



December 2015

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Reference Standards Highlights

Below are several Tables with the latest Reference Standard information including out-of-stock items now available; new Reference Standards released in December 2015; backordered items with estimated availability dates; items that have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.

Please contact your USP Customer Service Representative to place an order at +1-301-881-0666 or 1-800-227-8772. European customers can call 00-800-4875-5555. You can also order online at www.usp.org/products.

An expanded list of [USP Reference Standards Under Development](#) has been posted to the USP website. The list includes new **USP Reference Standards that we expect to release within a year**. And, the list is updated four times per year; most recently on **October 9**. The list can be sorted by calendar quarter, monograph name, compendium and more. As of October 9, the list can now also be sorted by Reference Standard category (impurity, small molecule, system suitability, etc).

The Reference Standards Release Notification Service can be used to notify you when a new never-before-released Reference Standard becomes available. The Notification Service does not communicate the release of back-ordered items or lot changeovers. To participate, fill out the form online at www.usp.org/reference-standards/find-reference-standard/notification-service.

USP has expanded its **Donor Recognition Program** to further recognize contributors who participate in the standards-setting process and help make an impact on global health. Visit the [donor recognition page](#) to learn more.

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New Reference Standards Now Available

Catalog #	Description	Size	Lot	Price (USD)
1036110	Aniline	250 mg	F036F0	\$671
1269367	Febantel Related Compound A	15 mg	F033J0	\$671
1269378	Febantel Related Compound B	15 mg	F033K0	\$671
1443431	Miconazole Related Compound C	50 mg	F03800	\$671
1443464	Miconazole Related Compound F	50 mg	F03770	\$671
1443497	Miconazole Related Compound I	50 mg	F03780	\$671
1457833	Nebivolol Hydrochloride	150 mg	F027M0	\$1,278
1466572	4-Nitrobenzoic Acid	50 mg	F036D0	\$671
1643736	Teniposide	200 mg	F02960	\$327
1643747	Teniposide Related Compound A	10 mg	F02970	\$671

Previously Out-of-Stock Items Now Available

Catalog #	Description	Size	Lot	Price (USD)
1012950	Alliin	25 mg	F2L004	\$615
1046205	Aztreonam	200 mg	R041F0	\$215

Backorder Availability Estimates, December 7, 2015

Catalog #	Description	Expected Availability*
1095517	Carbidopa Related Compound A (25 mg)	Q2/16
1224700	Docusate Calcium (500 mg)	Q2/16
1226014	Doxycycline Related Compound A (10 mg) (6-epidoxycycline)	Q2/16
1269119	FAME Standard Mixture (100 mg)	Q4/15
1295888	Glycyrrhizic Acid (25 mg)	Q1/16
1342106	Insulin Human (100 mg) (COLD SHIPMENT REQUIRED)	Q4/15
1396003	Metaraminol Bitartrate (200 mg)	Q2/16
1535788	Phosphatidylinositol (Soy) Sodium (10 mg) (INTERNATIONAL COLD CHAIN SHIPMENT REQUIRED)	Q4/15
1711461	Verteporfin (200 mg)	Q1/16

*Dates are targets and may change at any time. Q4/15 October–December 2015; Q1/16 January–March 2016; Q2/16 April–June 2016



Items with New Package Size or New Description

Catalog #	Description	Old Size	Size	Lot	Price (USD)
1048674	Benazepril Related Compound F*	15 mg	15 mg	R034C0	\$671
1224802	Docusate Sodium	500 mg	1 g	R030M0	\$215
1264501	Ethotoin	200 mg	500 mg	F036M1	\$215
1286650	Fulvestrant	150 mg	200 mg	R036R0	\$535
1353113	Diluted Isosorbide Mononitrate Related Compound A**	100 mg	150 mg	R01970	\$707

*The description of this item has changed from (3-Amino-2,3,4,5-tetrahydro-2-oxo-1H-1-(3S)-benzazepine-1-acetic acid, tert-butyl ester) to (tert-butyl (S)-2-(3-amino-2-oxo-2,3,4,5-tetrahydro-1H-benzo[b]azepin-1-yl)acetate)

