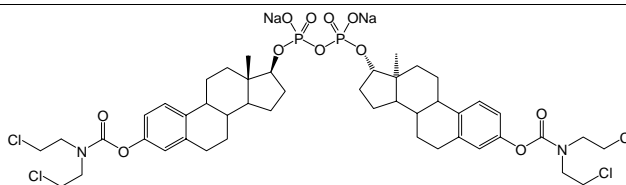
### Ebastine

MM 0468.04	<b>Imp. C</b> (EP) as Hydrochloride: 4-(Diphenylmethoxy)piperidine Hydrochloride	100 mg	535,00
MM 0468.05	<b>Imp. D</b> (EP): 1-[4-(1,1-Dimethylethyl)phenyl]-4-(4-hydroxypiperidin-1-yl)butan-1-one	100 mg	535,00
MM 0468.06	<b>Imp. E</b> (EP) as Hydrogen Fumarate: 1-[4-(1,1-Dimethylpropyl)phenyl]-4-[4-(diphenylmethoxy)piperidin-1-yl]butan-1-one Hydrogen Fumarate	100 mg	535,00



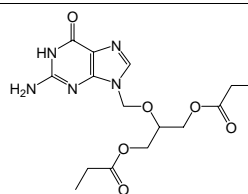
### Estramustine Sodium Phosphate

MM 0100.02	17β-17'β-Bis3-{bis(2-chloroethyl)carbamoyloxy}estra-1,3,5(10)-trienyl Pyrophosphate Disodium Salt	50 mg	1080,00
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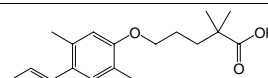
### Ganciclovir

MM 0485.09	<b>Imp. I</b> (Pharmeuropa): 2-Amino-9-[[2-(1-methylene-propoxy)-1-[(1-methylenepropoxy)methyl]ethoxy]-methyl]-1,9-dihydro-6 <i>H</i> -purin-6-one (Ganciclovir Dipropionate)	100 mg	535,00
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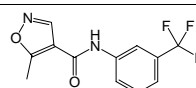
### Gemfibrozil

MM 0641.07	<b>Imp. E</b> (EP): 5-[2,5-Dimethyl-4-(prop-1-enyl)phenoxy]-2,2-dimethylpentanoic Acid	100 mg	1080,00
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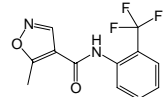
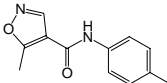
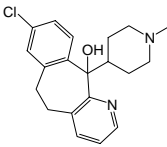
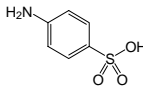
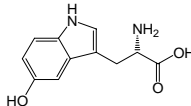
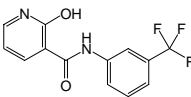
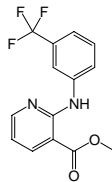
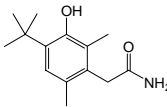
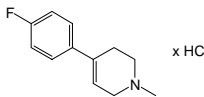
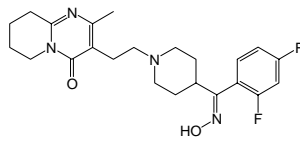
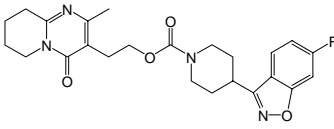


### Leflunomide

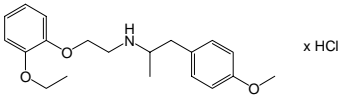
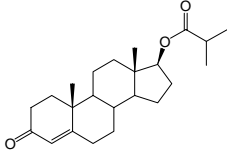
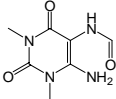
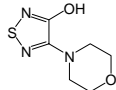
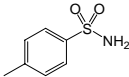
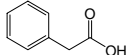
MM 0859.03	<b>Imp. C</b> (EP): 5-Methyl-N-[3-(trifluoromethyl)phenyl]isoxazole-4-carboxamide	100 mg	535,00
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## New LGC Impurity Standards

