APPENDIX A

# USPTO's Lax Policy Leads to Humira Formulation Thicket

Table A1

**US and EU Formulation Patents**

| | US Patents | EU Patents |
|---|---|---|
| 1 | US8802100B2 | EP2359856B1 |
| 2 | US8911741B2 | EP1528933B1 |
| 3 | US9272042B2 | |
| 4 | US9732152B2 | |
| 5 | US8916157B2 | |
| 6 | US9738714B2 | |
| 7 | US9750808B2 | |
| 8 | US8802102B2 | |
| 9 | US9295725B2 | |
| 10 | US8916158B2 | |
| 11 | US9220781B2 | |
| 12 | US8940305B2 | |
| 13 | US8216583B2 | |
| 14 | US8795670B2 | |
| 15 | US9272041B2 | |
| 16 | US8802101B2 | |
| 17 | US9302011B2 | |
| 18 | US8932591B2 | |
| 19 | US9289497B2 | |
| 20 | US9327032B2 | |
| 21 | US9114166B2 | |
| 22 | US9950066B2 | |



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Table A2

**Independent Claims from EU Humira Formulation Patents**

| Publication Number | Independent Claims | Antibody | Buffers | Stabilizers | Surfactants | Salt | pH |
|---|---|---|---|---|---|---|---|
| EP2359856B1 | 1. A liquid aqueous pharmaceutical formulation for injection in the form of a 0.8 mL solution comprising: a) 40.0 mg the anti-human Tumor Necrosis Factor alpha antibody D2E7 b) 9.6 mg mannitol c) 1.044 mg citric acid monohydrate d) 0.244 mg sodium citrate e) 1.224 mg disodium phosphate dihydrate f) 0.688 mg sodium dihydrogen phosphate dihydrate g) 4.932 mg sodium chloride h) 0.8 mg polysorbate 80 i) 759.028 - 759.048 mg water j) 0.02 - 0.04 mg sodium hydroxide, which gives a total of 817.6 mg per 0.8 ml solution. | 40 mg adalimumab | 1.044 mg citric acid monohydrate<br>0.244 mg sodium citrate<br>1.224 mg disodium phosphate dihydrate<br>0.688 mg sodium dihydrogen phosphate dihydrate | 9.6 mg mannitol | 0.8 mg polysorbate 80 | 4.932 mg sodium chloride | |
| EP1528933B1 | 1. A liquid aqueous pharmaceutical formulation having a pH of 4 to 8 and comprising (a) 20 to 130 mg/ml of a human IgG1 anti-Tumor Necrosis Factor alpha (TNFα) antibody comprising a light chain variable region comprising the amino acid sequence of SEQ ID NO: 1 and a heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 2, (b) 10-14 mg/ml of mannitol, (c) 0.1-5 mg/ml of polysorbate 80, (d) 1-1.5 mg/ml of citric acid monohydrate, (e) 0.25-0.5 mg/ml of sodium citrate, (f) 1.25-1.75 mg/ml of disodium phosphate dihydrate, (g) 0.7-1.1 mg/ml of sodium dihydrogen phosphate dihydrate, and (h) 6.0-6.4 mg/ml sodium chloride.<br><br>5. Use of the formulation of claims 1 to 4 in the preparation of a medicament for treating a disorder in which TNFα activity is detrimental. | 20 to 130 mg/ml adalimumab | 1-1.5 mg/ml of citric acid monohydrate<br>0.25-0.5 mg/ml of sodium citrate<br>1.25-1.75 mg/ml of disodium phosphate dihydrate<br>0.7-1.1 mg/ml of sodium dihydrogen phosphate dihydrate | 10-14 mg/ml of mannitol | 0.1-5 mg/ml of polysorbate 80 | 6.0-6.4 mg/ml sodium chloride | pH 4 to 8 |