** The description of this item has changed from (1,4:3,6-dianhydro-D-glucitol 2-nitrate) to (1,4:3,6-Dianhydro-D-glucitol 2-nitrate in lactose)

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RS Lots That are No Longer Valid

These Tables list previous RS lots that are (or will soon be) no longer valid for official use. If you still have any of these materials on hand, do not use them for compendial testing purposes after the last day of the month for the valid use dates listed. To test products, always be sure you use a current, valid lot of USP RS. Current lot numbers and valid use dates for previous lots are available in the USP Store online [here](#) using the Reference Standards: Alphabetical Listings to look up the item of interest.

Note:

- USP Sesame Oil Related Compound B Reference Standard (Catalog # 1612426, Lot F1L480)—New Valid Use Date December 8, 2015
- USP Levothyroxine Reference Standard (Catalog # 1365000, Lot R016X0)—New Valid Use Date March 31, 2016.
- USP Liothyronine Reference Standard (Catalog # 1368008, Lot O0L383), New Valid Use Date March 31, 2016.

No Longer Valid as of November 30, 2015					
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)	
1005706	Glacial Acetic Acid (1.5 mL/ampule; 3 ampules)	H0K218 (11/15)	I0M342	\$215	
1012553	Albendazole (200 mg)	H1K275 (11/15)	R02690	\$215	
1043706	Aspartame (200 mg)	R008X0 (11/15)	R008X1	\$215	
1044469	Atomoxetine Hydrochloride (125 mg)	F0J366 (11/15)	R008H0	\$550	
1082708	Butylated Hydroxytoluene (500 mg)	H0L344 (11/15)	H1L344	\$215	
1083008	2-tert-Butyl-4-hydroxyanisole (200 mg)	L1E348 (11/15)	L2E348	\$215	
1134390	Clarithromycin Identity (10 mg)	F3L128 (11/15)	R003C0	\$671	
1138904	Clofazimine (200 mg)	F2C392 (11/15)	R017W0	\$215	
1179005	Dexchlorpheniramine Maleate (300 mg)	H0D199 (11/15)	R005Q0	\$215	
1213318	Diosmin (300 mg)	F0K382 (11/15)	R02090	\$215	
1231808	Econazole Nitrate (100 mg)	H0K380 (11/15)	H1K380	\$215	
1295505	Glyburide (200 mg)	G1C347 (11/15)	R022S0	\$215	
1303002	Haloperidol (200 mg)	I1G285 (11/15)	R02330	\$215	
1347700	Irbesartan (200 mg)	G0H216 (11/15)	R022G0	\$215	
1349626	Isomalt (200 mg)	F0E263 (11/15)	R01880	\$215	
1354251	Itraconazole (100 mg)	G0K425 (11/15)	R021G0	\$215	
1374306	Magnesium Salicylate (200 mg)	F2B081 (11/15)	F3B081	\$215	
1392705	Mesalamine (200 mg)	I0F121 (11/15)	R001T0	\$215	
1409502	Methenamine Hippurate (200 mg)	G0K181 (11/15)	R02490	\$215	
1443952	Mineral Oil (1.5 mL)	G0I016 (11/15)	H0M307	\$215	
1449008	Myristyl Alcohol (1 g)	H0L436 (11/15)	R022M0	\$215	
1477502	Octoxynol 9 (200 mg)	G1L235 (11/15)	H0M519	\$215	
1500284	Paroxetine Related Compound G (10 mg)	H0I332 (11/15)	H1I332	\$671	
1553815	Pramipexole Related Compound D (25 mg)	F0J111 (11/15)	R02030	\$671	
1563342	Probucof Related Compound C (25 mg)	F-2 (11/15)	R018Y0	\$671	
1570428	2-Propanol (1.2 mL/ampule; 3 ampules)	H0J176 (11/15)	I0L393	\$215	
1607040	Saccharin Sodium (100 mg)	F1K245 (11/15)	R01870	\$215	
1612404	Sesame Oil (1 g)	F0E134 (11/15)	G0L435	\$215	
1612506	L-Serine (200 mg)	H0J185 (11/15)	H1J185	\$215	
1720600	Xylitol (1 g)	H0K260 (11/15)	R022C0	\$215	

