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(54)名稱

抗介白素－４受體（ＩＬ－４Ｒ）抗體調配物

(57)摘要

本發明提供包含特異性結合於人類介白素-4 受體α(hIL-4Rα)之抗體的醫藥調配物。除了抗IL-4Rα抗體之外，該調配物可含有一或多種緩衝液、至少一種胺基酸、至少一種糖及包含聚乙二醇或泊洛沙姆(poloxamer)之界面活性劑。在一個態樣中，醫藥調配物在脂肪酶存在下不具有明顯的亞可見顆粒形成，且在儲存期間及在經受熱及其他物理應力之後展現相當程度的抗體穩定性。

Pharmaceutical formulations comprising an antibody that specifically binds to human interleukin-4 receptor alpha (hIL-4Rα) are provided. The formulations may contain, in addition to an anti-IL-4Rα antibody, one or more buffers, at least one amino acid, at least one sugar, and a surfactant comprising a polyethylene glycol or a poloxamer. In one aspect, the pharmaceutical formulations do not have appreciable subvisible particle formation in the presence of lipase, and exhibit a substantial degree of antibody stability during storage and after being subjected to thermal and other physical stresses.

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【發明摘要】

【中文發明名稱】抗介白素-4受體(IL-4R)抗體調配物

【英文發明名稱】ANTI-INTERLEUKIN-4 RECEPTOR (IL-4R) ANTIBODY FORMULATIONS

【中文】

本發明提供包含特異性結合於人類介白素-4 受體 α (hIL-4Rα)之抗體的醫藥調配物。除了抗 IL-4Rα 抗體之外，該調配物可含有一或多種緩衝液、至少一種胺基酸、至少一種糖及包含聚乙二醇或泊洛沙姆(poloxamer)之界面活性劑。在一個態樣中，醫藥調配物在脂肪酶存在下不具有明顯的亞可見顆粒形成，且在儲存期間及在經受熱及其他物理應力之後展現相當程度的抗體穩定性。

【英文】

Pharmaceutical formulations comprising an antibody that specifically binds to human interleukin-4 receptor alpha (hIL-4Rα) are provided. The formulations may contain, in addition to an anti-IL-4Rα antibody, one or more buffers, at least one amino acid, at least one sugar, and a surfactant comprising a polyethylene glycol or a poloxamer. In one aspect, the pharmaceutical formulations do not have appreciable subvisible particle formation in the presence of lipase, and exhibit a substantial degree of antibody stability during storage and after being subjected to thermal and other physical stresses.

【指定代表圖】

無

【代表圖之符號簡單說明】

無

【發明說明書】

【中文發明名稱】抗介白素-4受體(IL-4R)抗體調配物

【英文發明名稱】ANTI-INTERLEUKIN-4 RECEPTOR (IL-4R) ANTIBODY FORMULATIONS

【技術領域】

相關申請案之交叉引用

【0001】 本申請案主張 2022 年 5 月 2 日申請之美國臨時專利申請案第 63/337,532 號之優先權，其內容以引用的方式併入本文中。

參考序列表

【0002】 本申請案以引用的方式併入 ST.26 XML 格式之電腦可讀序列表，其名稱為 11200WO01_Sequence，創建於 2023 年 4 月 24 日且含有 369,229 位元組。

【0003】 本發明係關於治療性抗體調配物領域。更具體而言，本發明係關於包含特異性結合於人類介白素-4 受體 α 之人類抗體的醫藥調配物領域。

【先前技術】

【0004】 介白素-4 (IL-4)及介白素-13 (IL-13)為驅動過敏性及 2 型 T 輔助細胞(Th2)極化發炎過程的關鍵細胞介素。IL-4 及 IL-13 訊號傳導係經由異二聚體受體複合物介導，其中 IL-4 受體 α (IL-4Rα)為 IL-4 及 IL-13 訊號傳導之共用受體次單元。因此，IL-4Rα 為一種有吸引力的治療目標，因為其提供阻斷 IL-4 及 IL-13 訊號傳導之單一目標。針對 hIL-4Rα 之抗體描述於例如美國專利第 5,717,072 號、第 7,186,809 號及第 7,605,237 號中。

【0005】 治療性大分子(*例如*抗體)必須以不僅使分子適合向患者投予且

亦在儲存期間維持其穩定性的方式調配。舉例而言，除非溶液配製得當，否則液體溶液中之治療性抗體容易發生降解、聚集及/或非所需化學修飾。抗體在液體調配物中之穩定性不僅取決於調配物中使用的賦形劑種類，且亦取決於賦形劑相對於彼此之量及比例。治療性調配物在儲存期間亦可能隨時間推移而形成顆粒物質。顆粒可為可見的或亞可見的；亞可見顆粒之直徑通常小於 150 微米或 100 微米。蛋白質濃度高的調配物，例如濃度為 30 mg/mL 或更高的調配物，更容易聚集及形成亞可見顆粒。

【0006】 聚山梨醇酯 20 及聚山梨醇酯 80 常用於調配生物大分子，諸如抗體。然而，據報導，聚山梨醇酯，包括聚山梨醇酯 20 及聚山梨醇酯 80，可在脂肪酶存在下降解，隨時間推移導致調配物中形成亞可見顆粒。不意欲受理論束縛，咸信在倉鼠、大鼠、小鼠、人類及牛中高度保守的推定磷脂酶 B 樣 2 (PLBL2)，在某些過程中與一些類別之蛋白質共純化。此問題之一種解決方案係採用蛋白質純化製程來移除或降低脂肪酶活性。參見例如 US 10,342,876。然而，仍需要用於調配抗體諸如抗 hIL-4Rα 抗體之替代方案，其方式為避免亞可見顆粒形成或使亞可見顆粒形成降至最低，同時仍維持足夠的穩定性及向患者投予的適合性。

【發明內容】

【0007】 本文提供穩定的液體醫藥調配物，其包含抗 IL-4Rα 抗體及一或多種賦形劑，以及包含此類調配物之遞送裝置、套組及單位劑型。

【0008】 在一個態樣中，本發明提供一種穩定的液體醫藥調配物，其包含：(i)人類抗體，其中該抗體特異性結合於人類介白素-4 受體 α (hIL-4Rα)；(ii)一或多種緩衝液；(iii)熱穩定劑；(iv)黏度降低劑；及(v)界面活性劑，包含濃度小於 0.2% w/v 之聚乙二醇或泊洛沙姆(poloxamer)，或濃度小於 1% w/v 之聚乙二醇，其中該調配物之 pH 為 5.7 至 6.1。

【0009】 在一個態樣中，本發明提供一種穩定的液體醫藥調配物，其包含：(i)人類抗體，其中該抗體特異性結合於人類介白素-4 受體 α (hIL-4Rα)且包含含有表 1 中所揭示之一或多個序列的重鏈可變區(HCVR)；(ii)濃度為 10 mM 至 15 mM 之乙酸鹽；(iii)濃度為 15 mM 至 25 mM 之組胺酸；(iv)濃度為 2.5% w/v 至 7.5% w/v 之蔗糖；(v)濃度為 20 mM 至 80 mM 之精胺酸；及(vi)界面活性劑，包含濃度小於 0.2% w/v 之聚乙二醇或泊洛沙姆，或濃度小於 1% w/v 之聚乙二醇，其中該調配物之 pH 為 5.7 至 6.1。

【0010】 在一些實施例中，抗體包含重鏈可變區(HCVR)及輕鏈可變區(LCVR)，HCVR 包含分別包含 SEQ ID NO: 3、4 及 5 之胺基酸序列的互補決定區 HCDR1、HCDR2 及 HCDR3； LCVR 包含分別包含 SEQ ID NO: 6、7 及 8 之胺基酸序列的互補決定區 LCDR1、LCDR2 及 LCDR3。在一些實施例中，抗體包含 HCVR，其包含 SEQ ID NO: 1 之胺基酸序列；及 LCVR，其包含 SEQ ID NO: 2 之胺基酸序列。

【0011】 在一些實施例中，抗體具有人類 IgG 重鏈恆定區。在一些情況下，重鏈恆定區屬於同型 IgG1。在一些情況下，重鏈恆定區屬於同型 IgG4。

【0012】 在一些實施例中，抗體包含含有 SEQ ID NO: 9 之胺基酸序列的重鏈及含有 SEQ ID NO: 10 之胺基酸序列的輕鏈。

【0013】 在一些實施例中，界面活性劑為聚乙二醇。在一些情況下，聚乙二醇為 PEG3350。在一些實施例中，界面活性劑以 0.0075% w/v 至小於 1% w/v、0.0075% w/v 至 0.75% w/v、0.01% w/v 至 0.5% w/v 或 0.01% w/v 至 0.25% w/v 之濃度存在。在一些實施例中，界面活性劑以 0.01% w/v 至 0.19% w/v，例如 0.01% w/v 至 0.15% w/v 或 0.05% w/v 至 0.15% w/v 之濃度存在。在一些實施例中，界面活性劑以不超過 0.15% w/v 之濃度存在。

【0014】 在一些實施例中，界面活性劑為泊洛沙姆。在一些情況下，泊洛

沙姆為泊洛沙姆 188。在一些實施例中，界面活性劑以 0.0075% w/v 至 0.19% w/v，或 0.01% w/v 至 0.19% w/v，例如 0.01% w/v 至 0.15% w/v 或 0.05% w/v 至 0.15% w/v 之濃度存在。在一些實施例中，界面活性劑以不超過 0.15% w/v 之濃度存在。

【0015】 在一些實施例中，緩衝液包含乙酸鹽緩衝液及/或組胺酸緩衝液。在一些實施例中，緩衝液包含濃度為 10 mM 至 15 mM 之乙酸鹽及/或濃度為 15 mM 至 25 mM 之組胺酸。在一些實施例中，乙酸鹽以 12.5 mM ± 1.25 mM 之濃度存在。在一些實施例中，組胺酸以 20 mM ± 2 mM 之濃度存在。在一些實施例中，熱穩定劑為濃度為 5% w/v±0.5% w/v 之蔗糖。在一些實施例中，黏度降低劑為濃度為 25 mM ± 2.5 mM 之精胺酸。在一些實施例中，精胺酸以 50 mM ± 2.5 mM 之濃度存在。在一些實施例中，精胺酸以 75 mM ± 2.5 mM 之濃度存在。

【0016】 在一些實施例中，抗體以至多 200 mg/mL 之濃度存在。在一些實施例中，抗體以 15 mg/mL 至 200 mg/mL 之濃度存在。在一些實施例中，抗體以 100 mg/mL 至 200 mg/mL 之濃度存在。在一些情況下，抗體以 150 mg/mL ± 15 mg/mL 之濃度存在。在一些情況下，抗體以 175 mg/mL ± 15 mg/mL 之濃度存在。

【0017】 在一個態樣中，本發明提供一種穩定的液體醫藥調配物，其包含：(i)濃度為 150 mg/mL ± 10 mg/mL 之人類抗體，其中該抗體特異性結合於人類介白素-4 受體 α (hIL-4Rα)且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 12.5 mM ± 1.25 mM 之乙酸鹽；(iii)濃度為 20 mM ± 2 mM 之組胺酸；(iv)濃度為 5% w/v ± 0.5% w/v 之蔗糖；(v)濃度為 25 mM ± 2.5 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 之 PEG3350 或泊洛沙姆 188 的界面活性劑，其中該調配物之 pH 為 5.9 ± 0.3 或 pH 為 5.9 ± 0.2。在一些情況下，抗體包含含有 SEQ ID NO: 9 之胺基酸序列的重鏈，及含有 SEQ ID NO: 10 之胺基酸序列的輕鏈。

【0018】 在一個態樣中，本發明提供一種穩定的液體醫藥調配物，其包含：(i)濃度為 175 mg/mL ± 10 mg/mL 之人類抗體，其中該抗體特異性結合於人類介白素-4 受體 α (hIL-4Rα)且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 12.5 mM ± 1.25 mM 之乙酸鹽；(iii)濃度為 20 mM ± 2 mM 之組胺酸；(iv)濃度為 5% w/v ± 0.5% w/v 之蔗糖；(v)濃度為 25 mM ± 2.5 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 之 PEG3350 或泊洛沙姆 188 的界面活性劑，其中該調配物之 pH 為 5.9 ± 0.3 或 pH 為 5.9 ± 0.2。在一些情況下，抗體包含含有 SEQ ID NO: 9 之胺基酸序列的重鏈，及含有 SEQ ID NO: 10 之胺基酸序列的輕鏈。

【0019】 在一些實施例中，調配物包含磷脂酶。在一些實施例中，磷脂酶蛋白為磷脂酶 B 樣 2 蛋白。

【0020】 在一些實施例中，如本文所論述之穩定的液體醫藥調配物在 25℃下攪拌 24 小時後，藉由 SE-UPLC 測定，包含不超過 4%的高分子量(HMW)物種。在一些實施例中，調配物在 25℃下攪拌 24 小時且(i)在 5℃下儲存 6、12 或 18 個月或(ii)在 25℃下儲存 6 個月後，藉由 SE-UPLC 測定，包含不超過 4%的高分子量(HMW)物種。

【0021】 在一些實施例中，調配物在室溫下藉由渦旋攪拌至多 120 分鐘後，藉由尺寸排阻-超高效液相層析(SE-UPLC)測定，包含不超過 3%的高分子量(HMW)物種。在一些情況下，調配物在室溫下藉由渦旋攪拌至多 120 分鐘後，藉由 SE-UPLC 測定，包含不超過 2.5%的高分子量(HMW)物種。

【0022】 在一些實施例中，調配物在 45℃下儲存 30 天後，藉由 SE-UPLC 測定，包含不超過 8%的高分子量(HMW)物種。在一些情況下，調配物在 45℃下儲存 40 天後，藉由 SE-UPLC 測定，包含不超過 9%的高分子量(HMW)物種。在一些情況下，調配物在 45℃下儲存 50 天後，藉由 SE-UPLC 測定，包含不超

過 11%的高分子量(HMW)物種。

【0023】 在一些實施例中，調配物在 5℃下儲存 6 個月後，藉由顯微術測定，在 2.25 mL 的體積中包含不超過 1000 個、不超過 500 個、不超過 300 個或不超過 150 個直徑≥10 μm 之顆粒，且其中該調配物含有磷脂酶蛋白。

【0024】 在一些實施例中，調配物在 5℃下儲存 36 個月後，藉由顯微術測定，在 2.25 mL 的體積中包含不超過 1000 個、不超過 500 個、不超過 300 個或不超過 150 個直徑≥10 μm 之顆粒，且其中該調配物含有磷脂酶蛋白。

【0025】 在一些實施例中，調配物在 5℃下儲存 6 個月後，藉由顯微術測定，在 2.25 mL 的體積中包含不超過 500 個、不超過 300 個、不超過 250 個或不超過 50 個直徑≥25 μm 之顆粒，且其中該調配物含有磷脂酶蛋白。

【0026】 在一些實施例中，調配物在 5℃下儲存 6 個月後，藉由顯微術測定，在 2.25 mL 的體積中包含不超過 500 個、不超過 300 個、不超過 250 個或不超過 50 個直徑≥25 μm 之顆粒，且其中該調配物含有磷脂酶蛋白。

【0027】 在一些實施例中，調配物不包括酯酶抑制劑。

【0028】 在一些實施例中，穩定的液體醫藥調配物包含在玻璃小瓶中。

【0029】 在一些實施例中，穩定的液體醫藥調配物包含在注射器中。在一些情況下，注射器包含經氟碳塗佈之柱塞。在一些情況下，注射器為低鎢注射器。在一些情況下，注射器為預填充注射器。在一些情況下，注射器為預填充固定針頭注射器。

【0030】 在一些實施例中，穩定的液體醫藥調配物包含在大容量裝置或推注注射器中。

【0031】 在一個態樣中，本發明提供一種筆式或自動注射器遞送裝置，其含有如上文或本文所論述之穩定的液體醫藥調配物。在一些情況下，遞送裝置為一次性筆式遞送裝置。在一些情況下，遞送裝置為可重複使用的筆式遞送裝