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Table A3

**Independent Claims from US Humira Formulation Patents**

| Publication Number | Independent Claims | Antibody | Buffer | Stabilizer | Surfactant | Salt | pH |
|---|---|---|---|---|---|---|---|
| US8802100B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody, or an antigen-binding portion thereof, at a concentration of 45 to 150 mg/ml,(b) a polyol,(c) a polysorbate at a concentration of 0.1 to 10 mg/ml, and(d) a buffer system having a pH of 4.5 to 7.0, wherein the antibody comprises the light chain variable region and the heavy chain variable region of D2E7.<br><br>19.A stable liquid aqueous pharmaceutical formulation comprising(a) 45-105 mg/ml of a human IgG1 anti-human Tumor Necrosis Factor alpha (hTNFα) antibody,(b) a polyol,(c) 0.1-10 mg/ml of polysorbate 80, and(d) a buffer system having a pH of 4.5 to 7.0, wherein the antibody comprises the light chain variable region and the heavy chain variable region of D2E7. | 45 to 150 adalimumab | Any buffer system | A polyol | 0.1 to 10 mg/ml of a polysorbate | | pH of 4.5 to 7.0 |
| US8911741B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody, or an antigen-binding portion thereof, at a concentration of 20 to 150 mg/ml,(b) a polyol,(c) a polysorbate, and(d) a buffer system comprising phosphate and having a pH of 4.0 to 8.0, wherein the antibody comprises the light chain variable region and the heavy chain variable region of D2E7.<br><br>22.A stable liquid aqueous pharmaceutical formulation comprising(a) 20 to 150 mg/ml of a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody,(b) a polyol,(c) polysorbate 80, and(d) a buffer system comprising phosphate and having a pH of 4.0 to 8.0, wherein the antibody comprises the light chain variable region and the heavy chain variable region of D2E7. | 20 to 150 mg/ml adalimumab | Phosphate | A polyol | A polysorbate | | pH 4 to 8 |
| US9272042B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody at a concentration of 50 mg/ml,(b) a polyol,(c) a polysorbate, and(d) a buffer system comprising phosphate and having a pH of 4 to 8, wherein the antibody is D2E7, and wherein the formulation is suitable for subcutaneous injection. | 50 mg/ml adalimumab | Phosphate | A polyol | A polysorbate | | pH 4 to 8 |
| US9732152B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody at a concentration of 45-105 mg/ml,(b) a polyol,(c) a polysorbate, and(d) a buffer system comprising histidine and having a pH of 4 to 8, wherein the antibody is D2E7, and wherein the formulation is suitable for subcutaneous injection. | 45-105 mg/ml adalimumab | Histidine | A polyol | A polysorbate | | pH 4 to 8 |





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| Publication Number | Independent Claims | Antibody | Buffer | Stabilizer | Surfactant | Salt | pH |
|---|---|---|---|---|---|---|---|
| US8916157B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody, or an antigen-binding portion thereof, at a concentration of 20 to 150 mg/ml,(b) a tonicity agent,(c) a surfactant, and(d) a buffer system having a pH of 4.0 to 8.0, wherein the antibody comprises the light chain variable region and the heavy chain variable region of D2E7.<br><br>24.A stable liquid aqueous pharmaceutical formulation comprising(a) 20 to 150 mg/ml of a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody,(b) a tonicity agent,(c) a polysorbate, and(d) a buffer system having a pH of 4.0 to 8.0, wherein the antibody comprises the light chain variable region and the heavy chain variable region of D2E7. | 20 to 150 mg/ml adalimumab | A buffer system | | A surfactant | A tonicity agent | pH 4 to 8 |
| US9738714B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody at a concentration of 45-105 mg/ml,(b) a polyol,(c) a polysorbate, and(d) a buffer system comprising succinate and having a pH of 4 to 8, wherein the antibody is D2E7, and wherein the formulation is suitable for subcutaneous injection. | 45-105 mg/ml adalimumab | Succinate | A polyol | A polysorbate | | pH 4 to 8 |
| US9750808B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising: a human anti-human Tumor Necrosis Factor alpha (TNFα) IgG1 antibody at a concentration of 45 to 105 mg/ml, wherein the antibody is D2E7, and a buffer system; wherein the formulation is isotonic, suitable for single-use subcutaneous injection, and has a pH of 4 to 8. | 45 to 105 mg/ml adalimumab | A buffer system | | | The formulation is isotonic | pH 4 to 8 |
| US8802102B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody, or an antigen-binding portion thereof, at a concentration of 45 to 105 mg/ml,(b) a polyol,(c) a polysorbate at a concentration of 0.1 to 10 mg/ml, and(d) a buffer system comprising succinate and having a pH of 4.5 to 7.0, wherein the antibody comprises the light chain variable region and the heavy chain variable region of D2E7.<br><br>21.A stable liquid aqueous pharmaceutical formulation comprising(a) 45 to 105 mg/ml of a human IgG1 anti-human Tumor Necrosis Factor alpha (hTNFα) antibody,(b) trehalose,(c) 0.1-10 mg/ml of polysorbate 80, and(d) a buffer system comprising succinate and having a pH of 4.5 to 7.0, wherein the antibody comprises the light chain variable region and the heavy chain variable region of D2E7. | 45 to 105 mg/ml adalimumab | Succinate | A polyol | 0.1 to 10 mg/ml of a polysorbate | | pH of 4.5 to 7.0 |
| US9295725B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody at a concentration of 50 mg/ml,(b) a polyol,(c) a polysorbate, and(d) a buffer system comprising succinate and having a pH of 4 to 8, wherein the antibody is D2E7, and wherein the formulation is suitable for subcutaneous injection. | 50 mg/ml adalimumab | Succinate | A polyol | A polysorbate | | pH 4 to 8 |





