

LGC Standards - Newsletter

Pharmaceutical reference substances and impurities Issue 2

New Reference Standards and Impurities

Since our first newsletter earlier this year, a further twenty two new impurity reference standards have been produced at our laboratories in Germany. These products are now available and are all accompanied by a detailed certificate of analysis. An example the certificate can be found in our catalogue "Pharmaceutical Reference Substances and Impurities 2009" on pages 169-172. The European Pharmacopoeia and the USP have released 62 new chemical reference substances (CRS) resp. reference standards (RS), which can be obtained from LGC Standards. These pharmacopoeial reference standards should be used in accordance with the corresponding compendium. No certificates of analysis are available for these 62 products, as is generally the case with pharmacopoeial reference standards.

"Pharmaceutical Reference Substances and Impurities 2009" – catalogue errata

In the chapter on pharmaceutical impurities, the column for the price code is headed incorrectly on some pages with "Use", which has no meaning at all. This column should still feature the price code, which is (A), (B), (C) or (D). This price code is explained in our most recent price list. Furthermore, on page 221, the first six products were included on this page by error, disrupting the list of Diclofenac impurities, which is resumed again with the next two products on page 221, MM0006.27 and MM0006.28.

We are sorry for any inconveniences these two errors might have caused.

Do not miss the following opportunities to meet representatives from LGC Standards this year:

12 -14 July 2009	IAFP, Grapevine, Texas, USA
16 - 20 August 2009	57th International Congress & Annual Meeting of the Society for Medicinal Plant Research, Geneva, Switzerland
23 - 27 August 2009	TIAFT 2009, Geneva, Switzerland
08 - 11 September 2009	5th Triennial meeting of the European Academy of Forensic Science (EAFS), Glasgow, UK
06 - 08 October 2009	BioTechnica, Hannover, Germany
13 - 15 October 2009	CPhI, Madrid, Spain
08 - 12 November 2009	AAPS 2009 Annual Meeting and Exposition, Los Angeles, USA (Exhibition takes place from 09 - 11 November 2009)

If you would like to place an order please email:
pfccustomerservice@lgcstandards.com

To arrange a meeting please contact Patrick Henry:
patrick.henry@lgcstandards.com



Excellence through measurement

New USP Standards

Code	Product	Unit	Price £
USP1010106	N-Acetyl-L-Tyrosine	100 mg	175,00
USP1012112	S-Adenosyl-L-Homocysteine	50 mg	193,00
USP1048550	Behenoyl Polyoxyglycerides	500 mg	175,00
USP1096688	Carvedilol System Suitability Mixture carvedilol spiked with carvedilol related compound F	25 mg	514,00
USP1098399	Silicified Microcrystalline Cellulose	1 g	175,00
USP1161586	Cystine	200 mg	175,00
USP1171455	Dermatan Sulfate	25 mg	514,00
USP1180015	Dextroamphetamine Related Compound A 1-Phenyl-2-propanol	25 mg	514,00
USP1235853	Enoxaparin Sodium Molecular Weight Calibrant A	6.2 mg	338,00
USP1235853	Enoxaparin Sodium Molecular Weight Calibrant A	6.2 mg	338,00
USP1269902	Fentanyl Controlled Substance CII	100 mg	347,00
USP1368201	Alpha Lipoic Acid	500 mg	175,00
USP1711133	Lypressin 8-L-lysine vasopressin	2.2 mg	175,00
USP1448016	Morphine Sulfate Related Compound A Morphine N-Oxide Controlled Substance CI	20 mg	514,00
USP1457618	Nateglinide Related Compound A trans-4-isopropylcyclohexanecarboxylic acid	10 mg	514,00
USP1457629	Nateglinide Related Compound B N-(trans-4-isopropylcyclohexanecarbonyl)-L-phenylalanine	10 mg	514,00
USP1457630	Nateglinide Related Compound C N-(cis-4-isopropylcyclohexanecarbonyl)-D-phenylalanine	5 mg	514,00
USP1479304	Oseltamivir Phosphate	200 mg	217,00
USP1491296	Oxytocin Identification	15 mg	217,00
USP1604610	Risedronate Sodium	350 mg	175,00
USP1600121	Rebaudioside A	300 mg	326,00
USP1604621	Risedronate Related Compound A [1-hydroxy-2-(2-pyridinyl)ethylidene]bis(phosphonic acid)	20 mg	514,00
USP1604632	Risedronate Related Compound B [3,6-bis[(3-pyridinyl)methyl]-2,5-dihydroxy-2,5-dioxido-1,4,2,5-dioxadiphosphorinane-3,6-diyl]bis[phosphonic acid]disodium tetrahydrate salt	20 mg	514,00
USP1604643	Risedronate Related Compound C [2-(3-pyridinyl)ethylidene-1,1]bis(phosphonic acid)	20 mg	514,00
USP1604916	Rocuronium Peak Identification Mixture rocuronium bromide spiked with rocuronium related compounds A,B,C,D,E,F,G and H	25 mg	875,00
USP1612539	Sertraline HCl	100 mg	497,00
USP1612517	Sertraline HCl Racemic Mixture 1:1 mixture of (1S,4S) and (1R, 4R)-4-(3,4-dichlorophenyl)N-methyl-1,2,3,4-tetrahydro-1-naphthylamine HCl	25 mg	514,00
USP1614578	Sodium Picosulfate	50 mg	175,00
USP1617474	Defatted Powdered Soy	2.5 g	175,00
USP1622408	Stevioside	30 mg	190,00
USP1667144	Ticlopidine HCl	150 mg	175,00
USP1667155	Ticlopidine Related Compound A 4-oxo-4,5,6,7-tetrahydrothieno-[3,2-c]pyridine	20 mg	514,00
USP1667166	Ticlopidine Related Compound B 5-(2-chlorobenzyl)4-oxo-4,5,6,7-tetrahydrothieno-[3,2-c]pyridine	20 mg	514,00
USP1673839	Trenbolone Acetate System Suitability Mixture Controlled Substance CIII	30 mg	514,00
USP1707855	Valacyclovir Related Compound C 2-[(2-amino-6-oxo-1,6-dihydro-9H-purin-9-yl)methoxy]ethyl N-methyl-L-valinate HCl	10 mg	514,00