置。

【0032】 在一個態樣中，本發明提供一種容器，其含有如上文或本文所論述之穩定的液體醫藥調配物。

【0033】 在一個態樣中，本發明提供一種套組，其包含(i)含有如上文或本文所論述之穩定的液體醫藥調配物之容器，及(ii)該醫藥調配物之使用標籤。在一些情況下，標籤敍述醫藥調配物之皮下投予。在一些情況下，標籤敍述醫藥調配物之靜脈內投予。

【0034】 在一個態樣中，本發明提供一種單位劑型，其包含如上文或本文所論述之穩定的液體醫藥調配物，其中抗體以 1 mg 至 500 mg 之量存在。在一些情況下，抗體以約 100 mg 之量存在。在一些情況下，抗體以約 200 mg 之量存在。在一些情況下，抗體以約 300 mg 之量存在。在一些實施例中，單位劑型之調配物包含在注射器中。在一些情況下，注射器為預填充注射器。在一些實施例中，單位劑型之調配物包含在預填充筆中。在一些實施例中，單位劑型之調配物包含在自動注射器中。

【0035】 在一個態樣中，本發明提供一種安全系統遞送裝置，其含有如上文或本文所論述之穩定的液體醫藥調配物。在一些情況下，安全系統遞送裝置包括經配置藉由人工操作來延伸的安全套管。在一些情況下，安全系統遞送裝置包括經配置在注射穩定的液體醫藥調配物後自動延伸的安全套管。

【0036】 在各種實施例中，上文或本文所論述之實施例之特徵或組分中之任一者可組合，且此類組合涵蓋在本發明之範疇內。上文或本文所論述之任何具體值可與上文或本文所論述之另一相關值組合以敍述範圍，其中該等值代表該範圍之上端及下端，且此類範圍涵蓋在本發明之範疇內。上文或本文所論述之值中之各者可用 1%、5%、10%或 20%之變化來表示。舉例而言，10 mM 濃度可表示為 10 mM ± 0.1 mM (1%變化)、10 mM ± 0.5 mM (5%變化)、10 mM ± 1

mM (10%變化)或 10 mM ± 2 mM (20%變化)。

【0037】 其他實施例將自實施方式之綜述變得顯而易見。

【圖式簡單說明】

【0038】 圖 1 展示含有脂肪酶及 PEG3350 或泊洛沙姆 188 (濃度為 0.02%、0.04%或 0.1% w/v)且在 5℃下儲存長達 36 個月之 150 mg/mL 抗 IL-4R 抗體的調配物藉由顯微術鑑別之≥10 μm (上圖)及≥25 μm (下圖)之顆粒的數目。

【0039】 圖 2A 及 2B 展示 PEG3350 濃度(圖 2A)及泊洛沙姆 188 濃度(圖 2B)對 150 mg/mL 抗 IL-4R 抗體之調配物在室溫下抵抗攪拌應力 30-120 分鐘時間段之穩定性(藉由 SE-UPLC 量測之高分子量(HMW 物種百分比)的影響。

【0040】 圖 3 展示聚山梨醇酯 20、聚山梨醇酯 80、PEG3350 及泊洛沙姆 188 (在不同濃度下)對 150 mg/mL 抗 IL-4R 抗體之調配物抵抗熱應力(45℃)至多 56 天時間段之穩定性(藉由 SE-UPLC 量測之高分子量(HMW 物種百分比)的影響。

【實施方式】

【0041】 在描述本發明之前，應理解，本發明不限於所描述之特定方法及實驗條件，因為此類方法及條件可變化。亦應理解，本文所用之術語僅用於描述特定實施例之目的，且不意欲為限制性的，因為本發明之範疇將僅由隨附申請專利範圍限制。

【0042】 除非另外規定，否則本文中所用之所有技術及科學術語具有與本發明所屬領域之具有通常知識者通常所理解相同之含義。如本文所用，術語「約」當參照特定敍述數值或值範圍使用時，意謂該值可與敍述值相差不超過 1%。舉例而言，如本文所用，表述「約 100」包括 99 及 101 及其間所有值(*例如* 99.1、

99.2、99.3、99.4 等)。

【0043】 儘管與本文所述方法及材料相似或等效的任何方法及材料可用於本發明之實施或測試，但現在描述例示性方法及材料。本說明書中所提及之所有專利、申請案及非專利出版物均以全文引用之方式併入本文中。

醫藥調配物

【0044】 如本文所用，表述「醫藥調配物」意謂至少一種活性成分(*例如*抗 IL-4Rα 抗體等，其能夠在人類或非人類動物體內發揮生物作用)及至少一種非活性成分之組合，該非活性成分在與活性成分及/或一或多種額外非活性成分組合時，適用於對人類或非人類動物進行治療性投予。如本文所用，術語「調配物」意謂「醫藥調配物」，除非另外特別指示。本發明提供包含至少一種治療性多肽之醫藥調配物。根據本發明之某些實施例，治療性多肽為特異性結合於人類介白素-4 受體 α (hIL-4Rα)或其抗原結合片段之抗體。更具體而言，本發明包括醫藥調配物，其包含：(i)特異性結合於 hIL-4Rα 之人類抗體；(ii)一或多種緩衝液；(iii)熱穩定劑；(iv)界面活性劑(例如有機共溶劑)；及(v)黏度調節劑。若額外組分不顯著干擾調配物之黏度及穩定性，則此類組分可包括在本發明之調配物中。下文詳細描述本發明中所包括之具體例示性組分及調配物。

【0045】 在某些實施例中，本發明之醫藥調配物可為流體調配物。如本文所用，表述「流體調配物」意謂在約 2℃至約 45℃下主要以流體狀態存在的至少兩種組分之混合物。流體調配物*尤其*包括液體調配物。流體調配物可具有低黏度、中等黏度或高黏度，視其特定成分而定。

特異性結合人類 IL-4 受體 α 之抗體

【0046】 本發明之醫藥調配物可包含特異性結合於人類介白素-4 受體 α

(IL-4Rα)之人類抗體或其抗原結合片段。本文中提及的 IL-4R 抗體亦指結合 hIL-4Rα 之抗體。

【0047】 如本文所用，術語「抗體」一般意欲指包含四條多肽鏈(藉由雙硫鍵互連之兩條重(H)鏈及兩條輕(L)鏈)之免疫球蛋白分子以及其多聚體(*例如* IgM)；然而，僅由重鏈組成(*亦即*缺乏輕鏈)之免疫球蛋白分子亦涵蓋在術語「抗體」之定義內。各重鏈包括一重鏈可變區(文中縮寫為 HCVR 或 VH)及一重鏈恆定區。重鏈恆定區包括三個結構域 CH1、CH2 和 CH3。各輕鏈包括一輕鏈可變區(文中縮寫為 LCVR 或 VL)及一輕鏈恆定區。輕鏈恆定區包含一個域(CL1)。VH 及 VL 區可進一步細分為高變區，稱為互補決定區(CDR)，其穿插有稱為構架區(FR)之更保守區。各 VH 和 VL 係由三個 CDR 和四個 FR 所組成，以下列順序由胺基端排列至羧基端：FR1、CDR1、FR2、CDR2、FR3、CDR3、FR4。

【0048】 在本發明之某些實施例中，本發明之抗 IL-4R 抗體為人類抗體。如本文所用，術語「人類抗體」意欲包括具有來源於人類生殖系免疫球蛋白序列之可變區及恆定區的抗體。本發明之人類抗體可包括不由人類生殖系免疫球蛋白序列編碼之胺基酸殘基(*例如*藉由*活體外*隨機或定點突變誘發或藉由*活體內*體細胞突變引入的突變)，例如在 CDR 且尤其 CDR3 中。然而，如本文所用，術語「人類抗體」不意欲包括來源於另一哺乳動物物種(諸如小鼠)之生殖系的 CDR 序列已移植於人類構架序列上的抗體。在各種實施例中，抗 IL-4R 抗體為人類 IgG 抗體。在各種實施例中，抗 IL-4R 抗體為同型 IgG1、IgG2、IgG3 或 IgG4 或混合同型之人類抗體。在一些實施例中，抗 IL-4R 抗體為人類 IgG1 抗體。在一些實施例中，抗 IL-4R 抗體為人類 IgG4 抗體。在上文或本文所論述之任何實施例中，抗 IL-4R 抗體可包含人類 κ 輕鏈。在上文或本文所論述之任何實施例中，抗 IL-4R 抗體可包含人類 λ 輕鏈。

【0049】 在一些實施例中，本發明之抗體可為重組人類抗體。如本文所

用，術語「重組人類抗體」意欲包括藉由重組手段製備、表現、產生或分離之所有人類抗體，諸如使用轉染至宿主細胞中之重組表現載體表現之抗體；自重組組合人類抗體文庫分離之抗體；自人類免疫球蛋白基因轉殖基因之動物(*例如*小鼠)分離之抗體(參見例如 Taylor 等人 (1992) Nucl. Acids Res. 20:6287-6295)；或藉由涉及將人類免疫球蛋白基因序列剪接至其他 DNA 序列之任何其他手段製備、表現、產生或分離之抗體。此類重組人類抗體具有來源於人類生殖系免疫球蛋白序列之可變及恆定區。然而，在某些實施例中，對此類重組人類抗體進行*活體外*突變誘發(或當使用人類 Ig 序列轉殖基因之動物時，進行*活體內*體細胞突變誘發)，且因此重組抗體之 V_H 及 V_L 區之胺基酸序列為雖然來源於人類生殖系 V_H 及 V_L 序列且與其相關，但可能不天然存在於*活體內*人類抗體生殖系庫內的序列。

【0050】 如本文所用，術語抗體之「抗原結合部分」或「抗原結合片段」(或簡稱「抗體部分」或「抗體片段」)係指抗體之保留特異性結合於 hIL-4Rα 之能力的一或多個片段。

【0051】 如本文所用，「經分離抗體」意欲指實質上不含其他具有不同抗原特異性之抗體的抗體(*例如*，特異性結合 hIL-4Rα 之經分離抗體實質上不含特異性結合除 hIL-4Rα 以外之抗原的抗體)。

【0052】 術語「特異性結合」或其類似術語意謂抗體或其抗原結合片段與抗原形成在生理條件下相對穩定的複合物。特異性結合之特徵可在於解離常數為至少約 1×10^{-6} M 或更大。用於判定兩個分子是否特異性結合之方法為此項技術中熟知的，且包括例如平衡透析、表面電漿子共振及類似者。然而，特異性結合 hIL-4Rα 之經分離抗體可對其他抗原具有交叉反應性，諸如來自其他物種之 IL-4Rα 分子(直系同源物)。在本發明之上下文中，結合 hIL-4Rα 以及一或多種額外抗原之多特異性(*例如*雙特異性)抗體視為「特異性結合」hIL-4Rα。此外，經

分離抗體可實質上不含其他細胞材料及/或化學物質。然而，在一些情況下，經分離抗體可與由產生抗 IL-4R 抗體之哺乳動物細胞株(*例如* CHO 細胞)表現之磷脂酶共純化。

【0053】 根據本發明之某些實施例，抗 hIL-4R 抗體或其抗原結合片段包含重鏈互補決定區 HCDR1-HCDR2-HCDR3，其分別包含 SEQ ID NO: 3-4-5 之胺基酸序列。根據本發明之某些實施例，抗 hIL-4R 抗體或其抗原結合片段包含輕鏈互補決定區 LCDR1-LCDR2-LCDR3，其分別包含 SEQ ID NO: 6-7-8 之胺基酸序列。在某些實施例中，抗 hIL-4R 抗體或其抗原結合片段包含 CDR HCDR1-HCDR2-HCDR3-LCDR1-LCDR2-LCDR3，其分別包含 SEQ ID NO:3-4-5-6-7-8 之胺基酸序列。在一些實施例中，IL-4R 拮抗劑為抗 IL-4Rα 抗體或其抗原結合片段，其包含三個 HCDR (HCDR1、HCDR2 及 HCDR3)及三個 LCDR (LCDR1、LCDR2 及 LCDR3)，其中 HCDR1 包含或由胺基酸序列 GFTFRDYA (SEQ ID NO: 3)組成，HCDR2 包含或由胺基酸序列 ISGSGGNT (SEQ ID NO: 4)組成，HCDR3 包含或由胺基酸序列 AKDRLSITIRPRYYGLDV (SEQ ID NO: 5)組成，LCDR1 包含或由胺基酸序列 QSLLYSIGYNY (SEQ ID NO: 6)組成，LCDR2 包含或由胺基酸序列 LGS (SEQ ID NO: 7)組成，且 LCDR3 包含或由胺基酸序列 MQALQTPYT (SEQ ID NO: 8)組成。

【0054】 在某些實施例中，抗 hIL-4R 抗體或其抗原結合片段包含分別包含 SEQ ID NO: 3-4-5 之胺基酸序列的重鏈互補決定區 HCDR1-HCDR2-HCDR3，且具有與 SEQ ID NO: 1 之胺基酸序列具有至少 90%序列一致性(例如至少 91%、92%、93%、94%、95%、96%、97%、98%或 99%序列一致性)之重鏈可變區(HCVR)。在某些實施例中，抗 hIL-4R 抗體或其抗原結合片段包含分別包含 SEQ ID NO: 6-7-8 之胺基酸序列的輕鏈互補決定區 LCDR1-LCDR2-LCDR3，且具有與 SEQ ID NO: 2 之胺基酸序列具有至少 90%序列一致性(例如至少 91%、92%、

93%、94%、95%、96%、97%、98%或 99%序列一致性)之輕鏈可變區(LCVR)。在某些實施例中，抗 hIL-4R 抗體或其抗原結合片段包含：分別包含 SEQ ID NO: 3-4-5 之胺基酸序列的重鏈互補決定區 HCDR1-HCDR2-HCDR3，且具有與 SEQ ID NO: 1 之胺基酸序列具有至少 90%序列一致性(例如至少 91%、92%、93%、94%、95%、96%、97%、98%或 99%序列一致性)之重鏈可變區(HCVR)；及分別包含 SEQ ID NO: 6-7-8 之胺基酸序列的輕鏈互補決定區 LCDR1-LCDR2-LCDR3，且具有與 SEQ ID NO: 2 之胺基酸序列具有至少 90%序列一致性(例如至少 91%、92%、93%、94%、95%、96%、97%、98%或 99%序列一致性)之輕鏈可變區(LCVR)。

【0055】 在某些實施例中，抗 hIL-4R 抗體或其抗原結合片段包含重鏈可變區(HCVR)，其包含 SEQ ID NO: 1 之胺基酸序列。在某些實施例中，抗 hIL-4R 抗體或其抗原結合片段包含輕鏈可變區(LCVR)，其包含 SEQ ID NO: 2 之胺基酸序列。在某些實施例中，抗 hIL-4R 抗體或其抗原結合片段包含 HCVR/LCVR 胺基酸序列對，其包含 SEQ ID NO: 1/2 之胺基酸序列。在一些實施例中，抗 IL-4R 抗體包含分別包含 SEQ ID NO: 1/2 之胺基酸序列的 HCVR/LCVR，及人類 IgG1 重鏈恆定區。在一些實施例中，抗 IL-4R 抗體包含分別包含 SEQ ID NO: 1/2 之胺基酸序列的 HCVR/LCVR，及人類 IgG4 重鏈恆定區。在一些實施例中，抗 IL-4R 抗體包含分別包含 SEQ ID NO: 1/2 之胺基酸序列的 HCVR/LCVR，及人類 IgG 重鏈恆定區。在一些實施例中，抗 IL-4R 抗體包含分別包含 SEQ ID NO: 1/2 之胺基酸序列的 HCVR/LCVR，及人類 IgG1 或 IgG4 重鏈恆定區。在一些實施例中，抗 IL-4R 抗體包含含有 SEQ ID NO: 9 之胺基酸序列的重鏈及含有 SEQ ID NO: 10 之胺基酸序列的輕鏈。在一些實施例中，抗 IL-4R 抗體為度匹魯單抗(dupilumab)。