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| Publication Number | Independent Claims | Antibody | Buffer | Stabilizer | Surfactant | Salt | pH |
|---|---|---|---|---|---|---|---|
| US8916158B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody, or an antigen-binding portion thereof, at a concentration of 20 to 150 mg/ml,(b) a polyol,(c) a surfactant, and(d) a buffer system having a pH of 4 to 8, wherein the antibody comprises the light chain variable region and the heavy chain variable region of D2E7. | 20 to 150 mg/ml adalimumab | A buffer system | A polyol | A surfactant | | pH 4 to 8 |
| US9220781B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody at a concentration of 50 mg/ml,(b) a polyol,(c) a polysorbate, and(d) a buffer system comprising an organic acid and having a pH of 4 to 8, wherein the antibody is D2E7, and wherein the formulation is suitable for subcutaneous injection. | 50 mg/ml adalimumab | A buffer system comprising an organic acid | A polyol | A polysorbate | | pH 4 to 8 |
| US8940305B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody, or an antigen-binding portion thereof, at a concentration of 20 to 150 mg/ml,(b) a polyol,(c) a surfactant, and(d) a buffer system comprising gluconate and having a pH of 4.0 to 8.0, wherein the antibody comprises the light chain variable region and the heavy chain variable region of D2E7.<br><br>22.A stable liquid aqueous pharmaceutical formulation comprising(a) 20 to 150 mg/ml of a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody,(b) a polyol,(c) a polysorbate, and(d) a buffer system comprising gluconate and having a pH of 4.0 to 8.0, wherein the antibody comprises the light chain variable region and the heavy chain variable region of D2E7. | 20 to 150 mg/ml adalimumab | Gluconate | A polyol | A surfactant | | pH 4 to 8 |