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No Longer Valid as of December 31, 2015					
Catalog #	Description	Previous Lot/ Valid Use Date		Current Lot	Price (USD)
1021000	Aminocaproic Acid (200 mg)	H0K201	(12/15)	I0M248	\$215
1042634	Aripiprazole (200 mg)	F0L064	(12/15)	R01490	\$215
1157024	Cyclophosphamide Related Compound B (25 mg)	F0I381	(12/15)	F1I381	\$671
1157035	Cyclophosphamide Related Compound C (25 mg)	F0I382	(12/15)	F1I382	\$671
1157046	Cyclophosphamide Related Compound D (25 mg)	F0I375	(12/15)	F1I375	\$671
1179333	Dexmedetomidine Hydrochloride (200 mg)	F0M052	(12/15)	R01590	\$215
1181506	Diacetylated Monoglycerides (200 mg)	G	(12/15)	R024D1	\$215
1237752	Eprinomectin (300 mg) (COLD SHIPMENT REQUIRED)	F0H199	(12/15)	R009C0	\$332
1311408	Homosalate (500 mg)	I0L427	(12/15)	J0M309	\$215
1351800	Isorhamnetin (15 mg)	G0L371	(12/15)	R002P0	\$236
1375069	Mangafodipir Trisodium (300 mg)	F0D272	(12/15)	G0M032	\$215
1445007	Mitotane (500 mg)	H1L374	(12/15)	H2L374	\$215
1445211	Mitoxantrone System Suitability Mixture (0.3 mg)	G0F107	(12/15)	R03950	\$691
1464001	Nitrofurantoin (500 mg)	K0I060	(12/15)	K1I060	\$215
1478312	Olanzapine Related Compound A (15 mg)	G0K232	(12/15)	R014L0	\$671
1559505	Prednisone Tablets (30 tablets)	R001B1	(12/15)	R031Y0	\$249
1566001	Prochlorperazine Maleate (200 mg)	H-1	(12/15)	R016Y0	\$215
1572547	Propofol Related Compound B (25 mg)	I1K250	(12/15)	R02420	\$671
1598201	Raloxifene Hydrochloride (200 mg)	F0G364	(12/15)	R023Q0	\$215
1598347	Ramipril Related Compound D (20 mg)	F0E036	(12/15)	R002S0	\$671
1604676	Risperidone Related Compounds Mixture (25 mg)	F0J004	(12/15)	R013B0	\$671
1609829	Saquinavir Mesylate (200 mg)	F0B008	(12/15)	R00430	\$215
1616008	1,4-Sorbitan (300 mg)	J0F351	(12/15)	R020Y0	\$215
1642019	Sulindac Related Compound A (20 mg)	F0E314	(12/15)	F1E314	\$671
1642857	Tacrolimus System Suitability Mixture (10 mg)	F0J361	(12/15)	F1J361	\$784
1673828	Trenbolone Acetate CIII (200 mg) (COLD SHIPMENT REQUIRED)	G0I045	(12/15)	R016B0	\$228
1708773	Valsartan Related Compound A (10 mg)	I1L358	(12/15)	R02460	\$859