【0056】 可用於本發明方法之情形中的其他抗 IL-4R 抗體包括例如此項

技術中提及且稱為 AMG317 之抗體(Corren 等人，2010, Am J Respir Crit Care Med., 181(8):788-796)，或 MEDI 9314，或如美國專利案第 7,186,809 號、美國專利案第 7,605,237 號、美國專利案第 7,638,606 號、美國專利案第 8,092,804 號、美國專利案第 8,679,487 號、美國專利案第 8,877,189 號、美國專利案第 10,774,141 號；美國專利申請公開案第 US2021/0238294 號；或國際專利公開案第 WO2019/228405 號、第 WO2020/096381 號、第 WO 2020/135471 號、第 WO2020/135710 號或第 WO 2020/239134 號中所闡述之抗 IL-4Rα 抗體中之任一者，該等案各自之內容以引用的方式併入本文中。

【0057】 在一些實施例中，抗 IL-4R 抗體包含下表 1 中所闡述之一或多個 CDR、HCVR 及/或 LCVR 序列。

【0058】 本發明之醫藥調配物中所含之抗體或其抗原結合片段的量可視調配物所需之具體特性以及意欲使用調配物之特定情況及目的而變化。在某些實施例中，醫藥調配物可含有約 1 mg/mL 至約 500 mg/mL 之抗體；約 5 mg/mL 至約 250 mg/mL 之抗體；約 5 mg/mL 至約 200 mg/mL 之抗體；約 15 mg/mL 至約 200 mg/mL；約 25 mg/mL 至約 200 mg/mL 之抗體；約 50 mg/mL 至約 200 mg/mL 之抗體；約 100 mg/mL 至約 200 mg/mL；約 125 mg/mL 至約 175 mg/mL；或約 150 mg/mL 至約 200 mg/mL 之抗體。舉例而言，本發明之調配物可為液體調配物，其包含約 1 mg/mL；約 2 mg/mL；約 5 mg/mL；約 10 mg/mL；約 15 mg/mL；約 20 mg/mL；約 25 mg/mL；約 30 mg/mL；約 35 mg/mL；約 40 mg/mL；約 45 mg/mL；約 50 mg/mL；約 55 mg/mL；約 60 mg/mL；約 65 mg/mL；約 70 mg/mL；約 75 mg/mL；約 80 mg/mL；約 85 mg/mL；約 90 mg/mL；約 95 mg/mL；約 100 mg/mL；約 105 mg/mL；約 110 mg/mL；約 115 mg/mL；約 120 mg/mL；約 125 mg/mL；約 130 mg/mL；約 135 mg/mL；約 140 mg/mL；約 145 mg/mL；約 150 mg/mL；約 155 mg/mL；約 160 mg/mL；約 165 mg/mL；約 170 mg/mL；約 175

mg/mL；約 180 mg/mL；約 185 mg/mL；約 190 mg/mL；約 195 mg/mL；或約 200 mg/mL 之特異性結合於 hIL-4Rα 之抗體或其抗原結合片段。在某些實施例中，醫藥調配物為液體調配物，其可含有 5 ± 0.5 mg/mL 至 200 ± 20 mg/mL 之抗體；15 ± 1.5 mg/mL 至 200 ± 20 mg/mL 之抗體；25 ± 2.5 mg/mL 至 200 ± 20 mg/mL 之抗體；50 ± 5 mg/mL 至 200 ± 20 mg/mL 之抗體；100 ± 10 mg/mL 至 200 ± 20 mg/mL 之抗體；150 ± 10 mg/mL 之抗體；或 175 ± 10 mg/mL。在一些實施例中，醫藥調配物含有 140 ± 5 mg/mL 至 160 ± 5 mg/mL 之抗 IL-4R 抗體。在一些情況下，醫藥調配物含有 165 mg/mL ± 5 mg/mL 至 185 mg/mL ± 5 mg/mL 之抗 IL-4R 抗體。在一些情況下，醫藥調配物含有 150 mg/mL ± 5 mg/mL 之抗 IL-4R 抗體。在一些情況下，醫藥調配物含有 175 mg/mL ± 5 mg/mL 之抗 IL-4R 抗體。

生物等效物

【0059】 本發明涵蓋具有與本文所揭示之例示性分子的胺基酸序列不同的胺基酸序列但保留結合 hIL-4R 之能力的抗體。當與親本序列相比時，此類變異體分子可包含一或多個胺基酸之添加、缺失或取代，但展現與本文所論述之抗體的生物活性基本上等效的生物活性。

【0060】 本發明包括與本文所記載之例示性抗體中之任一者生物等效的抗原結合分子。在一些實施例中，抗原結合分子為度匹魯單抗之生物等效物。舉例而言，若兩種抗體為醫藥等效物或醫藥替代物，當在相似的實驗條件下以相同的莫耳劑量(單次劑量或多次劑量)投予時，其吸收速率及程度不顯示顯著差異，則其視為生物等效物。若一些抗體在吸收程度方面等效，但在吸收速率方面不等效，則其被視為等效物或醫藥替代物，且亦可視為生物等效物，因為在吸收速率方面的此類差異為有意的且反映在標籤中，對於*例如*在長期使用時達到有效的身體藥物濃度並非必不可少，且對於所研究之特定藥品而言被視為醫

學上無關緊要的。

【0061】 在一個實施例中，若兩種抗體在安全性、純度及效力方面不存在臨床上有意義的差異，則其為生物等效的。

【0062】 在一個實施例中，若患者可在參考產品與生物產品之間轉換一或多次而與無此類轉換之持續療法相比，不良作用之風險沒有預期增加，包括免疫原性之臨床顯著變化或有效性減弱，則兩種抗體為生物等效的。

【0063】 生物等效性可藉由活體內及活體外方法證明。生物等效性量測包括例如(a)人類或其他哺乳動物中之*活體內*測試，其中隨時間變化量測血液、血漿、血清或其他生物體液中抗體或其代謝物的濃度；(b)與人類活體內生物可用性資料相關且合理地預測人類活體內生物可用性資料之活體外測試；(c)人類或其他哺乳動物中之活體內測試，其中隨時間變化量測抗體(或其目標)之適當急性藥理作用；及(d)在一項良好控制的臨床試驗中，確定抗原結合蛋白之安全性、功效、或生物可用性或生物等效性。

調配物賦形劑及 pH

【0064】 本發明之醫藥調配物包含一或多種賦形劑。如本文所用，術語「賦形劑」意謂添加至調配物中以提供期望的稠度、黏度或穩定作用之任何非治療劑。

【0065】 本發明之醫藥調配物亦可包含緩衝液或緩衝液系統，其用以維持穩定的 pH 且幫助穩定抗 IL-4R 抗體。在一些實施例中，緩衝液或緩衝液系統包含至少一種緩衝液，其緩衝範圍與 pH 5.5 至 6.3 之範圍完全或部分重疊。在各種實施例中，調配物之 pH 為 5.5、5.6、5.7、5.8、5.9、6.0、6.1、6.2 或 6.3。在一些實施例中，調配物之 pH 為 5.9 ± 0.3。在一些實施例中，調配物之 pH 為 5.9 ± 0.2。在一些實施例中，調配物之 pH 為 5.9 ± 0.1。在某些實施例中，緩衝液包含

組胺酸緩衝液。在某些實施例中，緩衝液包含乙酸鹽緩衝液。在某些實施例中，緩衝液(*例如*組胺酸及/或乙酸鹽)以約 1 mM 至約 40 mM、約 5 mM 至約 30 mM、約 10 mM 至約 15 mM；或約 15 mM 至約 25 mM 之濃度存在。在一些實施例中，緩衝液包括濃度為 15 mM 至 25 mM 之組胺酸緩衝液。在一些實施例中，緩衝液包括濃度為 20 mM ± 2 mM 之組胺酸緩衝液。在一些情況下，組胺酸緩衝液以 15 mM、16 mM、17 mM、18 mM、19 mM、20 mM、21 mM、22 mM、23 mM、24 mM 或 25 mM 之濃度存在。在一些實施例中，緩衝液包含濃度為 10 mM 至 15 mM 之乙酸鹽緩衝液。在一些實施例中，緩衝液包含濃度為 12.5 mM ± 1.25 mM 之乙酸鹽緩衝液。在一些情況下，乙酸鹽緩衝液以 10 mM、10.5 mM、11 mM、11.5 mM、12 mM、12.5 mM、13 mM、13.5 mM、14 mM、14.5 mM 或 15 mM 之濃度存在。在一些實施例中，本發明之調配物包括上文所論述之任一濃度的組胺酸及乙酸鹽緩衝液。在一些情況下，調配物含有濃度為 15 mM 至 25 mM 之組胺酸緩衝液及濃度為 10 mM 至 15 mM 之乙酸鹽緩衝液。在一些情況下，調配物含有濃度為 20 mM ± 2 mM 之組胺酸緩衝液及濃度為 12.5 mM ± 1.25 mM 之乙酸鹽緩衝液。

【0066】 本發明之醫藥調配物亦可包含一或多種碳水化合物，*例如*一或多種糖。糖可為還原糖或非還原糖。「還原糖」包括*例如*具有酮基或醛基且含有反應性半縮醛基之糖，其允許糖充當還原劑。還原糖之具體實例包括果糖、葡萄糖、甘油醛、乳糖、阿拉伯糖、甘露糖、木糖、核糖、鼠李糖、半乳糖及麥芽糖。非還原糖可包含變旋異構碳，其為縮醛且實質上不與胺基酸或多肽反應以引發梅納反應(Maillard reaction)。非還原糖之具體實例包括蔗糖、海藻糖、山梨糖、蔗糖素、松三糖及棉子糖。糖酸包括例如葡萄糖二酸、葡萄糖酸鹽及其他多羥基糖及其鹽。在一些實施例中，糖為蔗糖。在一些情況下，糖(*例如*蔗糖)充當抗 IL-4R 抗體之熱穩定劑。

【0067】 本發明之醫藥調配物中所含之糖(*例如*蔗糖)的量將視使用調配物之具體情況及預期目的而變化。在某些實施例中，調配物可含有約 0.1%至約 20%的糖；約 0.5%至約 20%的糖；約 1%至約 20%的糖；約 2%至約 15%的糖；約 3%至約 8%的糖；或約 4%至約 6%的糖。舉例而言，本發明之醫藥調配物可包含約 0.5%；約 1.0%；約 1.5%；約 2.0%；約 2.5%；約 3.0%；約 3.5%；約 4.0%；約 4.5%；約 5.0%；約 5.5%；約 6.0%；約 6.5%；約 7.0%；約 7.5%；約 8.0%；約 8.5%；約 9.0%；約 9.5%；約 10.0%；約 15%；或約 20%的糖(*例如*蔗糖)。在一些實施例中，調配物含有約 5%的糖(*例如*蔗糖)。在一些實施例中，調配物含有約 5% ± 0.5%的糖(*例如*蔗糖)。上述百分比中之各者對應於重量/體積百分比(w/v)。

【0068】 本發明之醫藥調配物亦可包含一或多種有機共溶劑，其類型及量使抗 IL-4R 抗體在粗糙處理或攪拌(諸如軌道震盪)條件下穩定。在一些實施例中，有機共溶劑為界面活性劑。如本文所用，術語「界面活性劑」意謂降低溶解其之流體的表面張力及/或降低油與水之間的界面張力的物質。界面活性劑可為離子型或非離子型的。可包括在本發明之調配物中的特定非離子型界面活性劑包括*例如*泊洛沙姆，諸如泊洛沙姆 188，及聚乙二醇(PEG)，諸如 PEG3350。

【0069】 本發明之醫藥調配物中所含之界面活性劑的量可視調配物所需之具體特性以及意欲使用調配物之特定情況及目的而變化。在某些實施例中，調配物可含有至少約 0.0075%的界面活性劑。在某些實施例中，調配物可含有至少約 0.01%的界面活性劑。在某些實施例中，調配物可含有約 0.0075%至約 0.5%的界面活性劑。在某些實施例中，調配物可含有小於 0.2%的界面活性劑。在某些實施例中，調配物可含有約 0.0075%至約 0.19%的界面活性劑；約 0.01%至約 0.19%的界面活性劑；約 0.0075%至約 0.15%的界面活性劑；約 0.01%至約 0.15%的界面活性劑；約 0.0075%至約 0.12%的界面活性劑；約 0.01%至約 0.12%的界

面活性劑；約 0.0075%至約 0.11%的界面活性劑；約 0.01%至約 0.11%的界面活性劑；約 0.0075%至約 0.1%的界面活性劑；約 0.01%至約 0.1%的界面活性劑；約 0.0075%至約 0.09%的界面活性劑；或約 0.01%至約 0.09%的界面活性劑。舉例而言，本發明之調配物可包含約 0.0075%；約 0.01%；約 0.02%；約 0.03%；約 0.04%；約 0.05%；約 0.06%；約 0.07%；約 0.08%；約 0.09%；約 0.1%；約 0.11%；約 0.12%；約 0.13%；約 0.14%；約 0.15%；約 0.16%；約 0.17%；約 0.18%；或約 0.19%的界面活性劑(*例如*泊洛沙姆 188 或 PEG3350)。在一些實施例中，調配物含有小於 0.2%的泊洛沙姆(例如泊洛沙姆 188)。在一些實施例中，調配物含有約 0.0075%至 0.19%的泊洛沙姆 188。在一些實施例中，調配物含有約 0.01%至 0.19%的泊洛沙姆 188。在一些實施例中，調配物含有小於 1%的聚乙二醇(例如 PEG3350)。在一些實施例中，調配物含有約 0.0075%至約 0.5%的 PEG3350。在一些實施例中，調配物含有約 0.01%至 0.19%的 PEG3350。上述百分比中之各者對應於重量/體積百分比(w/v)。

【0070】 在某些實施例中，本發明之醫藥調配物包含至少一種胺基酸。在一些實施例中，胺基酸為精胺酸。在一些實施例中，精胺酸以精胺酸鹽酸鹽之形式提供。在一些情況下，胺基酸(*例如*精胺酸)充當抗 IL-4R 抗體調配物之黏度調節劑。

【0071】 本發明之醫藥調配物中所含之胺基酸的量可視調配物所需之具體特性以及意欲使用調配物之特定情況及目的而變化。在某些實施例中，調配物可含有約 1 mM 至約 200 mM 之胺基酸；約 5 mM 至約 150 mM；約 10 mM 至約 100 mM 之胺基酸；約 20 mM 至約 80 mM 之胺基酸；約 20 mM 至約 30 mM 之胺基酸；約 45 mM 至約 55 mM 之胺基酸；或約 70 mM 至約 80 mM 之胺基酸。舉例而言，本發明之醫藥調配物可包含約 5 mM；約 10 mM；約 15 mM；約 20 mM；約 25 mM；約 30 mM；約 35 mM；約 40 mM；約 45 mM；約 50 mM；約

55 mM；約 60 mM；約 65 mM；約 70 mM；約 75 mM；約 80 mM；約 85 mM；約 90 mM；約 95 mM；或約 100 mM 之胺基酸(*例如*精胺酸)。在一些實施例中，調配物含有約 25 mM 之胺基酸(*例如*精胺酸)。在一些實施例中，調配物含有約 50 mM 之胺基酸(*例如*精胺酸)。在一些實施例中，調配物含有約 75 mM 之胺基酸(*例如*精胺酸)。

例示性調配物

【0072】 根據本發明之一個態樣，醫藥調配物包含：(i)特異性結合於 hIL-4R 之人類抗體(*例如*包含下表 1 中所揭示之一或多個序列的抗體)；(ii)乙酸鹽；(iii)組胺酸；(iv)蔗糖；(v)精胺酸；及(v)包含聚乙二醇或泊洛沙姆之界面活性劑。

【0073】 在一些情況下，穩定的液體醫藥調配物包含：(i)特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)的人類抗體；(ii)濃度為 10 mM 至 15 mM 之乙酸鹽；(iii)濃度為 15 mM 至 25 mM 之組胺酸；(iv)濃度為 2.5% w/v 至 7.5% w/v 之蔗糖；(v)濃度為 20 mM 至 80 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 之聚乙二醇或泊洛沙姆的界面活性劑，其中該調配物之 pH 為 5.7 至 6.1。

【0074】 在一些情況下，穩定的液體醫藥調配物包含：(i)特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)的人類抗體；(ii)濃度為 10 mM 至 15 mM 之乙酸鹽；(iii)濃度為 15 mM 至 25 mM 之組胺酸；(iv)濃度為 2.5% w/v 至 7.5% w/v 之蔗糖；(v)濃度為 20 mM 至 80 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至小於 1% w/v (例如 0.01%至 0.75% w/v，或 0.01%至 0.5% w/v)之聚