New EP Standards

Code	Product	Unit	Price £
USP1707861	Valacyclovir Related Compound D 2-[(2-amino-6-oxo-1,6-dihydro-9H-purin-9-yl)methoxy]ethyl N-ethyl-L-valinate	10 mg	514,00
USP1707872	Valacyclovir Related Compound E 2-[(2-amino-6-oxo-1,6-dihydro-9H-purin-9-yl)methoxy]ethyl N-[(benzyloxy)carbonyl]-L-valinate	25 mg	514,00
USP1707894	Valacyclovir Related Compound G N,N-dimethylpyridin-4-amine	50 mg	514,00
USP1711100	Vasopressin 8-L-arginine vasopressin	1.78 mg	175,00
USP1724893	Zolpidem Controlled Substance CIV	10 mg	217,00
USP1724918	Zolpidem Related Compound A N,N-Dimethyl-2-[7-methyl-2-p-tolylimidazo[1,2-a]pyridin-3-yl]acetamide Controlled Substance CIV	15 mg	514,00
USP1724907	Zolpidem Tartrate Controlled Substance CIV	200 mg	217,00

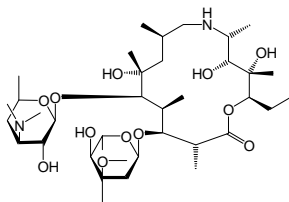
New EP Standards

Code	Product	Unit	Price £
EPY0001119	Adapalene for peak identification	2.022 mg	87,00
EPY0001148	Budesonide for system suitability	10 mg	87,00
EPY0001130	Cimetidine for peak identification	10 mg	87,00
EPY0001146	Cimetidine for system suitability	0.5085 mg	87,00
EPY0001137	Clobetasone butyrate for system suitability	30 mg	87,00
EPY0001150	Dextropropoxyphene for system suitability Controlled Substance	5 mg	87,00
EPY0001058	Dextropropoxyphene hydrochloride Controlled Substance	10 mg	87,00
EPY0001139	Epinastine hydrochloride	20 mg	87,00
EPY0001128	Epinastine hydrochloride for system suitability	10 mg	87,00
EPY0001140	Glipizide impurity mixture	0.002 mg	87,00
EPY0001136	Lovastatine for peak identification	20 mg	87,00
EPY0001125	Orbifloxacin	200 mg	87,00
EPY0001147	Orbifloxacin impurity mixture	0.0008 mg	87,00
EPY0001167	Phenytoin for system suitability	20 mg	87,00
EPY0001168	Potassium clavulanate impurity G	5 mg	87,00
EPY0001134	Raloxifene hydrochloride	110 mg	87,00
EPY0001135	Raloxifene hydrochloride for peak identification	10 mg	87,00
EPY0001074	Rifaximin	160 mg	87,00
EPY0001126	Spike lavender oil	400 µl	87,00
EPY0001143	Terbinafine for system suitability	10 mg	87,00
EPY0001132	Valsartan	10 mg	87,00
EPY0001131	Valsartan for peak identification	10 mg	87,00
EPY0001145	Valsartan for system suitability	0.202 mg	87,00