No Longer Valid as of January 31, 2016					
Catalog #	Description	Previous Lot/ Valid Use Date		Current Lot	Price (USD)
1031570	Amoxicillin Related Compound G (15 mg)	F0J278	(01/16)	R019S0	\$671
1164700	Daunorubicin Hydrochloride (200 mg)	M0I190	(01/16)	M1M099	\$660
1197007	Diethyltoluamide (3 g)	I0H013	(01/16)	R021J0	\$215
1278302	Fluoroquinolonic Acid (150 mg)	H1H402	(01/16)	H2H402	\$671
1283415	Fosinopril Related Compound A (25 mg)	F0G019	(01/16)	R003W0	\$671
1296031	Glycopyrrolate Related Compound B	G0L513	(01/16)	H0M349	\$671
1335010	Hyoscyamine Related Compound A (10 mg)	F0E250	(01/16)	R005K0	\$671
1345002	Iothalamic Acid (200 mg)	G	(01/16)	R03200	\$215
1359801	Levobunolol Hydrochloride (200 mg)	H0E047	(01/16)	H1E047	\$215
1372005	L-Lysine Hydrochloride (200 mg)	I1K037	(01/16)	R027F0	\$215
1374907	Maltitol (200 mg)	G1H293	(01/16)	R022L0	\$215
1430327	Methyl Linoleate (5 x 50 mg)	G0D107	(01/16)	R00930	\$215
1612652	Simethicone (50 g)	L0J395	(01/16)	M0M432	\$215
1631500	Sulfamethoxazole N4-glucoside (25 mg)	I0K227	(01/16)	R029X0	\$671
1667290	Tiamulin Fumarate (250 mg)	G0J295	(01/16)	G1J295	\$215
1724532	Zidovudine Related Compound C (100 mg)	G0G181	(01/16)	R01930	\$671

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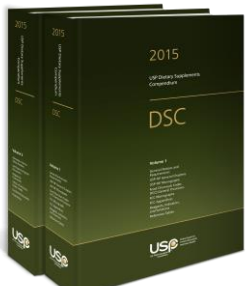
Items with New Lots

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1000408	Abacavir Sulfate (200 mg)	F1L487 (12/16)	R028L0	\$215
1012950	Alliin (25 mg)	F1L004 (11/16)	F2L004	\$615
1046205	Aztreonam (200 mg)	R01520 (11/16)	R041F0	\$215
1048200	Baclofen (350 mg)	J0H297 (11/16)	J1H297	\$215
1048222	Baclofen Related Compound A (50 mg)	J0I383 (11/16)	R03750	\$671
1048674	Benazepril Related Compound F (15 mg)	F0F150 (11/16)	R034C0	\$671
1203008	Dihydrostreptomycin Sulfate (200 mg)	K0I335 (11/16)	R031Q0	\$215
1233009	Edetate Disodium (200 mg)	J0J421 (11/16)	R028C0	\$215
1250008	Estradiol (500 mg)	N0J191 (12/16)	R025F0	\$215
1264501	Ethotoin (500 mg)	F (11/16)	F036M1	\$215
1269243	Famotidine Related Compound D (25 mg)	F0K058 (11/16)	F1K058	\$671
1286650	Fulvestrant (200 mg)	F0H065 (11/16)	R036R0	\$535
1353113	Diluted Isosorbide Mononitrate Related Compound A (150 mg)	F0G154 (11/16)	R01970	\$707
1356508	Ketoconazole (200 mg)	H0F086 (11/16)	H1F086	\$215
1359302	Levamisole Hydrochloride (125 mg)	F3K315 (11/16)	F4K315	\$171
1380546	Memantine Related Compound D (50 mg)	G0M216 (11/16)	R03270	\$671
1414025	Methotrexate Related Compound B (75 mg)	H0M151 (11/16)	R02860	\$750
1478480	Omeprazole Related Compound B (15 mg)	F00670 (11/16)	R03690	\$671
1481237	Oxaliplatin Related Compound C (20 mg)	H0L353 (12/16)	R029E0	\$671
1492007	Palmitic Acid (500 mg)	L0K054 (11/16)	R029M0	\$215
1498706	Parbendazole (200 mg)	H0L293 (11/16)	R02810	\$215
1500218	Paroxetine Hydrochloride (350 mg)	G1F261 (11/16)	R033M0	\$215
1538902	Pilocarpine Hydrochloride (200 mg)	I0D055 (11/16)	R033R0	\$215
1576708	Propylene Glycol (5 x 1 mL)	L0J287 (11/16)	L1J287	\$215
1604811	Rivastigmine Related Compound C (15 mg)	F0L287 (11/16)	R03470	\$671
1612947	Beta-Sitosterol (100 mg)	H0M503 (11/16)	R026A0	\$410
1672304	Torsemide (200 mg)	G0E293 (11/16)	R025J0	\$215
1678005	Triamcinolone Diacetate (350 mg)	I0L189 (11/16)	R007H0	\$215
1683559	Triethylamine (2 mL/ampule; 4 ampules) (N,N-diethylethanamine)	F0J160 (11/16)	R040E0	\$215