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| Publication Number | Independent Claims | Antibody | Buffer | Stabilizer | Surfactant | Salt | pH |
|---|---|---|---|---|---|---|---|
| US8216583B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising a human anti-Tumor Necrosis Factor alpha (TNFα) antibody, or antigen-binding fragment thereof, at a concentration of between about 20 and about 150 mg/ml, a polyol, a surfactant, and a buffer system comprising citrate and phosphate, wherein said formulation has a pH of about 4 to about 8, and wherein the antibody, or antigen-binding portion thereof, comprises a light chain variable region comprising a complementary determining region (CDR) 1 domain comprising the amino acid sequence set forth in SEQ ID NO:7; a CDR2 domain comprising the amino acid sequence set forth in SEQ ID NO:5; and a CDR3 domain comprising the amino acid sequence set forth in SEQ ID NO: 3, or modified from SEQ ID NO: 3 by a single alanine substitution at position 1, 4, 5, 7, or 8, or by one to five conservative amino acid substitutions at positions 1, 3, 4, 6, 7, 8, and/or 9; and comprises a heavy chain variable region comprising a CDR 1 domain comprising the amino acid sequence set forth in SEQ ID NO:8; a CDR2 domain comprising the amino acid sequence set forth in SEQ ID NO:6; and a CDR3 domain comprising the amino acid sequence set forth in SEQ ID NO: 4, or modified from SEQ ID NO: 4 by a single alanine substitution at position 2, 3, 4, 5, 6, 8, 9, 10, or 11, or by one to five conservative amino acid substitutions at positions 2, 3, 4, 5, 6, 8, 9, 10, 11, and/or 12.<br><br>11.A liquid aqueous pharmaceutical formulation comprising(a) about 20 to about 150 mg/ml of a human anti-Tumor Necrosis Factor alpha (TNFα) antibody, or antigen-binding portion thereof;(b) 5-20 mg/ml of mannitol,(c) 0.1-10 mg/ml of polysorbate-80, and(d) a buffer system comprising citrate and phosphate, with a pH of 4 to 8, wherein the antibody, or antigen-binding portion thereof, comprises a light chain variable region comprising a complementary determining region (CDR) 1 domain comprising the amino acid sequence set forth in SEQ ID NO:7; a CDR2 domain comprising the amino acid sequence set forth in SEQ ID NO:5; and a CDR3 domain comprising the amino acid sequence set forth in SEQ ID NO: 3, or modified from SEQ ID NO: 3 by a single alanine substitution at position 1, 4, 5, 7, or 8, or by one to five conservative amino acid substitutions at positions 1, 3, 4, 6, 7, 8, and/or 9; and comprises a heavy chain variable region comprising a CDR 1 domain comprising the amino acid sequence set forth in SEQ ID NO:8; a CDR2 domain comprising the amino acid sequence set forth in SEQ ID NO:6; and a CDR3 domain comprising the amino acid sequence set forth in SEQ ID NO: 4, or modified from SEQ ID NO: 4 by a single alanine substitution at position 2, 3, 4, 5, 6, 8, 9, 10, or 11, or by one to five conservative amino acid substitutions at positions 2, 3, 4, 5, 6, 8, 9, 10, 11, and/or 12. | about 20 and about 150 mg/ml adalimumab | Citrate Phosphate | A polyol | A surfactant | | |





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| Publication Number | Independent Claims | Antibody | Buffer | Stabilizer | Surfactant | Salt | pH |
|---|---|---|---|---|---|---|---|
| US8795670B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody, or an antigen-binding portion thereof, at a concentration of 45 to 105 mg/ml,(b) a polyol,(c) a polysorbate at a concentration of 0.1 to 10 mg/ml, and(d) a buffer system comprising histidine and having a pH of 4.5 to 7.0, wherein the antibody comprises the light chain variable region and the heavy chain variable region of D2E7.<br><br>7.A stable liquid aqueous pharmaceutical formulation comprising(a) 45 to 105 mg/ml of a human IgG1 anti-human Tumor Necrosis Factor alpha (hTNFα) antibody,(b) a polyol,(c) 0.1-10 mg/ml of polysorbate 80, and(d) a buffer system comprising histidine and having a pH of 4.5 to 7.0, wherein the antibody comprises the light chain variable region and the heavy chain variable region of D2E7. | 45 to 105 mg/ml adalimumab | Histidine | A polyol | 0.1 to 10 mg/ml of a polsorbate | | pH 4.5 to 7 |
| US9272041B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody at a concentration of 50 mg/ml,(b) a polyol,(c) a polysorbate, and(d) a buffer system comprising acetate and having a pH of 4 to 8, wherein the antibody is D2E7, and wherein the formulation is suitable for subcutaneous injection. | 50 mg/ml adalimumab | Acetate | A polyol | A polysorbate | | pH 4 to 8 |
| US8802101B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody, or an antigen-binding portion thereof, at a concentration of 45 to 105 mg/ml,(b) a polyol,(c) a polysorbate at a concentration of 0.1 to 10 mg/ml, and(d) a buffer system comprising acetate and having a pH of 4.5 to 7.0, wherein the antibody comprises the light chain variable region and the heavy chain variable region of D2E7.<br><br>21.A stable liquid aqueous pharmaceutical formulation comprising(a) 45 to 105 mg/ml of a human IgG1 anti-human Tumor Necrosis Factor alpha (hTNFα) antibody,(b) trehalose,(c) 0.1-10 mg/ml of polysorbate 80, and(d) a buffer system comprising acetate and having a pH of 4.5 to 7.0, wherein the antibody comprises the light chain variable region and the heavy chain variable region of D2E7. | 45 to 105 mg/ml adalimumab | Acetate | A polyol | 0.1 to 10 mg/ml of a polsorbate | | pH 4.5 to 7 |
| US9302011B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) 50 mg/ml of a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody, wherein the antibody comprises a light chain variable region comprising the amino acid sequence of SEQ ID NO:1 and a heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 2;(b) a polyol;(c) a polysorbate; and(d) a buffer system comprising an organic acid; wherein the formulation has a pH of 4 to 8, and wherein the formulation is suitable for subcutaneous injection. | 50 mg/ml adalimumab | A buffer system comprising an organic acid | A polyol | A polysorbate | | pH 4 to 8 |