乙二醇的界面活性劑，其中該調配物之 pH 為 5.7 至 6.1。

【0075】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 15 mg/mL 至 200 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 10 mM 至 15 mM 之乙酸鹽；(iii)濃度為 15 mM 至 25 mM 之組胺酸；(iv)濃度為 2.5% w/v 至 7.5% w/v 之蔗糖；(v)濃度為 20 mM 至 80 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 之聚乙二醇或泊洛沙姆的界面活性劑，其中該調配物之 pH 為 5.7 至 6.1。

【0076】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 15 mg/mL 至 200 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 10 mM 至 15 mM 之乙酸鹽；(iii)濃度為 15 mM 至 25 mM 之組胺酸；(iv)濃度為 2.5% w/v 至 7.5% w/v 之蔗糖；(v)濃度為 20 mM 至 80 mM 之精胺酸；及(vi)濃度為 0.01% w/v 至 0.19% w/v 之 PEG3350 或泊洛沙姆 188，其中該調配物之 pH 為 5.7 至 6.1。

【0077】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 15 mg/mL 至 200 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 12.5 mM ± 1.25 mM 之乙酸鹽；(iii)濃度為 20 mM ± 2 mM 之組胺酸；(iv)濃度為 5% w/v ± 0.5% w/v 之蔗糖；(v)濃度為 25 mM ± 2.5 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 或濃度為 0.01% w/v 至 0.5% w/v 之 PEG3350 的界面活性劑，其中該調配物之 pH 為 5.9 ± 0.3 或 pH 為 5.9 ± 0.2。

【0078】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 15 mg/mL

至 200 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 12.5 mM ± 1.25 mM 之乙酸鹽；(iii)濃度為 20 mM ± 2 mM 之組胺酸；(iv)濃度為 5% w/v ± 0.5% w/v 之蔗糖；(v)濃度為 25 mM ± 2.5 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 之泊洛沙姆 188 的界面活性劑，其中該調配物之 pH 為 5.9 ± 0.3 或 pH 為 5.9 ± 0.2。

【0079】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 100 mg/mL 至 200 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 10 mM 至 15 mM 之乙酸鹽；(iii)濃度為 15 mM 至 25 mM 之組胺酸；(iv)濃度為 2.5% w/v 至 7.5% w/v 之蔗糖；(v)濃度為 20 mM 至 80 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 之聚乙二醇或泊洛沙姆的界面活性劑，其中該調配物之 pH 為 5.7 至 6.1。

【0080】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 100 mg/mL 至 200 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 10 mM 至 15 mM 之乙酸鹽；(iii)濃度為 15 mM 至 25 mM 之組胺酸；(iv)濃度為 2.5% w/v 至 7.5% w/v 之蔗糖；(v)濃度為 20 mM 至 80 mM 之精胺酸；及(vi)濃度為 0.01% w/v 至 0.19% w/v 之 PEG3350 或泊洛沙姆 188，其中該調配物之 pH 為 5.7 至 6.1。

【0081】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 100 mg/mL 至 200 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 12.5 mM ± 1.25 mM 之乙酸鹽；(iii)

濃度為 20 mM ± 2 mM 之組胺酸；(iv)濃度為 5% w/v ± 0.5% w/v 之蔗糖；(v)濃度為 25 mM ± 2.5 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 或濃度為 0.01% w/v 至 0.5% w/v 之 PEG3350 的界面活性劑，其中該調配物之 pH 為 5.9 ± 0.3 或 pH 為 5.9 ± 0.2。

【0082】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 100 mg/mL 至 200 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 12.5 mM ± 1.25 mM 之乙酸鹽；(iii)濃度為 20 mM ± 2 mM 之組胺酸；(iv)濃度為 5% w/v ± 0.5% w/v 之蔗糖；(v)濃度為 25 mM ± 2.5 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 之泊洛沙姆 188 的界面活性劑，其中該調配物之 pH 為 5.9 ± 0.3 或 pH 為 5.9 ± 0.2。

【0083】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 150 mg/mL ± 10 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 10 mM 至 15 mM 之乙酸鹽；(iii)濃度為 15 mM 至 25 mM 之組胺酸；(iv)濃度為 2.5% w/v 至 7.5% w/v 之蔗糖；(v)濃度為 20 mM 至 80 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 之聚乙二醇或泊洛沙姆的界面活性劑，其中該調配物之 pH 為 5.7 至 6.1。

【0084】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 150 mg/mL ± 10 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 10 mM 至 15 mM 之乙酸鹽；(iii)濃度為 15 mM 至 25 mM 之組胺酸；(iv)濃度為 2.5% w/v 至 7.5% w/v 之蔗糖；(v)濃度為 20 mM 至 80 mM 之精胺酸；及(vi)濃度為 0.01% w/v 至 0.19% w/v 之 PEG3350

或泊洛沙姆 188，其中該調配物之 pH 為 5.7 至 6.1。

【0085】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 150 mg/mL ± 10 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 12.5 mM ± 1.25 mM 之乙酸鹽；(iii)濃度為 20 mM ± 2 mM 之組胺酸；(iv)濃度為 5% w/v ± 0.5% w/v 之蔗糖；(v)濃度為 25 mM ± 2.5 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 或濃度為 0.01% w/v 至 0.5% w/v 之 PEG3350 的界面活性劑，其中該調配物之 pH 為 5.9 ± 0.3 或 pH 為 5.9 ± 0.2。

【0086】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 150 mg/mL ± 10 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 12.5 mM ± 1.25 mM 之乙酸鹽；(iii)濃度為 20 mM ± 2 mM 之組胺酸；(iv)濃度為 5% w/v ± 0.5% w/v 之蔗糖；(v)濃度為 25 mM ± 2.5 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 之泊洛沙姆 188 的界面活性劑，其中該調配物之 pH 為 5.9 ± 0.3 或 pH 為 5.9 ± 0.2。

【0087】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 175 mg/mL ± 10 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 10 mM 至 15 mM 之乙酸鹽；(iii)濃度為 15 mM 至 25 mM 之組胺酸；(iv)濃度為 2.5% w/v 至 7.5% w/v 之蔗糖；(v)濃度為 20 mM 至 80 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 之聚乙二醇或泊洛沙姆的界面活性劑，其中該調配物之 pH 為 5.7 至 6.1。

【0088】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 175

mg/mL ± 10 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 10 mM 至 15 mM 之乙酸鹽；(iii)濃度為 15 mM 至 25 mM 之組胺酸；(iv)濃度為 2.5% w/v 至 7.5% w/v 之蔗糖；(v)濃度為 20 mM 至 80 mM 之精胺酸；及(vi)濃度為 0.01% w/v 至 0.19% w/v 之 PEG3350 或泊洛沙姆 188，其中該調配物之 pH 為 5.7 至 6.1。

【0089】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 175 mg/mL ± 10 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 12.5 mM ± 1.25 mM 之乙酸鹽；(iii)濃度為 20 mM ± 2 mM 之組胺酸；(iv)濃度為 5% w/v ± 0.5% w/v 之蔗糖；(v)濃度為 25 mM ± 2.5 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 或濃度為 0.01% w/v 至 0.5% w/v 之 PEG3350 的界面活性劑，其中該調配物之 pH 為 5.9 ± 0.3 或 pH 為 5.9 ± 0.2。

【0090】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 175 mg/mL ± 10 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 12.5 mM ± 1.25 mM 之乙酸鹽；(iii)濃度為 20 mM ± 2 mM 之組胺酸；(iv)濃度為 5% w/v ± 0.5% w/v 之蔗糖；(v)濃度為 25 mM ± 2.5 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 之泊洛沙姆 188 的界面活性劑，其中該調配物之 pH 為 5.9 ± 0.3 或 pH 為 5.9 ± 0.2。

【0091】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 175 mg/mL ± 10 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺

基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 12.5 mM ± 1.25 mM 之乙酸鹽；(iii)濃度為 20 mM ± 2 mM 之組胺酸；(iv)濃度為 5% w/v ± 0.5% w/v 之蔗糖；(v)濃度為 50 mM ± 2.5 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 或濃度為 0.01% w/v 至 0.5% w/v 之 PEG3350 的界面活性劑，其中該調配物之 pH 為 5.9 ± 0.3 或 pH 為 5.9 ± 0.2。

【0092】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 175 mg/mL ± 10 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 12.5 mM ± 1.25 mM 之乙酸鹽；(iii)濃度為 20 mM ± 2 mM 之組胺酸；(iv)濃度為 5% w/v ± 0.5% w/v 之蔗糖；(v)濃度為 50 mM ± 2.5 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 之泊洛沙姆 188 的界面活性劑，其中該調配物之 pH 為 5.9 ± 0.3 或 pH 為 5.9 ± 0.2。

【0093】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 175 mg/mL ± 10 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 12.5 mM ± 1.25 mM 之乙酸鹽；(iii)濃度為 20 mM ± 2 mM 之組胺酸；(iv)濃度為 5% w/v ± 0.5% w/v 之蔗糖；(v)濃度為 75 mM ± 2.5 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 或濃度為 0.01% w/v 至 0.5% w/v 之 PEG3350 的界面活性劑，其中該調配物之 pH 為 5.9 ± 0.3 或 pH 為 5.9 ± 0.2。

【0094】 在一些情況下，穩定的液體醫藥調配物包含：(i)濃度為 175 mg/mL ± 10 mg/mL 之人類抗體，其中該抗體特異性結合於人類 IL-4Rα 且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；(ii)濃度為 12.5 mM ± 1.25 mM 之乙酸鹽；(iii)

濃度為 20 mM ± 2 mM 之組胺酸；(iv)濃度為 5% w/v ± 0.5% w/v 之蔗糖；(v)濃度為 75 mM ± 2.5 mM 之精胺酸；及(vi)包含濃度為 0.01% w/v 至 0.19% w/v 之泊洛沙姆 188 的界面活性劑，其中該調配物之 pH 為 5.9 ± 0.3 或 pH 為 5.9 ± 0.2。

【0095】 在上文或本文所論述之醫藥調配物之各種實施例中之任一者中，人類 IL-4R 抗體可包含人類 IgG1 重鏈恆定區。

【0096】 在上文或本文所論述之醫藥調配物之各種實施例中之任一者中，人類 IL-4R 抗體可包含人類 IgG4 重鏈恆定區。

【0097】 在一些實施例中，人類 IL-4R 抗體可包含含有 SEQ ID NO: 9 之胺基酸序列的重鏈及含有 SEQ ID NO: 10 之胺基酸序列的輕鏈。

【0098】 本發明所涵蓋之醫藥調配物的其他非限制性實例在本文別處列出，包括下文呈現之實施例。

醫藥調配物之穩定性

【0099】 本發明之醫藥調配物展現高水平的穩定性。如本文所用之關於醫藥調配物的術語「穩定」意謂醫藥調配物內之抗體在儲存規定時間量後保留可接受程度的結構及/或功能及/或生物活性。即使調配物中所含之抗體在儲存規定時間量後未 100%維持其結構及/或功能及/或生物活性，該調配物亦可為穩定的。在某些情況下，抗體在儲存規定時間量後維持約 90%、約 95%、約 96%、約 97%、約 98%或約 99%之結構及/或功能及/或生物活性可視為「穩定」。

【0100】 穩定性可*尤其*藉由在規定溫度下或在應力條件(*例如*攪拌)下儲存規定時間量後，測定調配物內形成聚集體之抗體的百分比來量測，其中穩定性與形成的聚集體百分比成反比。聚集抗體之百分比可*尤其*藉由尺寸排阻層析(*例如*尺寸排阻高效液相層析[SE-HPLC]或尺寸排阻超高效液相層析[SE-UPLC])來測定。如本文所用之片語「可接受之穩定性程度」意謂在給定溫度下或在特

定應力條件下儲存規定時間量後，在調配物中之聚集體中可偵測到至多約15%、10%、5%、4%、3%、2.5%、2%、1.5%、1%、0.5%或0.1%之抗體。量測穩定性之前的規定時間量可為至少2週、至少28天、至少1個月、至少2個月、至少3個月、至少4個月、至少5個月、至少6個月、至少7個月、至少8個月、至少9個月、至少10個月、至少11個月、至少12個月、至少18個月、至少24個月、至少30個月、至少36個月或更長時間。當評定穩定性時，醫藥調配物可儲存之溫度可為約-80℃至約 45℃的任何溫度，*例如*儲存在約-80℃、約-30℃、約-20℃、約0℃、約4°至8℃、約5℃、約25℃、約35℃、約37℃或約45℃下。經調配抗體可經受之「應力條件」可為攪拌應力(*例如*渦旋)持續10分鐘、20分鐘、30分鐘、40分鐘、50分鐘、60分鐘、70分鐘、80分鐘、90分鐘、100分鐘、110分鐘、120分鐘、150分鐘、180分鐘或更長時間。舉例而言，包含抗IL-4R抗體之醫藥調配物若在5℃下儲存九個月後，偵測到小於約2%、1.75%、1.5%、1.25%、1%、0.75%、0.5%、0.25%或0.1%之抗體呈聚集形式，則可視為穩定的。醫藥調配物若在45℃下儲存56天後，偵測到小於約12%之抗體呈聚集形式，則亦可視為穩定的。醫藥調配物若在45℃下儲存42天後，偵測到小於約10%或小於約9%之抗體呈聚集形式，則亦可視為穩定的。醫藥調配物若在45℃下儲存28天後，偵測到小於約8%或小於約7.5%或小於約7%之抗體呈聚集形式，則亦可視為穩定的。醫藥調配物若在45℃下儲存14天後，偵測到小於約6%之抗體呈聚集形式，則亦可視為穩定的。醫藥調配物若在-20℃、-30℃或-80℃下儲存三個月後，偵測到小於約2%、1.9%、1.8%、1.7%、1.6%、1.5%、1%、0.5%或0.1%之抗體呈聚集形式，則亦可視為穩定的。醫藥調配物若在室溫下攪拌(*例如*經由渦旋) 120分鐘後，偵測到小於3%或小於2.5%之抗體呈聚集形式，則亦可視為穩定的。在一些情況下，醫藥調配物若在25℃下攪拌24小時後，藉由SE-UPLC測定包含不超過4%的高分子量(HMW)物種，則可視為穩定的。在一些情況下，

調配物若在 25℃下攪拌 24 小時且(i)在 5℃下儲存 6、12 或 18 個月，或(ii)在 25℃下儲存 6 個月後，藉由 SE-UPLC 測定包含不超過 4%的高分子量(HMW)物種，則可視為穩定的。

【0101】 穩定性亦可*尤其*藉由在規定溫度下儲存規定時間量後測定調配物內之顆粒調配物來量測。顆粒形成可例如藉由顯微鏡技術或微流成像技術來確定。

【0102】 眾所周知，常規用於產生重組抗體之哺乳動物細胞株可含有可與抗體共純化且存在於抗體之醫藥調配物中的酶。在一些情況下，此類酶可隨時間推移降解醫藥調配物之賦形劑，且由此導致形成亞可見顆粒(*例如*約 10-25 μm 或更大)。舉例而言，磷脂酶為將磷脂水解成脂肪酸及其他產物之脂肪酶。磷脂酶分為四大類：磷脂酶 A (包括磷脂酶 A1 及磷脂酶 A2)、磷脂酶 B 以及磷酸二酯酶磷酸二酯酶 C 及磷酸二酯酶 D。除了典型磷脂酶之外，存在於溶酶體內腔之磷脂酶 B 樣酶被認為參與脂質催化。舉例而言，基於序列同源性及亞細胞定位，推測磷脂酶 B 樣 2 (PLBL2)具有酯酶活性(Jensen *等人*，Biochem. J. 402: 449-458 (2007))。PLBL2 在倉鼠、大鼠、小鼠、人類及牛中高度保守，且可在某些過程中與在哺乳動物細胞株中製造之一些類別的所關注蛋白質(*例如*治療性抗體，諸如抗 IL-4R 抗體)共純化。雖然可經由純化移除此類酶或包括抑制劑(*例如*酯酶抑制劑)以抵消酶活性(例如美國專利案第 10,342,876 號中所揭示)，但選擇防止顆粒形成同時亦穩定醫藥調配物中之抗體的賦形劑亦為所關注的。因此，在一些實施例中，本發明之調配物包含可偵測量之磷脂酶(例如 PLBL2)。偵測及定量磷脂酶之存在及活性的方法為此項技術中已知的。在一些實施例中，磷脂酶係藉由免疫分析(例如 ELISA)來偵測。在一些實施例中，磷脂酶係藉由液相層析-質譜分析(LC-MS)來偵測