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USP Publication Highlights

	<p>Be Prepared for Compliance in 2016—Order <i>USP 39–NF 34</i> Today! The 2016 edition of <i>USP–NF</i> published on November 2. Order today for access to important updates, including:</p> <ul style="list-style-type: none"> • 24 new or revised general chapters, including <661> Containers–Plastic, <711> Dissolution, <771> Ophthalmic Products—Quality Tests, and more! • More than 180 new or revised monographs for drug substances, drug products, excipients, and dietary supplements! <p>Available in 4-volume print, online, and USB flash drive formats. Subscribe today at http://www.usp.org/store/products-services/usp-nf or call USP Customer Service at 1-800- 227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (Select Europe).</p>
	<p>Order the <i>Food Chemicals Codex (FCC), Ninth Edition!</i> The <i>FCC, Ninth Edition</i>, features more than 1,200 monographs, appendices with step-by-step methods, and helpful information for manufacturers, suppliers, and users of food ingredients. Two-year subscription includes a main edition plus three supplements that publish with updates every six months. The Third Supplement published in early September 2015! Available in print and online formats. Save \$100 with promotion code HWPDZZ12. Order now at http://uspgo.to/fcc-9 or call USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (Select Europe).</p>
	<p>2015 <i>Dietary Supplements Compendium (DSC)</i> Available Now! The new 2015 <i>DSC</i> published June 30, 2015 and has about 100 new monographs; over 40 new and revised Admissions Evaluations; over 20 new General Chapters; plus more than 150 pages added of full-color illustrations and/or images. Save \$100 with promotion code HDWDZZ25. Order now at http://www.usp.org/dsc-2015 or by calling USP Customer Service 1-800-227-8772 (U.S. / Canada), +1-301-881-0666, or 00-800-4875-5555 (Select Europe).</p>
	<p>USP37–NF32 Archive Available Now! This new Archive complements the earlier Archive, which includes <i>USP28–NF23</i> through <i>USP36–NF31</i>. This valuable reference tool designed for scientists and industry professionals is now available electronically. Both Archives are provided as PDF files on USB flash drives. Order now at http://www.usp.org/store/products-services/usp-nf-archive or by calling USP Customer Service 1-800-227-8772 (U.S. / Canada), +1-301-881-0666, or 00-800-4875-5555 (Select Europe).</p>

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Event Highlights

USP User Forums Coming to a City Near You!

The USP Account Management Team will be traveling around the world holding free seminars to discuss timely USP initiatives and how to use available USP resources to your advantage.

More information including locations and dates is available [here](#), or contact USPUserForum@usp.org.

Workshops

USP web forums and workshops encourage discussion of a wide range of current scientific findings and regulatory trends. Participants discuss hot topics that concern the public and exchange practical advice.

Information on workshops is available [here](#).

USP Education

USP's Education division is dedicated to providing quality education for chemists, scientists, and healthcare practitioners in the United States and around the world. We seek to improve the effective implementation of standards that affect best practices for the development, manufacture, regulation, compounding, storage, and dispensing of pharmaceuticals, dietary supplements, food additives, and other therapeutics. To find a course, please visit Education.usp.org

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Compendial Highlights

New Official Text

Revision Bulletins

[Carbamazepine Tablets](#) (posted 20–Nov–2015; official 01–Dec–2015)

[Powdered Digitalis](#) (posted 20–Nov–2015; official 01–Dec–2015)

[Esomeprazole Magnesium](#) (posted 20–Nov–2015; official 01–Dec–2015)

[Galantamine Tablets](#) (posted 20–Nov–2015; official 01–Jan–2016)