New LGC Impurity Standards

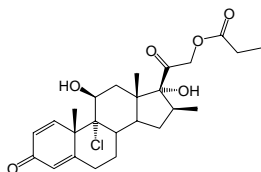
Azithromycin

Code	Product	Unit	Price £
MM 1075.01	Imp. A (EP): 6-Demethylazithromycin (Azaerythromycin A)	100 mg	1080,00

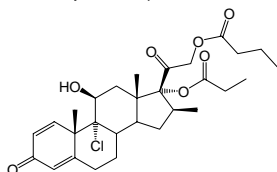


Beclometasone Dipropionate

MM 0199.02	Imp. A (EP): 9-Chloro-11 β , 17-dihydroxy-16 β -methyl-3,20-dioxopregna-1,4-dien-21-yl Propanoate (Beclometasone 21-Propionate)	100 mg	535,00
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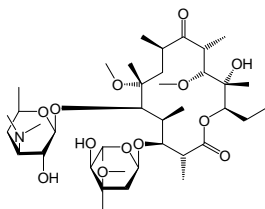


MM 0199.05	Imp. C (EP): 9-Chloro-11 β -hydroxy-16 β -methyl-3,20-dioxo-17-(propanoyloxy)-pregna-1,4-dien-21-yl Butanoate (Beclometasone 21-Butyrate 17-Propionate)	100 mg	535,00
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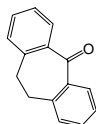
Clarithromycin

MM 0057.05	Imp. E (EP): 6,11-Di-O-methylerythromycin A	100 mg	1080,00
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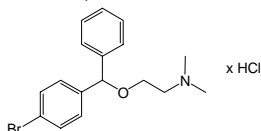
Cyproheptadine Hydrochloride

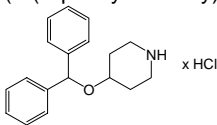
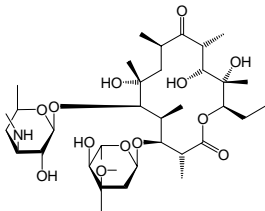
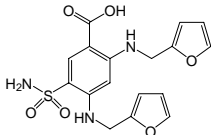
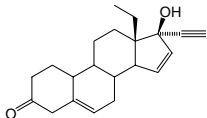
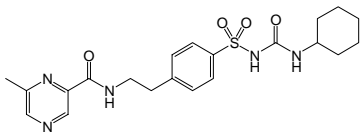
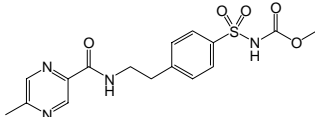
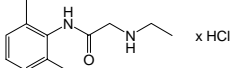
MM 0062.01	Imp. B (EP): 10,11-Dihydro-5H-dibenzo[a,d][7]-annulen-5-one (Dibenzosuberone)	100 mg	201,00
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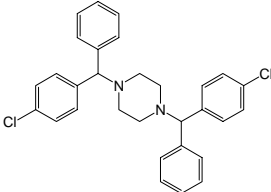
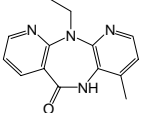
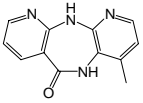
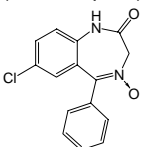
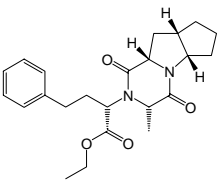
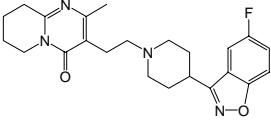
Dimenhydrinate

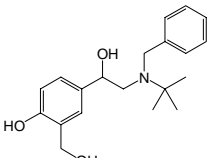
MM 0640.00	Imp. H (EP) as Hydrochloride: 2-[(RS)-(4-Bromophenyl)(phenyl)methoxy]-N,N-dimethylethanamine Hydrochloride (4-Bromodiphenhydramine Hydrochloride; Bromazine Hydrochloride)	100 mg	535,00
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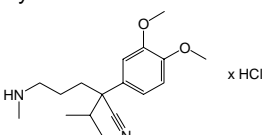


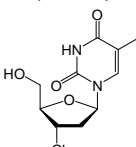
Code	Product	Unit	Price £
Diphenylpyraline Hydrochloride			
MM 0468.04	N-Desmethyldiphenylpyraline Hydrochloride (4-(Diphenylmethoxy)piperidine Hydrochloride)	100 mg	535,00
			
Erythromycin			
MM 0132.13	Imp. B (EP): N-Demethylerythromycin A	100 mg	1080,00
			
Furosemide			
MM 0014.04	Imp. D (EP): 2,4-Bis[(furan-2-ylmethyl)amino]-5-sulphamoylbenzoic Acid	100 mg	1080,00
			
