

LGC Standards - Newsletter

Pharmaceutical reference substances and impurities Issue 3

Nuevas patrones de referencia e impurezas farmacéuticas

Desde nuestra Newsletter enviada en verano, LGC Standards, la USP, la EP y la BP han emitido 103 nuevas referencias para aplicaciones farmacéuticas. Las nuevas impurezas farmacéuticas fabricadas en nuestros laboratorios de Luckenwalde en Alemania vienen acompañadas de un detallado Certificado de Análisis (puede ver un ejemplo del mismo en nuestro catálogo "Pharmaceutical Reference Substances and Impurities 2009" páginas 169-172). Sus aplicaciones son varias: desarrollo y validación de métodos, tests de estabilidad y en control de calidad entre otros.

Los estándares de Referencia de farmacopeas deben ser utilizados únicamente de acuerdo con la correspondiente Farmacopea y no para otros propósitos. Tal y como se explica en los documentos de la farmacopea, las consecuencias de cualquier otro uso de estos patrones recae solo en el usuario final. Los patrones de referencia de las farmacopeas se entregan sin Certificado de Análisis.

Periodos de validez más largos para nuestras impurezas

Nos complace anunciar que gracias a una revisión de nuestros procesos para monitorizar la estabilidad, para más de un 60% de nuestras impurezas farmacéuticas hemos extendido la caducidad a 2 años a partir de la fecha de envío en lugar de solo 1 año.

No se pierda la oportunidad de conocer a nuestros compañeros y asistir a una de las conferencias que damos:

- 08. - 12.11.2009 AAPS 2009 Annual Meeting and Exposition, Los Angeles, USA
(Exhibition takes place from 09. - 11.11.2009)
- 04.11.2009 LGC Standards Seminar*, Istanbul, Turkey
(English Language)
- 25.11.2009 LGC Standards Seminar*, Bukarest, Romania
(English Language)
- 01.12.2009 LGC Standards Seminar*, Darmstadt, Germany
(German Language)
- 10.12.2009 LGC Standards Seminar*, Basel, Switzerland
(German Language)

*todos los seminarios trataran los temas: Reference standards, impurities, pharmacopoeias and proficiency testing.

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Excellence through measurement

New Reference Standards and Impurities

Since our second newsletter from Summer this year, 103 new reference standards for pharmaceutical applications have been made available by LGC Standards, the USP, EP and BP. The new impurity reference standards from our own laboratories in Luckenwalde, Germany all come with a detailed certificate of analysis. An example of such a certificate you can find in our catalogue "Pharmaceutical Reference Substances and Impurities 2009" on pages 169-172. They are suitable for various applications in method development and validation as well as subsequently in quality/release control and stability testing.

Pharmacopoeial reference standards should be used in accordance with the corresponding compendium, and for no other purpose. As explained by official pharmacopoeial documents, off-compendial use lies solely in the responsibility of the user. No certificates of analysis are available for pharmacopoeial reference standards.

Longer validity periods for our impurity reference standards

We are pleased to announce that for more than 60% of our impurity reference standards we can now give validity periods for two years from the date of shipment instead of just one year. This is the result of our revised stability monitoring processes and adds further to the convenience of our products.

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

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|-------------------------|---|
| 08. - 12.11.2009 | AAPS 2009 Annual Meeting and Exposition, Los Angeles, USA
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| 04.11.2009 | LGC Standards Seminar*, Istanbul, Turkey (English language) |
| 25.11.2009 | LGC Standards Seminar*, Bukarest, Romania (English language) |
| 01.12.2009 | LGC Standards Seminar*, Darmstadt, Germany (German language) |
| 10.12.2009 | LGC Standards Seminar*, Basel, Switzerland (German language) |

*All seminars will deal with the following topics: Reference standards, impurities, pharmacopoeias and proficiency testing.