【0103】 因此，醫藥調配物(含有磷脂酶)若在規定溫度(*例如* 5℃)下儲存

一段時間(*例如*6、12、18、24 或 36 個月或更長時間)後，在 2.25 mL 之體積內鑑別出不超過規定數目之顆粒(*例如*每個容器 3000 個顆粒、1000 個顆粒、500 個顆粒、250 個顆粒、100 個顆粒或 50 個顆粒≥10 微米)，則可視為穩定的。舉例而言，醫藥調配物若在 5℃下儲存 24 個月後，經由顯微術在 2.25 mL 之體積內鑑別出不超過 1000 個顆粒，則可視為穩定的。醫藥調配物若在 5℃下儲存 24 個月後，經由顯微術在 2.25 mL 之體積內鑑別出不超過 500 個顆粒，則亦可視為穩定的。醫藥調配物若在 5℃下儲存 24 個月後，經由顯微術在 2.25 mL 之體積內鑑別出不超過 250 個顆粒，則亦可視為穩定的。醫藥調配物若在 5℃下儲存 24 個月後，經由顯微術在 2.25 mL 之體積內鑑別出不超過 150 個顆粒，則亦可視為穩定的。醫藥調配物若在 5℃下儲存 36 個月後，經由顯微術在 2.25 mL 之體積內鑑別出不超過 1000 個顆粒，則亦可視為穩定的。醫藥調配物若在 5℃下儲存 36 個月後，經由顯微術在 2.25 mL 之體積內鑑別出不超過 500 個顆粒，則亦可視為穩定的。醫藥調配物若在 5℃下儲存 36 個月後，經由顯微術在 2.25 mL 之體積內鑑別出不超過 250 個顆粒，則亦可視為穩定的。醫藥調配物若在 5℃下儲存 36 個月後，經由顯微術在 2.25 mL 之體積內鑑別出不超過 150 個顆粒，則亦可視為穩定的。醫藥調配物若在 5℃下儲存 36 個月後，經由顯微術在 2.25 mL 之體積內鑑別出不超過 100 個顆粒，則亦可視為穩定的。醫藥調配物若在 5℃下儲存 36 個月後，經由顯微術在 2.25 mL 之體積內鑑別出不超過 50 個顆粒，則亦可視為穩定的。

【0104】 穩定性亦可*尤其*藉由在給定溫度下儲存規定時間量後測定調配物中剩餘的原生抗體之百分比來量測。原生抗體之百分比可*尤其*藉由尺寸排阻層析(*例如*尺寸排阻高效液相層析[SE-HPLC])來測定。如本文所用之片語「可接受之穩定性程度」意謂在給定溫度下儲存規定時間量後，在調配物中可偵測到至少 90%之原生形式的抗體。在某些實施例中，在給定溫度下儲存規定時間量

後，在調配物中可偵測到至少約 90%、91%、92%、93%、94%、95%、96%、97%、98%、99%或 100%之原生形式的抗體。量測穩定性之前的規定時間量可為至少 1 個月、至少 2 個月、至少 3 個月、至少 4 個月、至少 5 個月、至少 6 個月、至少 7 個月、至少 8 個月、至少 9 個月、至少 10 個月、至少 11 個月、至少 12 個月、至少 18 個月、至少 24 個月、至少 30 個月、至少 36 個月或更長時間。當評定穩定性時，醫藥調配物可儲存之溫度可為約-80℃至約 45℃的任何溫度，*例如*儲存在約-80℃、約-30℃、約-20℃、約 0℃、約 2°至 8℃、4°至 8℃、約 5℃、約 25℃、約 35℃、約 37℃或約 45℃下。

【0105】 穩定性亦可*尤其*藉由測定在離子交換期間在比抗體之主要溶離份(「主要電荷形式」)酸性更強的溶離份(「酸性形式」)中遷移之抗體的百分比來量測，其中穩定性與酸形式之抗體的分率成反比。雖然不希望受理論束縛，但抗體之去醯胺化可能使抗體帶更多負電荷，且因此相對於未去醯胺之抗體酸性更強(參見*例如* Robinson, N., Protein Deamidation, *PNAS*, 4 月 16 日, 2002, 99(8):5283-5288)。「酸化」抗體之百分比可藉由離子交換層析(*例如*陽離子交換高效液相層析[CEX-HPLC]或陽離子交換超高效液相層析[CEX-UPLC])來測定。如本文所用之片語「可接受之穩定性程度」意謂在給定溫度下儲存規定時間量後，在調配物中可偵測到至多 50%、45%、40%、35%、30%、25%、20%、15%、10%、5%、4%、3%、2%、1%、0.5%或 0.1%之抗體呈酸性形式。量測穩定性之前的規定時間量可為至少 2 週、至少 28 天、至少 1 個月、至少 2 個月、至少 3 個月、至少 4 個月、至少 5 個月、至少 6 個月、至少 7 個月、至少 8 個月、至少 9 個月、至少 10 個月、至少 11 個月、至少 12 個月、至少 18 個月、至少 24 個月、至少 30 個月、至少 36 個月或更長時間。當評定穩定性時，醫藥調配物可儲存之溫度可為約-80℃至約 45℃的任何溫度，*例如*儲存在約-80℃、約-30℃、約-20℃、約 0℃、約 4°至 8℃、約 5℃、約 25℃或約 45℃下。

【0106】 量測抗體與其目標之結合親和力亦可用於評定穩定性。舉例而言，本發明之調配物若在*例如*-80℃、-30℃、-20℃、5℃、25℃、37℃、45℃等下儲存規定時間量(*例如* 14 天至 9 個月)後，調配物內所含之抗 IL-4R 抗體與 hIL-4Rα 結合之親和力為該抗體在該儲存前之結合親和力的至少 80%、85%、90%、95%或更高，則可視為穩定的。結合親和力可藉由任何方法測定，諸如 ELISA 或電漿子共振。生物活性可藉由例如量測 IL-4R 系統在抗體存在下之下游活性，且將該活性與 IL-4R 系統在抗體不存在下之活性進行比較來確定。

【0107】 提及醫藥調配物在特定時間段「後」的穩定性欲意謂在或約在特定時間段結束時對穩定性參數(*例如*原生形式%、HMW 物種%或酸性形式%)進行量測，且不欲意謂醫藥調配物在此後必然維持所量測參數之相同程度的穩定性。舉例而言，提及 12 個月後的特定穩定性意謂在或約在研究開始後的 12 個月進行穩定性量測。用於評定調配物中抗體之穩定性的額外方法展示於下文所呈現之實例中。

【0108】 如以下實例所示，本發明部分基於以下發現：將所主張之賦形劑與抗 IL-4R 抗體組合產生歷經長期(*例如* 36 個月)儲存穩定的調配物。

容器及投予方法

【0109】 本發明之醫藥調配物可容納於任何適用於儲存藥物及其他治療性組合物之容器內。舉例而言，醫藥調配物可容納於具有規定容積之密封且滅菌的塑膠或玻璃容器內，諸如小瓶、安瓿、注射器、藥筒、瓶子或 IV 袋。可使用不同類型的小瓶來容納本發明之調配物，包括*例如*透明及不透明(*例如*琥珀色)的玻璃或塑膠小瓶。同樣，可使用任何類型的注射器來容納及/或投予本發明之醫藥調配物。在一些實施例中，醫藥調配物容納於預填充注射器內。在一些實施例中，醫藥調配物容納於預填充固定針頭注射器內。

【0110】 本發明之醫藥調配物可容納於「正常鎢」注射器或「低鎢」注射器內。如一般熟習此項技術者應瞭解，製造玻璃注射器之製程一般涉及使用熱鎢棒，其用以刺穿玻璃，從而形成一個孔，液體可自該孔抽取且自注射器排出。此製程導致痕量鎢沈積於注射器之內表面上。後續洗滌及其他加工步驟可用於減少注射器中鎢之量。如本文所用，術語「正常鎢」意謂注射器含有大於 500 十億分率(ppb)之鎢。術語「低鎢」意謂注射器含有小於 500 ppb 之鎢。舉例而言，根據本發明之低鎢注射器可含有小於約 490、480、470、460、450、440、430、420、410、390、350、300、250、200、150、100、90、80、70、60、50、40、30、20、10 或更少 ppb 之鎢。

【0111】 注射器中使用的橡膠柱塞及用於封閉小瓶開口之橡膠塞可經塗佈以防止注射器或小瓶之藥物內容物受到污染及/或保持其穩定性。因此，根據某些實施例，本發明之醫藥調配物可容納於包含經塗佈之柱塞的注射器內，或容納於用經塗佈之橡膠塞密封的小瓶內。舉例而言，柱塞或塞子可塗佈有氟碳膜。適合與含有本發明之醫藥調配物的小瓶及注射器一起使用的經塗佈之塞子及/或柱塞之實例在*例如*美國專利第 4,997,423 號；第 5,908,686 號；第 6,286,699 號；第 6,645,635 號；及第 7,226,554 號中提及，該等專利之內容以全文引用的方式併入本文中。可在本發明之情形中使用的特定例示性經塗佈之橡膠塞子及柱塞可以商品名「FluroTec®」購自 West Pharmaceutical Services, Inc. (Lionville, PA)。根據本發明之某些實施例，醫藥調配物可容納於包含經氟碳塗佈之柱塞的低鎢注射器內。在一些實施例中，容器為注射器，諸如 Ompi EZ-Fill™ 注射器或 BD Neopak™ 注射器。在一些情況下，注射器為具有 1 mL iWest 活塞、27G 薄壁針頭及 FM30 針頭護罩或 BD260 針頭護罩之 1 mL 長玻璃注射器。在一些情況下，注射器為 2.25 mL 玻璃注射器(*例如* Nuova Ompi)。在各種實施例中，注射器為 0.5 mL、0.6 mL、0.7 mL、0.8 mL、0.9 mL、1.0 mL、1.1 mL、1.2 mL、1.3

mL、1.4 mL、1.5 mL、1.6 mL、1.7 mL、1.8 mL、1.9 mL、2.0 mL、2.1 mL、2.2 mL、2.3 mL、2.4 mL、2.5 mL、2.6 mL、2.7 mL、2.8 mL、2.9 mL、3.0 mL、3.5 mL、4.0 mL、4.5 mL、5.0 mL、5.5 mL、6.0 mL、6.5 mL、7.0 mL、7.5 mL、8.0 mL、8.5 mL、9.0 mL、9.5 mL 或 10 mL 注射器(*例如*玻璃注射器)。

【0112】 醫藥調配物可藉由非經腸途徑向患者投予，諸如注射(*例如*皮下、靜脈內、肌肉內、腹膜內等)或經皮、經黏膜、經鼻、經肺及/或經口投予。許多可重複使用的筆式及/或自動注射器遞送裝置可用於皮下遞送本發明之醫藥調配物。實例包括但不限於 AUTOPEN™ (Owen Mumford, Inc., Woodstock, UK)、DISETRONIC™筆(Disetronic Medical Systems, Bergdorf, Switzerland)、HUMALOG MIX 75/25™筆、HUMALOG™筆、HUMALIN 70/30™筆(Eli Lilly and Co., Indianapolis, IN)、NOVOPEN™ I、II 及 III (Novo Nordisk, Copenhagen, Denmark)、NOVOPEN JUNIOR™ (Novo Nordisk, Copenhagen, Denmark)、BD™筆(Becton Dickinson, Franklin Lakes, NJ)、OPTIPEN™、OPTIPEN PRO™、OPTIPEN STARLET™及 OPTICLIK™ (sanofi-aventis, Frankfurt, Germany)，僅舉數例。應用於皮下遞送本發明之醫藥組合物的一次性筆式及/或自動注射器遞送裝置之實例包括但不限於 SOLOSTAR™筆(sanofi-aventis)、FLEXPEN™ (Novo Nordisk)及 KWIKPEN™ (Eli Lilly)、SURECLICK™ 自動注射器(Amgen, Thousand Oaks, CA)、PENLET™ (Haselmeier, Stuttgart, Germany)、EPIPEN (Dey, L.P.)及 HUMIRA™ 筆(Abbott Labs, Abbott Park, IL)，僅舉數例。在一些情況下，醫藥調配物容納於特別適合與自動注射器一起使用的注射器中。皮下注射可使用 20 至 30 號針頭或 25 至 30 號針頭來投予。在一些情況下，皮下注射可使用 25 號針頭來投予。在一些情況下，皮下注射可使用 27 號針頭來投予。在一些情況下，皮下注射可使用 29 號針頭來投予。

【0113】 另一類型之遞送裝置可包括安全系統。此類裝置可能相對便宜，

且一旦注射完成，可操作以手動或自動地將安全套管延伸至針頭上。安全系統之實例可包括 West Pharmaceutical 之 ERIS 裝置或 Becton Dickinson 之 UltraSafe 裝置。另外，本文亦考慮使用大容量裝置(「LVD」)或推注注射器來遞送本發明之醫藥調配物。在一些情況下，LVD 或推注注射器可經配置以向患者注射藥物。舉例而言，LVD 或推注注射器可經配置以遞送「大」體積藥物(通常約 2 mL 至約 10mL)。

【0114】 在一些實施例中，包含抗 IL-4R 抗體之醫藥組合物係使用藥物遞送裝置來投予，該藥物遞送裝置為如 ISO 11608-1:2014(E)之第 5.2 節的表 1 中所述之基於針頭之注射系統。如 ISO 11608-1:2014(E)中所述，基於針頭之注射系統可大致分為多劑量容器系統及單劑量(部分或完全排空)容器系統。容器可為可更換容器或整合式不可更換容器。

【0115】 如 ISO 11608-1:2014(E)中進一步描述，多劑量容器系統可涉及具有可更換容器之基於針頭之注射裝置。在此類系統中，各容器容納多個劑量，其大小可為固定的或可變的(由使用者預先設定)。另一種多劑量容器系統可涉及具有整合式不可更換容器之基於針頭之注射裝置。在此類系統中，各容器容納多個劑量，其大小可為固定的或可變的(由使用者預先設定)。

【0116】 如 ISO 11608-1:2014(E)中進一步描述，單劑量容器系統可涉及具有可更換容器之基於針頭之注射裝置。在此類系統之一個實例中，各容器容納單一劑量，由此排出整個可遞送體積(完全排空)。在另一個實例中，各容器容納單一劑量，由此排出可遞送體積之一部分(部分排空)。亦如 ISO 11608-1:2014(E)中所述，單劑量容器系統可涉及具有整合式不可更換容器之基於針頭之注射裝置。在此類系統之一個實例中，各容器容納單一劑量，由此排出整個可遞送體積(完全排空)。在另一個實例中，各容器容納單一劑量，由此排出可遞送體積之一部分(部分排空)。

【0117】 國際公開案 WO2015/004052 中描述一種具有手動針頭插入之例示性套管觸發式自動注射器。國際公開案 WO2016/193346 及 WO2016/193348 中描述例示性聲響(audible)劑量結束反饋機構。國際公開案 WO2016/193352 中描述一種使用自動注射器後的例示性針頭安全機構。國際公開案 WO2016/193353 中描述一種用於注射器自動注射器之例示性針頭護套移除機構。國際公開案 WO2016/193355 中描述一種用於支撐注射器軸向位置之例示性支撐機構。