Gestodene			
MM 0124.06	Imp. L (EP): 13-Ethyl-17-hydroxy-18,19-dinor-17 α -pregna-5,15-dien-20-yn-3-one ($\Delta^5(6)$ -Gestodene)	100 mg	535,00
			
Glipizide			
MM 0942.05	Imp. E (EP): 1-Cyclohexyl-3-[[4-[2-[[[6-methylpyrazin-2-yl)carbonyl]amino]ethyl]phenyl]-sulphonyl]urea	100 mg	535,00
			
MM 0942.07	Imp. G (Pharmeuropa): Methyl [[4-[2-[[[5-Methylpyrazin-2-yl)carbonyl]amino]ethyl]phenyl]sulphonyl]carbamate	100 mg	535,00
			
Lidocaine Hydrochloride			
MM 0102.05	Imp. D (EP) as Hydrochloride: N-(2,6-Dimethylphenyl)-2-(ethylamino)acetamide Hydrochloride (Monoethylglycinexylidide Hydrochloride)	100 mg	535,00
			

New LGC Impurity Standards

Code	Product	Unit	Price £
Meclozine Hydrochloride			
MM 0380.04	Imp. F (Pharmeuropa): 1,4-Bis[(4-chlorophenyl)-phenylmethyl]piperazine	100 mg	535,00
			
Nevirapine Anhydrous			
MM 1146.01	Imp. A (EP): 11-Ethyl-4-methyl-5,11-dihydro-6H-dipyrido [3,2-b:2',3'-e][1,4]diazepin-6-one	100 mg	535,00
			
MM 1146.02	Imp. B (EP): 4-Methyl-5,11-dihydro-6H-dipyrido[3,2-b:2',3'-e][1,4]diazepin-6-one	100 mg	535,00
			
Oxazepam			
MM 0028.02	Imp. E (EP): 7-Chloro-5-phenyl-1,3-dihydro-2H-1,4-benzodiazepin-2-one 4-Oxide (Demoxepam)	100 mg	535,00
			
Ramipril			
MM 0448.05	Imp. D (EP): Ethyl (2S)-2-[(3S,5aS,8aS,9aS)-3-Methyl-1,4-dioxodecahydro-2H-cyclopenta[4,5]-pyrrolo[1,2-a]pyrazin-2-yl]-4-phenylbutanoate (Ramipril Diketopiperazine)	100 mg	535,00
			
Risperidone			
MM 0491.04	Imp. D (EP): 3-[2-[4-(5-Fluoro-1,2-benzisoxazol-3-yl)piperidin-1-yl]ethyl]-2-methyl-6,7,8,9-tetrahydro-4H-pyrido[1,2-a]pyrimidin-4-one	100 mg	1080,00
			

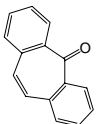
Code	Product	Unit	Price £
Salbutamol Sulphate			
MM 0381.05	Imp. E (EP): (1RS)-2-[Benzyl(1,1-dimethylethyl)amino]-1-[4-hydroxy-3-(hydroxymethyl)phenyl]ethanol	100 mg	535,00
			

Verapamil Hydrochloride			
MM 0022.10	Imp. F (EP) as Hydrochloride: (2RS)-2-(3,4-Dimethoxyphenyl)-5-(methylamino)-2-(1-methylethyl)pentanenitrile Hydrochloride	100 mg	535,00
			

Zidovudine			
MM 0173.02	Imp. B (EP): 1-(3-Chloro-2,3-dideoxy-β-D-erythro-pentofuranosyl)-5-methylpyrimidine-2,4(1H,3H)-dione	100 mg	535,00
			

Alterations

Code	Product	Unit	Price £
USP1270446	Fexofenadine Related Compound C (+)-4-[1-hydroxy-4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]-butyl]-isopropylbenzene (AS)	15 mg	514,00

Cyproheptadine Hydrochloride			
MM 0609.02	5H-Dibenzo[a,d]cyclohepten-5-one (Dibenzosuberone)	100 mg	251,00
			

Withdrawn Standards			
EPA0368010	Amikacin impurity A 4-O-(3-amino-3-desoxy-α-D-glycopyranosyl)-6-O-(6-amino-6-desoxy-α-D-glucopyranosyl)-N1-[(2S)-4-amino-2-hydroxybutanoyl]-2-desoxy-L-streptamine	10 mg	
EPA1341000	Atenolol for column validation	100 mg	
EPC1605000	(2-Chlorophenyl) diphenylmethanol	20 mg	
EPF0006000	Famotidine impurity A 3-[[[2-[(diaminomethylene)amino]thiazol-4-yl]methyl]-thio]propanamide	10 mg	
FPC2090	Sulfaquinoxaline	100 mg	

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