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New USP Standards

Code	Product	Unit
USP1027357	Amiodarone Related Compound E (2-butylbenzofuran-3-yl)(4-hydroxyphenyl)methanone	25 mg
USP1029512	Amlodipine Related Compound A 3-Ethyl,5-methyl [2-(2-aminoethoxymethyl)-4-(2-chlorophenyl)-6-methyl-3,5-pyridinedicarboxylate]fumarate	25 mg
USP1042907	Articaine	40 mg
USP1042918	Articaine HCl	125 mg
USP1042929	Articaine Related Compound A Methyl 4-methyl-3-[2-propylamino) acetamido]thiophene-2-carboxylate	40 mg
USP1042962	Articaine Related Compound E Methyl 3-[2-(isopropylamino)propanamido]-4-methylthiophene-2-carboxylate	40 mg
USP1044516	Atorvastatin Calcium	100 mg
USP1044527	Atorvastatin Related Compound A Desfluoro impurity, or (3R,5R)-7-[3-(phenylcarbamoyl)-2-isopropyl-4,5-diphenyl-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid calcium salt	20 mg
USP1044538	Atorvastatin Related Compound B 3S,5R isomer, or (3S,5R)-7-[3-(phenylcarbamoyl)-5-(4-fluorophenyl)-2-isopropyl-4-phenyl-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid calcium salt	20 mg
USP1044549	Atorvastatin Related Compound C Difluoro impurity, or (3R,5R)-7-[3-(phenylcarbamoyl)-4,5-bis(4-fluorophenyl)-2-isopropyl-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid calcium salt	20 mg
USP1044550	Atorvastatin Related Compound D Epoxide impurity, or 3-(4-Fluorobenzoyl)-2-isobutyl-3-phenyl-oxirane-2-carboxylic acid phenylamide	20 mg
USP1044571	Atorvastatin Related Compound E 3S,5S enantiomer of Atorvastatin Calcium	10 mg
USP1097590	Cefditoren Pivoxil	350 mg
USP1133580	Oversulfated Chondroitin Sulfate	25 mg
USP1134142	R-Citalopram Oxalate R-(-)-1-[3-(dimethylamino)propyl]-1-(p-fluorophenyl)-5-phthalanarbonitrile oxalate	10 mg
USP1134696	Clenbuterol Related Compound B 1-(4-amino-3,5-dichlorophenyl)-2-tert-butylaminoethanone HCl	10 mg
USP1180026	Dextroamphetamine Related Compound B Phenyl acetone [Controlled Substance] CII	25 mg
USP1231580	Ecamsule Solution	0.5 mL
USP1235820	Enoxaparin Sodium	300 mg
USP1235842	Enoxaparin Sodium Solution for Bioassays	1 mL
USP1249406	Escitalopram Oxalate	200 mg
USP1249417	Escitalopram Related Compound A (-)-4-[(4-dimethylamino)-1-(4-fluorophenyl)-1-(hydroxybutyl)]-3-(hydroxymethyl)benzotrile	10 mg
USP1272929	Fludeoxyglucose Related Compound B 2-chloro-2-deoxy-D-glucose	10 mg
USP1298208	Grape Seeds Oligomeric Proanthocyanidins	500 mg
USP1304016	Heparin Sodium for Assays	9.5 mg
USP1331008	12-Hydroxystearic Acid	200 mg
USP1356825	Lactobionic Acid	200 mg
USP1370101	Lopinavir	350 mg
USP1372050	Lysophosphatidylcholine	350 mg
USP1392818	Mesna Related Compound A 2-(Acetylsulfanyl)ethanesulfonic acid	50 mg
USP1392829	Mesna Related Compound B (2,2-(Disulfanediy)bis(ethanesulfonic acid))	50 mg
USP1478200	Oley Oleate	0.5 mL