【0118】 本發明之醫藥調配物亦可包含於單位劑型中。如本文所用，術語「單位劑型」係指適合作為待治療患者之單位劑量的物理離散單位，各單位含有預定量之活性化合物，經計算以與所需醫藥載劑、稀釋劑或賦形劑結合產生期望的治療效果。在各種實施例中，單位劑型容納於如本文所論述之容器中。本發明之調配物中活性成分(*例如*抗 IL-4R 抗體)之實際劑量水平可改變，以獲得有效達成特定患者、組合物及投予模式期望的治療反應的活性成分之量，且對患者無不良影響。所選劑量水平將視多種藥物動力學因素而定，包括所採用之本發明之特定組合物的活性；投予途徑；投予時間；所採用之特定化合物的排泄率；治療持續時間；與所採用之特定組成物組合使用之其他藥物、化合物及/或材料；所治療之患者的年齡、性別、體重、狀況、一般健康狀況及先前病史；及醫學技術中熟知之類似因素。如本文所用，術語「稀釋劑」係指適用於改變或實現如本文所述之一或多個例示性或適當濃度的溶液。

【0119】 在各種實施例中，單位劑型含有欲供單次使用之量的活性成分(*例如*抗 IL-4R 抗體)。在各種實施例中，單位劑型中活性成分之量為約 0.1 mg 至約 5000 mg、約 100 mg 至約 1000 mg、及約 100 mg 至約 500 mg、約 100 mg 至約 400 mg、約 100 mg 至約 200 mg、約 250 mg 至約 350 mg、約 125 mg 至約 175 mg、約 275 mg 至約 325 mg 或其範圍或區間。舉例而言，意欲包括使用任何上述值(或包含於上述範圍內之值)之組合作為上限及/或下限的值範圍。在一特定

實施例中調配物通常以呈單位劑型之液體形式供應。在一些實施例中，單位劑型含有約 100 mg 之活性成分。在一些實施例中，單位劑型含有約 150 mg。在一些實施例中，單位劑型含有約 200 mg。在一些實施例中，單位劑型含有約 300 mg。在一些實施例中，單位劑型含有約 350 mg。在一些實施例中，單位劑型含有約 600 mg。在一些實施例中，根據本發明之單位劑型適合於向患者皮下投予。

【0120】 本發明亦包括製備單位劑型之方法。在一例示性實施例中，用於製備醫藥單位劑型之方法包括將前述實施例中之任一者之調配物組合於適合的容器(*例如*本文所論述之彼等容器)中。

醫藥調配物之治療用途

【0121】 本發明之醫藥調配物*尤其*可用於治療、預防及/或改善任何與 IL-4R 活性相關之疾病或病症。

【0122】 本發明之治療方法包含向個體投予任何包含如本文所揭示之抗 hIL-4R 抗體的調配物。投予醫藥調配物之個體可為*例如*需要此類治療、預防及/或改善，或將另外受益於抑制或減弱 IL-4R 及/或 IL-4R 介導之活性的任何人類或非人類動物。本發明進一步包括本文所揭示之醫藥調配物中之任一者在製造用於治療、預防及/或改善任何與 IL-4R 活性相關之疾病或病症的藥物中之用途。

【0123】 在一些實施例中，與 IL-4R 活性相關之疾病或病症為發炎性病況、過敏性病況、肺/呼吸道病症、胃腸道病症或皮膚病症。在一些實施例中，該疾病或病症為 2 型發炎性病症。在一些實施例中，該疾病或病症為異位性疾病。與 IL-4R 活性相關之疾病及病症的非限制性實例包括過敏(例如食物過敏或環境過敏)、過敏反應、過敏性支氣管肺麴菌病、斑禿、哮喘(包括輕度、中度或重度哮喘、持續性哮喘或過敏性哮喘)、關節炎(包括敗血性關節炎)、異位性皮膚炎(包括中度或重度異位性皮膚炎)、異位性角膜結膜炎、自體免疫性溶血性貧

血、自體免疫性淋巴增生症候群、自體免疫性葡萄膜炎、巴雷斯特氏食道症(Barrett's esophagus)、良性前列腺增生、支氣管擴張、大皰性類天疱瘡、查格-施特勞斯症候群(Churg-Strauss syndrome)、慢性特發性蕁麻疹、慢性誘導性蕁麻疹、冷誘導性蕁麻疹、接觸性皮炎(例如過敏性接觸性皮炎)、COPD、嗜酸性球性食道炎、嗜酸性球性十二指腸炎、嗜酸性球性胃腸炎、格雷氏病(Grave's disease)、泡疹樣皮炎、肥厚性疤痕、發炎性腸病、川崎病(Kawasaki disease)、鼻息肉、腎病、奈瑟頓氏症候群(Netherton's syndrome)、子癇前症、結節性癢疹、搔癢症(例如原因不明的慢性搔癢症)、鼻炎(例如過敏性鼻炎)、鼻竇炎(例如過敏性真菌性鼻竇炎、伴有或不伴有鼻息肉之慢性鼻竇炎)、硬皮病、鐮狀細胞病、休格連氏症候群(Sjogren's syndrome)、結核病、潰瘍性結腸炎及惠普爾氏病(Whipple's Disease)。

【0124】 在一些實施例中，本發明提供套組，其包含如本文所論述之醫藥調配物(*例如*具有調配物或單位劑型之容器)及具有使用該醫藥調配物治療如上文所論述之疾病或病症之說明書的封裝或標籤(*例如*藥品說明書)。在一些情況下，說明書提供如本文所論述之單位劑型用於治療疾病或病症之用途。

【0125】 本文所提及之序列及相應 SEQ ID NO 的概述展示於下表 1 中。

表 1：非正式序列表

SEQ ID NO	序列	描述
1	EVQLVESGGGLEQPGGSLRLSCAGSGFTFRDYAMTWVRQAPGKGLEWVSSISGSGGNTYYADSVKGRFTISRDNSKNTLYLQMNSLRAEDTAVYYCAKDRLSITIRPRYYGLDVWGQGTTVTVS	度匹魯單抗 HCVR 胺基酸序列
2	DIVMTQSPLSLPVTPGEPASISCRSSQSLLYSIGYNYLDWYLQKSGQSPQLLIYLGSNRASGVPDRFSGSGSGTDFTLKISRVEAEDVGFYYCMQALQTPYTFGQGTKLEIK	度匹魯單抗 LCVR 胺基酸序列
3	GFTFRDYA	度匹魯單抗 HCDR1 胺基酸序列

4	ISGSGGNT	度匹魯單抗 HCDR2 胺基酸序列
5	AKDRLSITIRPRYYGLDV	度匹魯單抗 HCDR3 胺基酸序列
6	QSLLYSIGYNY	度匹魯單抗 LCDR1 胺基酸序列
7	LGS	度匹魯單抗 LCDR2 胺基酸序列
8	MQALQTPYT	度匹魯單抗 LCDR3 胺基酸序列
9	EVQLVESGGGLEQPGGSLRLSCAGSGFTFRDYAMTWVRQAPGKGLEWVSSISGSGGNTYYADSVKGRFTISRDNSKNTLYLQMNSLRAEDTAVYYCAKDRLSITIRPRYYGLDVWGQGTTVTVSSASTKGPSVFPLAPCSRSTSESTAALGCLVKDYFPEPVTVSWNSGALTSGVHTFPAVLQSSGLYSLSSVVTVPSSSLGTKTYTCNVDHKPSNTKVDKRVESKYGPPCPPCPAPEFLGGPSVFLFPPKPKDTLMISRTPEVTCVVVDVSQEDPEVQFNWYVDGVEVHNAKTKPREEQFNSTYRVVSVLTVLHQDWLNGKEYKCKVSNKGLPSSIEKTISKAKGQPREPQVYTLPPSQEEMTKNQVSLTCLVKGFYPSDIAVEWESNGQPENNYKTTPPVLDSDGSFFLYSRLTVDKSRWQEGNVFSCSVMHEALHNHYTQKSLSLSLGK	度匹魯單抗重鏈胺基酸序列
10	DIVMTQSPLSLPVTPGEPASISCRSSQSLLYSIGYNYLDWYLQKSGQSPQLLIYLGSNRASGVPDRFSGSGSGTDFTLKISRVEAEDVGFYYCMQALQTPYTFGQGTKLEIKRTVAAPSVFIFPPSDEQLKSGTASVVCLLNNFYPREAKVQWKVDNALQSGNSQESVTEQDSKDSTYSLSSTLTLSKADYEKHKVYACEVTHQGLSSPVTKSFNRGEC	度匹魯單抗輕鏈胺基酸序列
11	MKVLQEPTCVSDYMSISTCEWKMNGPTNCSTELRLLYQLVFLLSEAHTCIPENNGGAGCVCHLLMDDVVSADNYTLDLWAGQQLLWKGSFKPSEHVKPRAPGNLTVHTNVSDTLLLTWSNPYPPDNYLYNHLTYAVNIWSENDPADFRIYNVTYLEPSLRIAASTLKSGISYRARVRAWAQCYNTTWSEWSPSTKWHNSYREPFEQH	人類 IL-4Rα
12	EIVLTQSPGTLSLSPGERATLSCRASQSVSNSYLAWYQQKPGQAPRLLIFGASSRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYGSSPPWTFGQGTKVEIK	SCB-VL-39
13	EIVLTQSPGTLSLSPGERATLSCRASQSVSSSYLAWYQQKPGQAPRLLIYGASSRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYGSSPPWTFGQGTKVEIK	SCB-VL-40
14	EIVLTQSPGTLSLSPGERATLSCRASQSVSSSYLAWYQQKPGQAPRLLIFGASSRAPGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYGSSPPWTFGQGTKVEIK	SCB-VL-41
15	EIVLTQSPGTLSLSPGERATLSCRASQSVSNSYLAWYQQKPGQAPRLLIYGASSRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYGSSPPWTFGQGTKVEIK	SCB-VL-42

16	EIVLTQSPGTLSLSPGERATLSCRASQSVSNSYLAWYQQKPGQAPRL LIFGASSRAPGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYGSS PPWTFGQGTKVEIK	SCB-VL-43
17	EIVLTQSPGTLSLSPGERATLSCRASQSVSSSYLAWYQQKPGQAPRL LIYGASSRAPGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYGSS PPWTFGQGTKVEIK	SCB-VL-44
18	EIVLTQSPGTLSLSPGERATLSCRASQSVSSSYLAWYQQKPGQAPRL LIFGASSRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYDHS PPWTFGQGTKVEIK	SCB-VL-45
19	EIVLTQSPGTLSLSPGERATLSCRASQSVSSSYLAWYQQKPGQAPRL LIFGASSRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYGSS AGWTFGQGTKVEIK	SCB-VL-46
20	EIVLTQSPGTLSLSPGERATLSCRASQSVSSSYLAWYQQKPGQAPRL LIFGASSRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYDHS AGWTFGQGTKVEIK	SCB-VL-47
21	EIVLTQSPGTLSLSPGERATLSCRASQSVSNSYLAWYQQKPGQAPRL LIFGASSRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYDHS PPWTFGQGTKVEIK	SCB-VL-48
22	EIVLTQSPGTLSLSPGERATLSCRASQSVSSSYLAWYQQKPGQAPRL LIYGASSRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYDHS PPWTFGQGTKVEIK	SCB-VL-49
23	EIVLTQSPGTLSLSPGERATLSCRASQSVSSSYLAWYQQKPGQAPRL LIFGASSRAPGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYDHS PPWTFGQGTKVEIK	SCB-VL-50
24	EIVLTQSPGTLSLSPGERATLSCRASQSVSSSYLAWYQQKPGQAPRL LIYGASSRAPGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYDHS AGWTFGQGTKVEIK	SCB-VL-51
25	EIVLTQSPGTLSLSPGERATLSCRASQSVSNSYLAWYQQKPGQAPRL LIFGASSRAPGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYDHS AGWTFGQGTKVEIK	SCB-VL-52
26	EIVLTQSPGTLSLSPGERATLSCRASQSVSNSYLAWYQQKPGQAPRL LIYGASSRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYDHS AGWTFGQGTKVEIK	SCB-VL-53
27	EIVLTQSPGTLSLSPGERATLSCRASQSVSSSYLAWYQQKPGQAPRL LIFGASSRAPGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYDHS AGWTFGQGTKVEIK	SCB-VL-54
28	EIVLTQSPGTLSLSPGERATLSCRASQSVSSSYLAWYQQKPGQAPRL LIYGASSRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYDHS AGWTFGQGTKVEIK	SCB-VL-55
29	EIVLTQSPGTLSLSPGERATLSCRASQSVSNSYLAWYQQKPGQAPRL LIFGASSRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYDHS AGWTFGQGTKVEIK	SCB-VL-56
30	EIVLTQSPGTLSLSPGERATLSCRASQSVSSSYLAWYQQKPGQAPRL LIFGASSRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYGSS PPWTFGQGTKVEIK	SCB-VL-57
31	EIVLTQSPGTLSLSPGERATLSCRASQSVSNSYLAWYQQKPGQAPRL LIYGASSRAPGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQYDHS	SCB-VL-58

	AGWTFGQGTKVEIK	
32	EVQLVESGGGLVHPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFDYWGQGTLVTVSS	SCB-VH-59
33	EVQLVQSGGGLVQPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFDYWGQGTLVTVSS	SCB-VH-60
34	EVQLVQSGGGLVHPGGSLRLSCAASGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFDYWGQGTLVTVSS	SCB-VH-61
35	EVQLVQSGGGLVHPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATSYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFDYWGQGTLVTVSS	SCB-VH-62
36	EVQLVQSGGGLVHPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDT AVYYCARGRYYFDYWGQGTLVTVSS	SCB-VH-63
37	EVQLVESGGGLVQPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFDYWGQGTLVTVSS	SCB-VH-64
38	EVQLVESGGGLVHPGGSLRLSCAASGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFDYWGQGTLVTVSS	SCB-VH-65
39	EVQLVQSGGGLVQPGGSLRLSCAASGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFDYWGQGTLVTVSS	SCB-VH-66
40	EVQLVQSGGGLVHPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATSYADSVKGRFTISRDNAKNSLYLQMNSLRAEDT AVYYCARGRYYFDYWGQGTLVTVSS	SCB-VH-67
41	EVQLVQSGGGLVHPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFPWWGQGTLVTVSS	SCB-VH-68
42	EVQLVESGGGLVHPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFPWWGQGTLVTVSS	SCB-VH-69
43	EVQLVQSGGGLVQPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFPWWGQGTLVTVSS	SCB-VH-70
44	EVQLVQSGGGLVHPGGSLRLSCAASGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFPWWGQGTLVTVSS	SCB-VH-71
45	EVQLVQSGGGLVHPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATSYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFPWWGQGTLVTVSS	SCB-VH-72
46	EVQLVQSGGGLVHPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDT AVYYCARGRYYFPWWGQGTLVTVSS	SCB-VH-73
47	EVQLVQSGGGLVHPGRSLRLSCAGSGFTFSRNAMFWVRQAPGKGL	SCB-VH-74

	EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFDYWGQGTLVTVSS	
48	EVQLVQSGGGLVHPGGSLRLTCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFDYWGQGTLVTVSS	SCB-VH-75
49	EVQLVQSGGGLVHPGGSLRLSCAGSGFTFSRNAMHWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFDYWGQGTLVTVSS	SCB-VH-76
50	EVQLVQSGGGLVHPGGSLRLSCAGSGFTFSRNAMFWVRQAPGEGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFDYWGQGTLVTVSS	SCB-VH-77
51	EVQLVQSGGGLVHPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDEAKNSLYLQMNSLRAEDM AVYYCARGRYYFDYWGQGTLVTVSS	SCB-VH-78
52	EVQLVQSGGGLVHPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAGDM AVYYCARGRYYFDYWGQGTLVTVSS	SCB-VH-79
53	EVQLVQSGGGLVHPGGSLRLSCAGSGFTFDDYAMFWVRQAPGKG LEWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAED MAVYYCARGRYYFDYWGQGTLVTVSS	SCB-VH-80
54	EVQLVQSGGGLVQPGGSLRLSCAASGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATSYADSVKGRFTISRDNAKNSLYLQMNSLRAEDT AVYYCARGRYYFPWWGQGTLVTVSS	SCB-VH-81
55	EVQLVESGGGLVHPGGSLRLSCAASGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATSYADSVKGRFTISRDNAKNSLYLQMNSLRAEDT AVYYCARGRYYFPWWGQGTLVTVSS	SCB-VH-82
56	EVQLVESGGGLVQPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATSYADSVKGRFTISRDNAKNSLYLQMNSLRAEDT AVYYCARGRYYFPWWGQGTLVTVSS	SCB-VH-83
57	EVQLVESGGGLVQPGGSLRLSCAASGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDT AVYYCARGRYYFPWWGQGTLVTVSS	SCB-VH-84
58	EVQLVESGGGLVQPGGSLRLSCAASGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATSYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFPWWGQGTLVTVSS	SCB-VH-85
59	EVQLVQSGGGLVHPGGSLRLSCAASGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATSYADSVKGRFTISRDNAKNSLYLQMNSLRAEDT AVYYCARGRYYFPWWGQGTLVTVSS	SCB-VH-86
60	EVQLVQSGGGLVQPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATSYADSVKGRFTISRDNAKNSLYLQMNSLRAEDT AVYYCARGRYYFPWWGQGTLVTVSS	SCB-VH-87
61	EVQLVESGGGLVHPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATSYADSVKGRFTISRDNAKNSLYLQMNSLRAEDT AVYYCARGRYYFPWWGQGTLVTVSS	SCB-VH-88
62	EVQLVQSGGGLVHPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATSYADSVKGRFTISRDNAKNSLYLQMNSLRAEDT AVYYCARGRYYFPWWGQGTLVTVSS	SCB-VH-89