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| Publication Number | Independent Claims | Antibody | Buffer | Stabilizer | Surfactant | Salt | pH |
|---|---|---|---|---|---|---|---|
| US8932591B2 | 1.A liquid aqueous pharmaceutical formulation having a pH of about 4.5 to about 6, comprising an isolated human IgG1 anti-human Tumor Necrosis Factor alpha (hTNFα) antibody, or an antigen-binding portion thereof, at a concentration of 35-115 mg/ml, a polyol, a surfactant, and a buffer system comprising citrate and phosphate, wherein the antibody, or antigen-binding portion thereof, comprises a light chain variable region comprising a CDR1 domain comprising the amino acid sequence set forth in SEQ ID NO:7; a CDR2 domain comprising the amino acid sequence set forth in SEQ ID NO:5; and a CDR3 domain comprising the amino acid sequence set forth in SEQ ID NO:3; and a heavy chain variable region comprising a CDR1 domain comprising the amino acid sequence set forth in SEQ ID NO:8; a CDR2 domain comprising the amino acid sequence set forth in SEQ ID NO:6; and a CDR3 domain comprising the amino acid sequence set forth in SEQ ID NO:4.<br><br>10.A liquid aqueous pharmaceutical formulation comprising(a) 35-115 mg/ml of an isolated human IgG1 anti-human Tumor Necrosis Factor alpha (hTNFα) antibody, or an antigen-binding portion thereof,(b) 5-20 mg/ml of mannitol,(c) 0.1-10 mg/ml of polysorbate-80, and(d) a buffer system comprising citrate and phosphate, with a pH of 4.5 to 6.0,wherein the antibody, or antigen-binding portion thereof, comprises a light chain variable region comprising a CDR1 domain comprising the amino acid sequence set forth in SEQ ID NO:7; a CDR2 domain comprising the amino acid sequence set forth in SEQ ID NO:5; and a CDR3 domain comprising the amino acid sequence set forth in SEQ ID NO:3; and a heavy chain variable region comprising a CDR1 domain comprising the amino acid sequence set forth in SEQ ID NO:8; a CDR2 domain comprising the amino acid sequence set forth in SEQ ID NO:6; and a CDR3 domain comprising the amino acid sequence set forth in SEQ ID NO:4.<br><br>17.A liquid pharmaceutical formulation having a pH of about 4 to about 8, comprising an isolated human IgG1 anti-human Tumor Necrosis Factor alpha (hTNFα) antibody at a concentration of 35-115 mg/ml, a sugar alcohol, a polysorbate, and a buffer system comprising citrate and phosphate, wherein the antibody comprises a light chain variable region (LCVR) comprising the amino acid sequence of SEQ ID NO: 1 and a heavy chain variable region (HCVR) comprising the amino acid sequence of SEQ ID NO: 2.<br><br>25.A liquid aqueous pharmaceutical formulation having a pH of about 4.5 to about 6, comprising an isolated human IgG1 anti-human Tumor Necrosis Factor alpha (hTNFα) antibody, or an antigen-binding portion thereof, at a concentration of 35-115 mg/ml, a polyol, a surfactant, and a buffer system comprising citrate and phosphate, wherein the antibody, or antigen-binding portion thereof, comprises a light chain variable region comprising the light chain complementarity determining region (CDR) 1, CDR2, and CDR3 of D2E7; and a heavy chain variable region comprising the heavy chain CDR1, CDR2, and CDR3 of D2E7. | 35-115 mg/ml adalimumab | Citrate Phosphate | A polyol | A surfactant | | pH 4.5 to 6 |