New EP Standards

Code	Product	Unit
USP1478855	Orlistat Related Compound E N-formyl-S-isoleucin-(S)-1-[[[(2S, 3S)-3-hexyl-4-oxo-2-oxetanyl]methyl]dodecyl ester	10 mg
USP1483152	Oxcarbazepine	100 mg
USP1485238	Oxycodone Related Compound C Codeinone [Controlled Substance] CII	15 mg
USP1535733	Phosphatidylcholine	350 mg
USP1535744	Phosphatidylethanolamine	100 mg
USP1548043	Polyvinyl Acetate Dispersion	1 g
USP1562011	Primidone Related Compound A 2-ethyl-2-phenylmalonamide	20 mg
USP1562033	Primidone Related Compound C 2-phenylbutyramide	20 mg
USP1576763	Propylene Glycol Dilaurate	500 mg
USP1584014	Pyrantel Related Compound A 1-methyl-2-[(Z)-2-(thiophen-2-yl)ethenyl]-1,4,5,6-tetrahydropyrimidine Pamoate	25 mg
USP1604337	Riluzole	200 mg
USP1604869	Rivastigmine Related Compound A (+)-Di-p-toluoyl-D-(+)-tartaric acid	15 mg
USP1604870	Rivastigmine Related Compound B (R,S)-3-[1-(Dimethylamino)ethyl]phenyl dimethylcarbamate	15 mg
USP1609603	Salmeterol Xinafoate	150 mg
USP1609614	Salmeterol Related Compound A 4-[1-Hydroxy-2-(4-phenylbutylamino)ethyl]-2-(hydroxymethyl)phenol	10 mg
USP1609625	Salmeterol Related Compound B 4-{1-Hydroxy-2-[6-(4-phenylbutan-2-yloxy)hexylamino]ethyl}2-(hydroxymethyl)phenol	10 mg
USP1612018	Sennoside A	20 mg
USP1680029	Triamterene Related Compound B 2,7-diamino-4-hydroxy-6-phenylpteridine	50 mg
USP1700512	Tryptophan Related Compound A 1,1'-ethylidene-bis-(L-tryptophan)	15 mg
USP1707839	Valacyclovir HCl	200 mg
USP1707883	Valacyclovir Related Compound F 2-hydroxyethyl valinate praluenesulfonate salt	25 mg
USP1708751	Valrubicin Resolution Mixture Valrubicin spiked with seven related substance	25 mg

New EP Standards

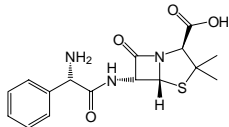
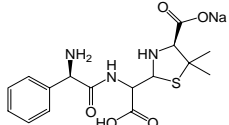
Code	Product	Unit
EPY0001121	Adapalene	100 mg
EPY0001120	Adapalene impurity C 1-[2-(methyloxy)phenyl]tricyclo[3.3.1.1]decane	5 mg
EPY0001154	Aprotinin for system suitability	2.7 mg
EPY0001170	Ascorbic acid impurity D Methyl D-sorbosonate	10 mg
EPY0001149	Berberine chloride	20 mg
EPY0001161	Carbasalate impurity B 2-[[2-(acetyloxy)benzoyl]oxy]benzoic acid (acetylsalicylsalicylic acid)	5 mg
EPY0001169	Dexamethasone acetate impurity E 9-fluoro-11beta,17-dihydroxy-16alpha-methyl-3,20-dioxopregn-4-en-21-yl acetate	0.013 mg
EPY0001177	Dexamethasone for system suitability	10 mg
EPY0001155	Docetaxel for system suitability	10 mg
EPY0001133	Docetaxel trihydrate	160 mg