63	EVQLVESGGGLVQPGGSLRLSCAASGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFPWWGQGTLVTVSS	SCB-VH-90
64	EVQLVESGGGLVQPGGSLRLSCAASGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATSYADSVKGRFTISRDNAKNSLYLQMNSLRAEDT AVYYCARGRYYFDYWGQGTLVTVSS	SCB-VH-91
65	EVQLVQSGGGLVHPGGSLRLSCAGSGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATNYADSVKGRFTISRDNAKNSLYLQMNSLRAEDM AVYYCARGRYYFDYWGQGTLVTVSS	SCB-VH-92
66	EVQLVESGGGLVQPGGSLRLSCAASGFTFSRNAMFWVRQAPGKGL EWVSGIGTGGATSYADSVKGRFTISRDNAKNSLYLQMNSLRAEDT AVYYCARGRYYFPWWGQGTLVTVSS	SCB-VH-93
67	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKWWLDYWGKGTLVTVSS	MEDI-1-VH
68	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT SLSANYVFGTGTKLTVL	MEDI-1-VL
69	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKWWLYNWGKGTLVTVSS	MEDI-2-VH
70	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT SQPPNPLFGTGTKLTVL	MEDI-2-VL
71	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKLLKNPWGKGTLVTVSS	MEDI-3-VH
72	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWFG TPASNYVFGTGTKLTVL	MEDI-3-VL
73	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKWWLYNWGKGTLVTVSS	MEDI-4-VH
74	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT SSPPQPIFGTGTKLTVL	MEDI-4-VL
75	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKWWLYDWGKGTLVTVSS	MEDI-5-VH
76	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT SSPPQPIFGTGTKLTVL	MEDI-5-VL
77	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-6-VH
78	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT	MEDI-6-VL

	STTYHPIFGTGTKLTVL	
79	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKWWWQYWGKGTLVTVSS	MEDI-7-VH
80	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT SSPPQPIFGTGTKLTVL	MEDI-7-VL
81	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKWWWQYWGKGTLVTVSS	MEDI-8-VH
82	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT STTYHPIFGTGTKLTVL	MEDI-8-VL
83	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKWWLYNWGKGTLVTVSS	MEDI-9-VH
84	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT STTMYPLFGTGTKLTVL	MEDI-9-VL
85	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKWWLYDWGKGTLVTVSS	MEDI-10-VH
86	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT STVLTPIFGTGTKLTVL	MEDI-10-VL
87	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKWWFYDWGKGTLVTVSS	MEDI-11-VH
88	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT SPSMIPLFGTGTKLTVL	MEDI-11-VL
89	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKWWFYDWGKGTLVTVSS	MEDI-12-VH
90	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT STTMYPLFGTGTKLTVL	MEDI-12-VL
91	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKWWLYDWGKGTLVTVSS	MEDI-13-VH
92	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT STTLQPLFGTGTKLTVL	MEDI-13-VL
93	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKWWLYNWGKGTLVTVSS	MEDI-14-VH
94	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL	MEDI-14-VL

	LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT SPPTKPLFGTGTKLTVL	
95	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKWWLYNWGKGTLVTVSS	MEDI-15-VH
96	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT STHRHPLFGTGTKLTVL	MEDI-15-VL
97	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKWWLYNWGKGTLVTVSS	MEDI-16-VH
98	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT STTYHPIFGTGTKLTVL	MEDI-16-VL
99	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKWWWQHWGKGTLVTVSS	MEDI-17-VH
100	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT SPVDRPIFGTGTKLTVL	MEDI-17-VL
101	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKWWWQHWGKGTLVTVSS	MEDI-18-VH
102	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT STTPMPVFGTGTKLTVL	MEDI-18-VL
103	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKWWWQHWGKGTLVTVSS	MEDI-19-VH
104	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT STTYHPIFGTGTKLTVL	MEDI-19-VL
105	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-20-VH
106	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT STVWEWPFGTGTKLTVL	MEDI-20-VL
107	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSASYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-21-VH
108	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEAVYFCGTWDT STVWEWPFGTGTKLTVL	MEDI-21-VL
109	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-22-VH

110	QPVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYFCGTWDT STVWEWPFGTGTKLTVL	MEDI-22-VL
111	QVQLVQSGAEVRKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-23-VH
112	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNNYVSWYQQLPGTAPK LLIYDNNKRPPGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWD TSTVWEWPFGTGTKLTVL	MEDI-23-VL
113	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPRGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-24-VH
114	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYFCGTWDT STVWEWPFGTGTKLTVL	MEDI-24-VL
115	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPRGGSASYAQKFQGRVSMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-25-VH
116	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTTATLAITGLQTGDEADYYCGTWV TSTVWEWPFGTGTKLTVL	MEDI-25-VL
117	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-26-VH
118	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYFCGTWDT STVWEWPFGTGTKLTVL	MEDI-26-VL
119	QVQLVQSGAEVRKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRPED TAVYYCARGKYWMYDWGKGTQVTVSS	MEDI-27-VH
120	QSVLTQPPLVSAAPGQKVTISCSGGSSNIGNSYVSWYQRLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT STVWEWPFGTGTKLTVL	MEDI-27-VL
121	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGNGTLVTVSS	MEDI-28-VH
122	LPVLTQPPSVSAAPGQKVTISCSGGSSSIGNSYVSWYQQLPGAAPKL LIYDNNKRPSGIPDRFSGFRSGTSATLAITGLQTGDEADYYCGTWDT SPVWEWPFGTGTKLTVL	MEDI-28-VL
123	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTRVTVSS	MEDI-29-VH
124	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT SPVWEWPFGTGTKLTVL	MEDI-29-VL
125	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED	MEDI-30-VH

	TAVYYCARGKYWMYDWGKGTLVTVSS	
126	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQRLPGAAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT STVWEWPFGTGTKLTVL	MEDI-30-VL
127	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-31-VH
128	QSVLTQPPSVSAAPGQKVTISCSGGSSSIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWAT SPVWEWPFGTGTKLTVL	MEDI-31-VL
129	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-32-VH
130	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYFCGTWDT STAWEWPFGTGTKLTVL	MEDI-32-VL
131	QVQLVQSGAEEKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-33-VH
132	QSALTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYFCGTWDT STVWEWPFGTGTKLTVL	MEDI-33-VL
133	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVSMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-34-VH
134	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYFCGTWDT STVWEWPFGTGTKLTVL	MEDI-34-VL
135	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-35-VH
136	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT SPVWEWPFGTGTKLTVL	MEDI-35-VL
137	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSASYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-36-VH
138	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDS STVWEWPFGTGTKLTVL	MEDI-36-VL
139	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPRGGSTSYAQKFQGRVAMTRDTSTSTVYMELSSLRPED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-37-VH
140	QSVLTQPPSVSAAPGQKVTISCSGGGSSIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGVPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWD TSPVWEWPFGTGTKLTVL	MEDI-37-VL
141	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG	MEDI-38-VH

	LEWMGIINPSGGSASYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	
142	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYFCGTWDT STVWEWPFGTGTKLTVL	MEDI-38-VL
143	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPRGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-39-VH
144	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT STAWEWPFGTGTKLTVL	MEDI-39-VL
145	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-40-VH
146	QSVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDS STVWEWPFGTGTKLTVL	MEDI-40-VL
147	QVQLVQSGAEVRKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWMGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRPED TAVYYCARGKYWMYDWGKGTLVTVSG	MEDI-41-VH
148	QSVLTQPPSVSAAPGQKVTISCSGGSTNIGNSYVSWYQRLPGTAPKL LIYDNNKRPPGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWDT STVWEWPFGTGTKLTVL	MEDI-41-VL
149	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWARQAPGQG LEWVGIINPSGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSGD TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-42-VH
150	QAVLTQPPSVSAAPGQKVTISCSGGSSNIGNSYVSWYQRLPGAAPK LLIYDNNKRPSGIPDRFSGSKSGTSATLAITGLQTGDEADYYCGTWD TSTGWEWPFGTGTKLTVL	MEDI-42-VL
151	QVQLVQSGAEVKKPGASVKVSCKASGYAFTSYYMHWVRQAPGQG LEWMGIINPRGGSTSYAQKFQGRVTMTRDTSTSTVYMELSSLRSED TAVYYCARGKYWMYDWGKGTLVTVSS	MEDI-37GL-VH
152	QSVLTQPPSVSAAPGQKVTISCSGGGSSIGNSYVSWYQQLPGTAPKL LIYDNNKRPSGIPDRFSGSKSGTSATLGITGLQTGDEADYYCGTWDT SPVWEWPFGTGTKLTVL	MEDI-37GL-VL
153	EVQLLESGGGLVQPGGSLRLSCAVSGFTFSNYAMSWVRQAPGKGL EWVSAISSGGGNIYYADSVKGRFTISRDNSKNTLYLQMNSLRAEDT AVYYCAKLRRYFDYWGQGTLVTVSS	AJOU-1-VH
154	EVQLLESGGGLVQPGGSLRLSCAASGFTFSDYAMSWVRQAPGKGL EWVSAISSGGSSIYYADSVKGRFTISRDNSKNTLHLQMNSLRAEDT AVYYCARGPQRSATAVFDYWGQGTLVTVSS	AJOU-2-VH
155	EVQLLESGGGLVQPGGSLRLSCAASGFTFSNYAMSWVRQAPGKGL EWVSWISPNSGNIYYADSVKGRFTISRDNSKNTLYLQMNSLRAEDT AVYYCARRPLSAAWSHSSYYNAMDVWGQGTLVTVSS	AJOU-3-VH
156	EVQLLESGGGLVQPGGSLRLSCAASGFTFSGYAMSWVRQAPGKGL EWVSLISHSGSNTYYADSVKGRFTISRDNSKNTLYLQMNSLRAEDT AVYYCARPHRAFDYWGQGTLVTVSS	AJOU-4-VH

157	EVQLLESGGGLVQPGGSLRLSCAASGFTFSNYAMSWVRQAPGKGL EWVSGISHGSGSIYYADSVKGRFTISRDNSKNTLYLQMNSLRAEDT AVYYCARPHRAFDYWGQGTLVTVSS	AJOU-5-VH
158	EVQLLESGGGLVQPGGSLRLSCAASGFTFSNYAMSWVRQAPGKGL EWVSGISHGNGSIYYADSVKGRFTISRDNSKNTLYLQMNSLRAEDT AVYYCAKTGRHFDYWGQGTLVTVSS	AJOU-6-VH
159	EVQLLESGGGLVQPGGSLRLSCAASGFTFSNYAMSWVRQAPGKGL EWVSSISPSGSSIYYADSVKGRFTISRDNSKNTLYLQMNSLRAEDTA VYYCARSYRAFDYWGQGTLVTVSS	AJOU-7-VH
160	EVQLLESGGGLVQPGGSLRLSCAASGFTFSNYAMSWVRQAPGKGL EWVSAISPSGGSIYYADSVKGRFTISRDNSKNTLYLQMNSLRAEDT AVYYCARAKRAFDYWGQGTLVTVSS	AJOU-8-VH
161	EVQLLESGGGLVQPGGSLRLSCAASGFTFSNYAMSWVRQAPGKGL EWVSAISPGSGSTYYADSVKGRFTISRDNSKNTLYLQMNSLRAEDT AVYYCAKFRRHFDYWGQGTLVTVSS	AJOU-9-VH
162	EVQLLESGGGLVQPGGSLRLSCAASGFTFSNYAMSWVRQAPGKGL EWVSAISSGGGNIYYADSVKGRFTISRDNSKNTLYLQMNSLRAEDT AVYYCARVHRAFDYWGQGTLVTVSS	AJOU-10-VH
163	EVQLLESGGGLVQPGGSLRLSCAASGFTFSNYAMSWVRQAPGKGL EWVSAITSSGRSIYYADSVKGRFTISRDNSKNTLYLQMNSLRAEDT AVYYCARVHRAFDYWGQGTLVTVSS	AJOU-69-VH
164	EVQLLESGGGLVQPGGSLRLSCAASGFTFSNYAMSWVRQAPGKGL EWVSAITSSGANIYYADSVKGRFTISRDNSKNTLYLQMNSLRAEDT AVYYCARVHRAFDYWGQGTLVTVSS	AJOU-70-VH
165	EVQLLESGGGLVQPGGSLRLSCAASGFTFSNYAMSWVRQAPGKGL EWVSAITSSGGNIYYADSVKGRFTISRDNSKNTLYLQMNSLRAEDT AVYYCARVHRAFDYWGQGTLVTVSS	AJOU-71-VH
166	EVQLLESGGGLVQPGGSLRLSCAASGFTFSNYAMSWVRQAPGKGL EWVSAITAGGGSIYYADSVKGRFTISRDNSKNTLYLQMNSLRAEDT AVYYCARVHRAFDYWGQGTLVTVSS	AJOU-72-VH
167	EVQLLESGGGLVQPGGSLRLSCAASGFTFSRHAMAWVRQAPGKGL EWVSAITSSGRSIYYADSVKGRFTISRDNSKNTLYLQMNSLRAEDT AVYYCARVHRAFDYWGQGTLVTVSS	AJOU-83-VH
168	QSVLTQPPSASGTPGQRVTISCSGSSSNIGNNYVNWYQQLPGTAPKL LIYDNSHRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCGTWDA SLSAYVFGGGTKLTVL	AJOU-33-VL
169	QSVLTQPPSASGTPGQRVTISCSGSSSNIGNNNVSWYQQLPGTAPKL LIYANSKRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCGSWDD SLSAYVFGGGTKLTVL	AJOU-34-VL
170	QSVLTQPPSAPGTPGQRVTISCTGSSSNIGSNSVNWYQQLPGTAPKL LIYDDSHRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCDAWDS SLSAYVFGGGTKLTVL	AJOU-35-VL
171	QSVLTQPPSASGTPGQRVTLSCTGSSSNIGSNYVSWYQQLPGTAPKL LIYADSQRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCGTWDD SLSGYVFGGGTKLTVL	AJOU-36-VL
172	QSVLTQPPSASGTPGQRVTISCSSSSSNIGSNYVSWYQQLPGTAPKL LIYSDSHRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCGSWDY	AJOU-37-VL