[Insulin Human](#) (posted 20–Nov–2015; official 01–Dec–2015)

[Insulin Lispro](#) (posted 20–Nov–2015; official 01–Dec–2015)

[Lactulose Concentrate](#) (posted 20–Nov–2015; official 01–Dec–2015)

[Lactulose Solution](#) (posted 20–Nov–2015; official 01–Dec–2015)

[Levocetirizine Dihydrochloride Tablets](#) (posted 20–Nov–2015; official 01–Dec–2015)

[Morphine Sulfate Extended-Release Capsules](#) (posted 20–Nov–2015; official 01–Dec–2015)

[Nifedipine Extended-Release Tablets](#) (posted 20–Nov–2015; official 01–Dec–2015)

[Olanzapine Tablets](#) (posted 20–Nov–2015; official 01–Dec–2015)

[Prochlorperazine Maleate Tablets](#) (posted 20–Nov–2015; official 01–Dec–2015)

[Ribavirin Capsules](#) (posted 20–Nov–2015; official 01–Dec–2015)

[Sertraline Hydrochloride Tablets](#) (posted 20–Nov–2015; official 01–Dec–2015)

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IRA IRAs

[Methocarbamol](#) (posted 20–Nov–2015; official 01–Jan–2016)
[Omega-3-Ethyl Esters Capsules](#) (posted 20–Nov–2015; official 01–Jan–2016)
[Omega-3-Ethyl Esters](#) (posted 20–Nov–2015; official 01–Jan–2016)
[Protamine Sulfate Injection](#) (posted 20–Nov–2015; official 01–Jan–2016)

E [Access new USP–NF Errata](#)

H6 [New Stage 6 Notices](#)

[Dextrose](#) (posted 20–Nov–2015; official 01–Dec–2016)
[Hypromellose](#) (posted 20–Nov–2015; official 01–Dec–2016)
[Methylcellulose](#) (posted 20–Nov–2015; official 01–Dec–2016)
[Povidone](#) (posted 20–Nov–2015; official 01–Dec–2016)
[Sodium Chloride](#) (posted 20–Nov–2015; official 01–Dec–2016)

[Compendial Notices](#)

[General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings to be Published in USP 39–NF 34 1S](#) (posted 20–Nov–2015)
[Second Supplement to USP 38–NF 33 Online: Search Results](#) (posted 13–Nov–2015)
[USP 39–NF 34 1S Compendial Approvals, Deferrals, and Cancellations](#) (posted 20–Nov–2015)
[Commentary for IRAs Published in PF 41\(4\)](#) (posted 20–Nov–2015)
[Commentary for IRAs Published in PF 41\(3\)](#) (updated 20–Nov–2015)
[Compounding FAQs](#) (updated 20–Nov–2015)
[Pending Monographs Page Updated](#) (20–Nov–2015)
[Errata Table Updated](#) (20–Nov–2015)

Sign up to receive updates electronically at www.usp.org/store/free-resources/newsletter-and-information.

[Stimuli Articles](#)

Featured in *PF 41(6)* November–December 2015

- GUIDELINE FOR ASSIGNING TITLES TO USP DIETARY SUPPLEMENT MONOGRAPHS

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Tip of the Month

New USP Dissolution Methods Database – Introducing a free tool to help answer questions related to dissolution test conditions found in USP monographs. Easily find out what monographs specify use of a specific apparatus, which methods require mediums with a certain pH value, where the preparation of a particular dissolution medium can be found, and more. Search and sort by monograph name, dissolution medium, apparatus, duration of test, analytical finish, and exceptions. Data is updated with the release of each new *USP-NF*, including its supplements. Learn more and download today at www.usp.org/dissolutionDB.

Question of the Month

When relative retention times are listed in a monograph, are they considered a system suitability requirement?

No, relative retention times are provided as an aid only. This is cited in USP General Chapter <621>: "Relative retention times may be provided in monographs for informational purposes only to aid in peak identification. There are no acceptance criteria applied to relative retention times."

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