Code	Product	Unit
EPY0001124	Ethinylestradiol for system suitability	25.3 mg
EPY0001173	Filgrastim	0.2 mL
EPY0001129	Ganciclovir	220 mg
EPY0001144	Ganciclovir impurity mixture	0.005 mg
EPY0001192	Hepatitis A Vaccine (Inactivated, Non-Adsorbed)	0.8 ml
EPY0001151	Hydrastine hydrochloride	20 mg
EPY0001166	Irbesartan	60 mg
EPY0001156	Irbesartan impurity A 1-(pentylamino)-N-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]cyclopentanecarboxamide	10 mg
EPY0001138	Phenazone impurity A 5-methyl-2-phenyl-2,4-dihydro-3-pyrazol-3-one	20 mg
EPY0000868	Streptokinase for system suitability	30 µl
EPY0001163	Ursodeoxycholic acid for system suitability	1.26 mg
EPY0001198	Varicella vaccine (live)	420 mg

New BP Standards

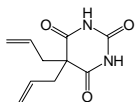
Code	Product	Unit
BP 019	Amoxicillin Trihydrate Assay Standard	500 mg
BP 021	Ampicillin trihydrate	500 mg
BP 824	Betahistine dihydrochloride Assay Standard	100 mg
BP 075	2-(4-Chloro-3-sulphamoylbenzoyl)benzoic acid	25 mg
BP 834	Clarithromycin impurity E	20 mg
BP 816	Desogestrel impurity D	25 mg
BP 817	Desogestrel impurity E	25 mg
BP 865	Dimethyl-2,6-dimethyl-4-(2-nitrophenyl)pyridine-3,5-dicarboxylate	25 mg
BP 866	Dimethyl-2,6-dimethyl-4-(2-nitrosophenyl)pyridine-3,5-dicarboxylate	25 mg
BP 174	Gentamicin sulphate	25 mg
BP 846	N-methyl-bis[beta-(2-pyridyl)ethyl]amine trihydrochloride	25 mg
BP 808	Ondansetron hydrochloride dihydrate Assay Standard	100 mg
BP 812	Zopiclone Assay Standard	100 mg

New LGC Impurity Standards

Code	Product	Unit
Ampicillin Sodium		
MM 0253.02	Imp. B (EP): (2S,5R,6R)-6-[[[(2S)-2-Amino-2-phenylacetyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic Acid (L-Ampicillin)	100 mg
		
MM 0253.04	Imp. D (EP) as Sodium Salt: (4S)-2-[[[(2R)-2-Amino-2-phenylacetyl]amino]-carboxymethyl]-5,5-dimethylthiazolidine-4-carboxylic Acid Sodium Salt (Penicilloic Acids of Ampicillin Sodium Salt)	100 mg
		

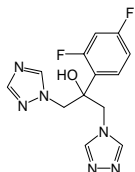
New LGC Impurity Standards

Code	Product	Unit
Butalbital		
MM 0899.00	5,5-Diallylbarbituric acid (Allobarbital) [Controlled Substance]	100 mg



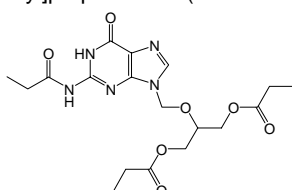
Fluconazole

MM 0235.11	Imp. A (EP): (2 <i>RS</i>)-2-(2,4-Difluorophenyl)-1-(1 <i>H</i> -1,2,4-triazol-1-yl)-3-(4 <i>H</i> -1,2,4-triazol-4-yl)propan-2-ol	100 mg
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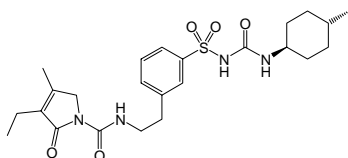
Ganciclovir

MM 0485.10	Imp. J (Pharmeuropa): <i>N</i> -[9-[[2-(1-Methylene-propoxy)-1-[(1-methylenepropoxy)methyl]-ethoxy]methyl]-6-oxo-1,9-dihydro-6 <i>H</i> -purin-2-yl]propanamide (Ganciclovir Tripropionate)	100 mg
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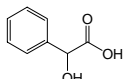
Glimepiride