Code	Product		Unit	Price £
MM 0859.06	<b>Imp. F</b> (EP): 5-Methyl-N-[2-(trifluoromethyl)-phenyl]isoxazole-4-carboxamide		100 mg	535,00
MM 0859.07	<b>Imp. G</b> (EP): 5-Methyl-N-(4-methylphenyl)-isoxazole-4-carboxamide		100 mg	535,00
<b>Loratadine</b>				
MM 0257.06	(11RS)-8-Chloro-11-hydroxy-11-(1-methylpiperidin-4-yl)-6,11-dihydro-5H-benzo[5,6]cyclohepta[1,2-b]pyridine		100 mg	535,00
<b>Mesalazine</b>				
MM 0227.04	<b>Imp. O</b> (Pharmeuropa): 4-Aminobenzenesulphonic Acid (Sulphanilic Acid)		100 mg	535,00
<b>N-Acetyltryptophan</b>				
MM 0172.03	<b>Imp. D</b> (EP): (S)-2-Amino-3-(5-hydroxy-1H-indol-3-yl)propanoic Acid (5-Hydroxytryptophan)		100 mg	535,00
<b>Niflumic Acid</b>				
MM 0850.05	<b>Imp. B</b> (EP): 2-Hydroxy-N-[3-(trifluoromethyl)phenyl]pyridine-3-carboxamide		100 mg	535,00
MM 0850.01	<b>Imp. F</b> (EP): Methyl 2-[[3-(Trifluoromethyl)phenyl]amino]pyridine-3-carboxylate (Niflumic Acid Methyl Ester)		100 mg	535,00
<b>Oxymetazoline Hydrochloride</b>				
MM 0177.07	<b>Imp. C</b> (EP): 2-[4-(1,1-Dimethylethyl)-3-hydroxy-2,6-dimethylphenyl]acetamide		100 mg	535,00
<b>Paroxetine Hydrochloride Anhydrous</b>				
MM 1032.07	<b>Imp. G</b> (EP) as Hydrochloride: 4-(4-Fluorophenyl)-1-methyl-1,2,3,6-tetrahydropyridine Hydrochloride		100 mg	535,00
<b>Risperidone</b>				
MM 0491.01	<b>Imp. A</b> (EP): 3-[2-[4-[(E)-(2,4-Difluorophenyl)-(hydroxyimino)methyl]piperidin-1-yl]ethyl]-2-methyl-6,7,8,9-tetrahydro-4H-pyrido[1,2-a]pyrimidin-4-one		100 mg	1080,00
MM 0491.08	<b>Imp. F</b> (EP): 2-[2-Methyl-4-oxo-6,7,8,9-tetrahydro-4H-pyrido[1,2-a]pyrimidin-3-yl]ethyl 4-(6-Fluoro-1,2-benzisoxazol-3-yl)piperidin-1-carboxylate		100 mg	535,00

## Withdrawn Standards

Code	Product		Unit	Price £
<b>Tamsulosin Hydrochloride</b>				
MM 0938.01	<b>Imp. H</b> (EP) as Racemate Hydrochloride: (2 <i>RS</i> )- <i>N</i> -[2-(2-Ethoxyphenoxy)ethyl]-1-(4-methoxyphenyl)propan-2-amine Hydrochloride		100 mg	535,00
<b>Testosterone Propionate</b>				
MM 0863.07	<b>Imp. B</b> (EP): 3-Oxoandrost-4-en-17β-yl 2-Methylpropanoate (Testosterone Isobutyrate)		100 mg	535,00
<b>Theophylline-Ethylenediamine</b>				
MM 0176.02	<b>Imp. C</b> (Pharmeuropa): <i>N</i> -(6-Amino-1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydropyrimidin-5-yl)formamide		100 mg	535,00
<b>Timolol Maleate</b>				
MM 0440.04	<b>Imp. D</b> (Pharmeuropa): 4-Morpholin-4-yl-1,2,5-thiadiazol-3-ol		100 mg	535,00
<b>Tolbutamide</b>				
MM 0325.01	<b>Imp. A</b> (Pharmeuropa): (4-Methylphenyl)sulphonamide (Toluenesulphonamide; 4-Methylbenzenesulphonamide)		100 mg	251,00
<b>Tropicamide</b>				
MM 0160.03	<b>Imp. D</b> (Pharmeuropa): Phenylacetic Acid		100 mg	201,00

## Withdrawn Standards

Code	Product	Unit	Price £
EPY0000230	Atropine for system suitability	0.4 mg	87,00
FPC2700	Adrénaline Reference Spectrum	unit	60,00
FPC0320	Chloro-2 nicotinique acide	100 mg	60,00
FPC0422	Diavéridine (usage vétérinaire)	250 mg	60,00
FPC0930	Hydroxy-2 N-(trifluorométhyl-3'phényl) nicotinamide	60 mg	60,00
FPC1540	Niflumique acide	120 mg	60,00
REA3005000	0.5M Potassium hydroxide, alcoholic	1 L	44,00

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