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| Publication Number | Independent Claims | Antibody | Buffer | Stabilizer | Surfactant | Salt | pH |
|---|---|---|---|---|---|---|---|
| US8932591B2 | 34.A liquid aqueous pharmaceutical formulation comprising(a) 35-115 mg/ml of an isolated human IgG1 anti-human Tumor Necrosis Factor alpha (hTNFα) antibody, or an antigen-binding portion thereof,(b) 5-20 mg/ml of mannitol,(c) 0.1-10 mg/ml of polysorbate-80, and(d) a buffer system comprising citrate and phosphate, with a pH of 4.5 to 6.0,wherein the antibody, or antigen-binding portion thereof, comprises a light chain variable region comprising the light chain complementarity determining region (CDR) 1, CDR2, and CDR3 of D2E7; and a heavy chain variable region comprising the heavy chain CDR1, CDR2, and CDR3 of D2E7.<br><br>41.A liquid pharmaceutical formulation having a pH of about 4 to about 8, comprising an isolated human IgG1 anti-human Tumor Necrosis Factor alpha (hTNFα) antibody at a concentration of 35-115 mg/ml, a sugar alcohol, a polysorbate, and a buffer system comprising citrate and phosphate, wherein the antibody comprises the light and heavy chain variable regions of D2E7. | 35-115 mg/ml adalimumab | Citrate Phosphate | A polyol | A surfactant | | pH 4.5 to 6 |
| US9289497B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody at a concentration of 50 mg/ml,(b) a polyol,(c) a polysorbate, and (d) a buffer system comprising gluconate and having a pH of 4 to 8, wherein the antibody is D2E7, and wherein the formulation is suitable for subcutaneous injection. | 50 mg/ml adalimumab | Gluconate | A polyol | A polysorbate | | pH 4 to 8 |
| US9327032B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody at a concentration of 50 mg/ml,(b) a polyol,(c) a polysorbate, and(d) a buffer system comprising histidine and having a pH of 4 to 8, wherein the antibody is D2E7, and wherein the formulation is suitable for subcutaneous injection. | 50 mg/ml adalimumab | Histidine | A polyol | A polysorbate | | pH 4 to 8 |
| US9114166B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising: a human anti-human Tumor Necrosis Factor alpha (TNFα) IgG1 antibody at a concentration of 50 mg/ml, wherein the antibody comprises the light chain variable region and the heavy chain variable region of D2E7, and a buffer system; wherein the formulation is isotonic, suitable for single-use subcutaneous injection, and has a pH of 4.0 to 8.0. | 50 mg/ml adalimumab | Buffer system | | | The formulation is isotonic | pH 4 to 8 |
| US9950066B2 | 1.A stable liquid aqueous pharmaceutical formulation comprising(a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody at a concentration of 50 mg/ml,(b) a polyol,(c) a polysorbate, and(d) a buffer system comprising citrate and phosphate and having a pH of 4 to 8, wherein the antibody is D2E7, and wherein the formulation is suitable for subcutaneous injection. | 50 mg/ml adalimumab | Phosphate Citrate | A polyol | A polysorbate | | pH 4 to 8 |





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