MM 0647.04	Imp. D (EP): 1-[[3-[2-[[[(3-Ethyl-4-methyl-2-oxo-2,3-dihydro-1 <i>H</i> -pyrrol-1-yl)carbonyl]amino]ethyl]-phenyl]sulphonyl]-3-(<i>trans</i> -4-methylcyclohexyl)-urea	100 mg
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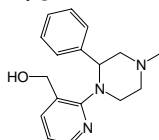
Glycopyrronium Bromide

MM 0792.03	Imp. C (Pharmeuropa): (2 <i>RS</i>)-Hydroxyphenyl-acetic Acid (Mandelic Acid)	100 mg
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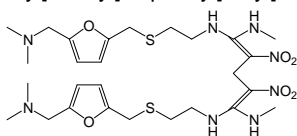
Mirtazapine

MM 1005.03	Imp. B (EP): [2-[(2 <i>RS</i>)-4-Methyl-2-phenyl-piperazin-1-yl]pyridin-3-yl]methanol	100 mg
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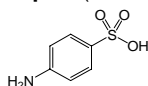


Ranitidine Hydrochloride

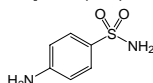
MM 0086.10	Imp. I (EP): 2,2'-Methylenebis[N-2-[[[5-[(dimethyl-amino)methyl]furan-2-yl]methyl]sulphonyl]ethyl]-N'-methyl-2-nitroethene-1,1-diamine]	100 mg
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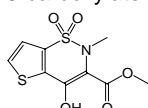
Code	Product	Unit
Sulfadiazine		
MM 0227.04	Imp. B (Pharmeuropa): 4-Aminobenzenesulfonic Acid (Sulphanilic Acid)	100 mg



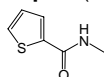
Sulfaguanidine		
MM 0227.05	Imp. A (EP): 4-Aminobenzenesulphonamide (Sulphanilamide)	100 mg



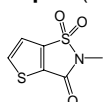
Tenoxicam		
MM 0247.01	Imp. B (EP): Methyl 4-Hydroxy-2-methyl-2H-thieno[2,3-e]1,2-thiazine-3-carboxylate 1,1-Dioxide	100 mg



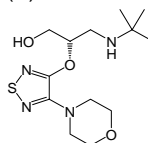
MM 0247.04	Imp. C (EP): <i>N</i> -Methylthiophene-2-carboxamide	100 mg
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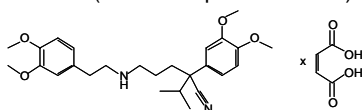
MM 0247.06	Imp. E (EP): 2-Methylthieno[2,3- <i>d</i>]isothiazol-3(2 <i>H</i>)-one 1,1-Dioxide	100 mg
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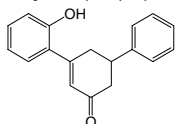
Timolol Maleate		
MM 0440.02	(<i>S</i>)-Isotimolol	100 mg



Verapamil Hydrochloride		
MM 0022.21	Imp. J (EP) as Maleate: (2 <i>RS</i>)-2-(3,4-Dimethoxy-phenyl)-5-[[2-(3,4-dimethoxyphenyl)ethyl]amino]-2-(1-methylethyl)pentanenitrile Maleate (<i>N</i> -Norverapamil Maleate)	100 mg



Warfarin Sodium		
MM 0732.01	Imp. A (EP): (5 <i>RS</i>)-3-(2-Hydroxyphenyl)-5-phenylcyclohex-2-enone	100 mg



Withdrawn Standards

Code	Product	Unit
EPC0698000	Cellulose acetate - Reference Spectrum	unit
MM 0022.01	Verapamil Hydrochloride Imp. J (EP): (2 <i>RS</i>)-2-(3,4-Dimethoxyphenyl)-5-[[2-(3,4-dimethoxyphenyl)ethyl]amino]-2-(1-methylethyl)pentanenitrile (<i>N</i> -Norverapamil)	100 mg
REA1007301	Anisaldehyde, solution	100 mL