	SLSAYVFGGGTKLTVL	
173	QSVLTQPPSASGTPGQRVTISCTGSSSNIGNNTVSWYQQLPGTAPKL LIYDNSHRPSGVPDRFSGSKSGTSASLAISGLQSEDEADYYCGSWDY SLSAYVFGGGTKLTVL	AJOU-38-VL
174	QSVLTQPPSASGTPGQRVTISCTGSSSNIGNNDVNWYQQLPGTAPKL LIYYDSQRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCATWDA SLSAYVFGGGTKLTVL	AJOU-39-VL
175	QSVLTQPPSASGTPGQRVTISCSGSSSNIGSNAVNWYQQLPGTAPKL LIYYDNQRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCGTWD DSLNGYVFGGGTKLTVL	AJOU-40-VL
176	QSVLTQPPSASGTPGQRVTISCSGSSSNIGNNAVTWYQQLPGTAPKL LIYDDSHRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCGSWDY SLSAYVFGGGTKLTVL	AJOU-41-VL
177	QSVLTQPPSASGTPGQRVTISCSGSSSNIGSNTFNWYQQLPGTAPKL LIYADSHRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCGTWDY SLSGYVLGGGTKLTVL	AJOU-42-VL
178	QSVLTQPPSASGTPGQRVTISCSGSSSNIGSNTFNWYQQLPGTAPKL LIYADSHRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCGTWDY SLSGYVLGGGTKLTVL	AJOU-77-VL
179	QSVLTQPPSASGTPGQRVTISCSGSSSNIGSNTFNWYQQLPGTAPKL LIYADSHRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCGTWDY SLRGYVLGGGTKLTVL	AJOU-78-VL
180	QSVLTQPPSASGTPGQRVTISCSGSSSNIGSNTFNWYQQLPGTAPKL LIYADSHRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCGYWD YSLSGYVLGGGTKLTVL	AJOU-79-VL
181	QSVLTQPPSASGTPGQRVTISCSGSSSNIGSNTFNWYQQLPGTAPKL LIYADSHRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCGTWDY SLSGYVLGGGTKLTVL	AJOU-80-VL
182	QSVLTQPPSASGTPGQRVTISCSGSSANSRTDGFNWYQQLPGTAPKL LIYADSHRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCGTWDY SLSGYVLGGGTKLTVLG	AJOU-86-VL
183	QSVLTQPPSASGTPGQRVTISCSGSAQFGSRDNFNWYQQLPGTAPK LLIYADSHRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCGTWD YSLSGYVLGGGTKLTVLG	AJOU-87-VL
184	QSVLTQPPSASGTPGQRVTISCSGSTKQMHNYQFNWYQQLPGTAPK LLIYADSHRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCGTWD YSLSGYVLGGGTKLTVLG	AJOU-88-VL
185	QSVLTQPPSASGTPGQRVTISCSGSLLRGENLQFNWYQQLPGTAPKL LIYADSHRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCGTWDY SLSGYVLGGGTKLTVLG	AJOU-89-VL
186	QSVLTQPPSASGTPGQRVTISCSGSPLFPDSGSFNWYQQLPGTAPKL LIYADSHRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCGTWDY SLSGYVLGGGTKLTVLG	AJOU-90-VL
187	QSVLTQPPSASGTPGQRVTISCSGSAALDLSPSFNWYQQLPGTAPKL LIYADSHRPSGVPDRFSGSKSGTSASLAISGLRSEDEADYYCGTWDY SLSGYVLGGGTKLTVLG	AJOU-91-VL
188	QVQLVQSGAEVKKPGASVKVSCKASGYTFTNYGISWVRQAPGQGL	REGN-VH-3

	EWMGWISVYNGKTNYAQKLQGRVTMTTDTSTTTAYMEMRSLRSD DTAVYYCARGSGYDLDYWGQGTLVSVSS	
189	EVQLVESGGGLVQPGGSLRLSCAASGFTFSSFWMTWVRQAPGKGL EWVANIKQDGSEKYYVDSVKGRFTISRDNAKNSLYLQMNSLRAED TAVYYCARDPGRTMVRGGIRYYYGMDVWGQGTTVTVSS	REGN-VH-19
190	EVKLAESGGGLVQPGGSLRLSCAASGFTFSSHWMNWVRQAPGKGL EWVANIKQDGSDKYYVDSVKGRFTISRDNAKNSLYLQLNSLIAEDT AVYYCARDRGVRPPRGAFDIWGQGTMVTVSS	REGN-VH-35
191	QVQLVQSGAEVKKPGASVKVSCKASGYTFNSYGISWVRQAPGQGL EWMGWIRTYNGNTNYAQKLQGRVTMTTDTSTSTAYMELRSLRSD DTAVYYCARDEARIVVAGTTPYYYGMDVWGQGTTVTVSS	REGN-VH-51
192	QVQLVESGGGLVQPGGSLRLSCAVSGFTISDHYMSWIRQAPGKGLE WISYISSSGSKIYYADSVKGRFTISRDNAKNSLFLQMNSLRAEDTAV YYCARTRQLVGDYWGQGTLVTVSS	REGN-VH-67
193	EVQLVESGGGLVQPGRSLRLSCAASGFTFDNYAMHWVRQAPGKG LEWVSGIRWNSGSIGYADSVKGRFTISRDNAKNSLYLQMNSLRAED TALYYCAKEGGYSGYRPGPFFDYWGQGTLVTVSS	REGN-VH-83
194	QVQLVQSGAEVKKPGASVKVSCKASGYTFTNYGISWVRQAPGQGL EWMGWISVYNGHTNYAQKLQGRVTMTTDTSTSTAYMELRSLRSD DTAVYYCARGSGYDFDSWGQGTLVTVSS	REGN-VH-99
195	QVQLVQSGAEVKKPGASVKVSCKASRYTFTSYDINWVRQATGQGL EWMGWMNPNSGNTGYAQKFQGRVTMTRNTSTSTAYMELSSLRSE DTAVYYCARVRRFFDYWGQGTLVTVSS	REGN-VH-115
196	QVQLVQSGPEVKKPGASVKVSCKASGYTFTNYGISWVRQAPGQGL EWMGWISVYNGNINYAQKLQGRVTMTTDTSTSTAYMDLRSLRSD DTAVYYCARGSGYDFDYWGQGTLVTVSS	REGN-VH-147
197	QVQLVQSGAEVKKPGASVKVSCKDSAYTFNRYGISWVRQAPGQGL EWMGWISAYTGNTVYAQKLQGRVTMTTDNSTSTAYMELRSLRSD DTAVYYCARDKSIFGVVRGFDYWGQGTLVTVSS	REGN-VH-163
198	AIQMTQSPSSLSASVGDRVTITCRASQGIRNALGWYQQKPGKAPKL LIYAASSLQSGVPSRFSGSGSGTDFTLTFSSLQPEDFATYYCLQDFNY PYTFGQGTKLEIK	REGN-VL-11
199	DIQMTQSPSSVSASVGDRVTISCRASQGVSSWLAWYQQKPGNAPK LLISAASSIQSGVPSRFSGSGSGTDFTLTISSLQPEDFATYYCQQANSF PLTFGGGTKVEIK	REGN-VL-27
200	DIQMTQSPSSVSASVGDRVTITCRASQGISSWLAWYQQKPGKAPKL LIYAASSFQSGVPSRFSGSGSGTDFTLTISSLQPEDFATYFCQQANSF PLTFGGGTTVEIK	REGN-VL-43
201	DIQMTQSPSSVSASVGDRVTITCRASQDISIWLAWYQQSPGKAPKLL INVASRLQSGVPSRFSGSGSGTDFTLTINSLQPEDFVTYYCQQANSFP ITFGQGTRLATK	REGN-VL-59
202	DIQLTQSPSFLSASVGDRVTITCWASQGISSYLAWYQQKPGKAPKLL IFAASTLQSGVPSRFSGSGSGTEFTLTISSLQPEDFATYYCQQLNSYP LTFGGGTKVEIR	REGN-VL-75
203	EIVMTQSPATLSVSPGERATLSCRASQSVNYNLAWYQHKPGQAPRL LIYGASTRATGIPARFSGSGSGTEFTLTISSLQSEDFAVYYCQQYNN WPLTFGGGTKVEIK	REGN-VL-91

204	AIQMTQSSSSLSASVGDRVTITCRASQAIRNALGWYQQKPGKAPKV LIYAASSLQSGIPSRFSGSGSGTDFTLTISSLQPEDFATYYCLQDYDY PYTFGQGTKLEIK	REGN-VL-107
205	DIQLTQSPSFLSASVGDRVTITCWASQGIISYLAWYQQKPGKAPKLL IYAASTLHSGVPSRFSGSGSGTEFTLTISSLQPEDFATYYCHQLKSYPI TFGQGTRLEIK	REGN-VL-123
206	AIQMTQSPSSLSASVGDRVTITCRASQDIRNALGWYQQKPGKAPKL LIYAASSLQSGVPSRFSGSASGTDFTLTISSLQPEDFAAYYCLQDYN YPYTFGQGTKLEIK	REGN-VL-155
207	EIVMTQSPVTLSLSPGERATLPCRASQSVSSSLAWYQQKAGQSPRLL IYGASTRATGIPARFSGSGSGTEFTLTISNLQSEDFAVYYCQQYNNW PLTFGGGTKVEIK	REGN-VL-171
208	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISSNGGSTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA VYYCVRVKVGYRGGMDVWGQGTTVTVSS	STSA-C27-VH
209	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISPSGSSTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA VYYCVRSKVRYRGGMDVWGQGTTVTVSS	STSA-C27-6-33-VH
210	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISPSGVSTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA VYYCVRVKVKYRGGMDVWGQGTTVTVSS	STSA-C27-7-33-VH
211	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISPTSGSTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA VYYCVRVKVRYRGGMDVWGQGTTVTVSS	STSA-C27-24-56-VH
212	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISPTGTSTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA VYYCVRVKGAYRGGMDVWGQGTTVTVSS	STSA-C27-47-56-VH
213	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISSSGSSTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA VYYCVRVKVAYRGGMDVWGQGTTVTVSS	STSA-C27-33-33-VH
214	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISPSSTSTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA VYYCVRVKVLYRGGMDVWGQGTTVTVSS	STSA-C27-56-56-VH
215	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISPSSASTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA VYYCVRVKSKYRGGMDVWGQGTTVTVSS	STSA-C27-78-78-VH
216	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISGNSASTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA VYYCVRVKLKYRGGMDVWGQGTTVTVSS	STSA-C27-82-58-VH
217	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISHSGTSTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA VYYCVRVRVLYRGGMDVWGQGTTVTVSS	STSA-C27-54-54-VH
218	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISPSGVSTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA VYYCVRVKVKYRGGMDVWGQGTTVTVSS	STSA-C27-36-36-VH
219	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISSNGGSTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA	STSA-C27-53-53-VH

	VYYCVRVFVRYRGGMDVWGQGTTVTVSS	
220	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISPTSASTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA VYYCVRVKGRYRGGMDVWGQGTTVTVSS	STSA-C27-67-67 -VH
221	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISPTGGSTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA VYYCVRVKGRYRGGMDVWGQGTTVTVSS	STSA-C27-55-55 -VH
222	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISHSGNSTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA VYYCVRVKRRYRGGMDVWGQGTTVTVSS	STSA-C27-59-59 -VH
223	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISPSSNSTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA VYYCVRVKVRYRGGMDVWGQGTTVTVSS	STSA-C27-58-58 -VH
224	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISSSGSSTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA VYYCVRVKPAYRGGMDVWGQGTTVTVSS	STSA-C27-52-52 -VH
225	EVQLLESGGGLVQPGGSLRLSCAASGFTLSSYAMHWVRQAPGKGL EYVSGISYSSASTYYANSVKGRFTISRDNPKNTLFLQMSSLRAEDTA VYYCVRVKVRYRGGMDVWGQGTTVTVSS	STSA-C27-Y2-Y 2-VH
226	ETTLTQSPDTLPLSPGDRASLSCRASQSVSSAYLAWYQQKPGQAPR LLIYGTSRRATGVPGRFSGSGSGTDFTLTISRLEPEDFAVYYCQLYG SSSVTFGQGTKLEIK	STSA-C27-VL
227	EIVLTQSPGTLSLSPGERATLSCRASQGISSAYLAWYQQKPGQAPRL LIYGTSRRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQLYGAT SVTFGQGTKLEIK	STSA-C27-6-33- VL
228	EIVLTQSPGTLSLSPGERATLSCRASQGISSAYLAWYQQKPGQAPRL LIYGTSRRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQLYGAT SVTFGQGTKLEIK	STSA-C27-7-33- VL
229	EIVLTQSPGTLSLSPGERATLSCRASQSVSSAYLAWYQQKPGQAPRL LIYGTSRRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQLYGAS SVTFGQGTKLEIK	STSA-C27-24-56 -VL
230	EIVLTQSPGTLSLSPGERATLSCRASQSVSSAYLAWYQQKPGQAPRL LIYGTSRRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQLYGAS SVTFGQGTKLEIK	STSA-C27-47-56 -VL
231	EIVLTQSPGTLSLSPGERATLSCRASQGISSAYLAWYQQKPGQAPRL LIYGTSRRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQLYGAT SVTFGQGTKLEIK	STSA-C27-33-33 -VL
232	EIVLTQSPGTLSLSPGERATLSCRASQSVSSAYLAWYQQKPGQAPRL LIYGTSRRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQLYGAS SVTFGQGTKLEIK	STSA-C27-56-56 -VL
233	EIVLTQSPGTLSLSPGERATLSCRASQSISTAYLAWYQQKPGQAPRL LIYGTSRRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQLYGAS SVTFGQGTKLEIK	STSA-C27-78-78 -VL
234	EIVLTQSPGTLSLSPGERATLSCRASQDISSAYLAWYQQKPGQAPRL LIYGTSRRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQLYGAT SVTFGQGTKLEIK	STSA-C27-82-58 -VL
235	EIVLTQSPGTLSLSPGERATLSCRASQDVSSAYLAWYQQKPGQAPR	STSA-C27-54-54

	LLIYGTSRRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQLYGA TSVTFGQGTKLEIK	-VL
236	EIVLTQSPGTLSLSPGERATLSCRASQNISTAYLAWYQQKPGQAPRL LIYGTSRRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQLYGAT SVTFGQGTKLEIK	STSA-C27-36-36 -VL
237	EIVLTQSPGTLSLSPGERATLSCRASQDASNAYLAWYQQKPGQAPR LLIYGTSRRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQLYGS SSVTFGQGTKLEIK	STSA-C27-53-53 -VL
238	EIVLTQSPGTLSLSPGERATLSCRASQGVSSAYLAWYQQKPGQAPR LLIYGTSRRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQLYGR SSVTFGQGTKLEIK	STSA-C27-67-67 -VL
239	EIVLTQSPGTLSLSPGERATLSCRASQNISTAYLAWYQQKPGQAPRL LIYGTSRRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQLYGTS SVTFGQGTKLEIK	STSA-C27-55-55 -VL
240	EIVLTQSPGTLSLSPGERATLSCRASQSVSTAYLAWYQQKPGQAPRL LIYGTSRRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQLYGAT SVTFGQGTKLEIK	STSA-C27-59-59 -VL
241	EIVLTQSPGTLSLSPGERATLSCRASQDISSAYLAWYQQKPGQAPRL LIYGTSRRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQLYGAT SVTFGQGTKLEIK	STSA-C27-58-58 -VL
242	EIVLTQSPGTLSLSPGERATLSCRASQGVSTAYLAWYQQKPGQAPR LLIYGTSRRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQLYGA TSVTFGQGTKLEIK	STSA-C27-52-52 -VL
243	EIVLPQSPGTLSLSPGERATLSCRASQGVSSAYLAWYQQKPGQAPR LLIYGTSRRATGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQL YGSTSVTFGQGTKLEIK	STSA-C27-Y2-Y 2-VL
244	EVQLVESGGGLVQPKGSLKLSCAASGFTFNTYGMHWVRQAPGKG LEWVAHIRSKSSNYATYYADSVKDRFTISRDDSQSMLYLQMNNLK TEDTAMYYCVRWFRAMDYWGQGTSVTVSS	Y0188-1 VH
245	EVQLIESGGGLVQPKGSLKLSCAASGFTFNMYAMDWVRQAPGKGL EWVARIRSKGSNFETNYADSVKDRFTISRDDSQSMVYLQMINLKTE DTAMYYCVRHRGGAWFAYWGQGTLVSVSA	Y0188-2 VH
246	QVQLVETGGGLVRPGNSLKLSCVTSGFTFSNYRMHWLRQPPGKRL EWIAVITVKSNNYGANYAESVKGRFAISRDDSKSSVYLEMNRLREE DTATYFCSRERAYGNPFDYWGQGTTLTVSS	Y0188-3 VH
247	EVQLVESGGGLVQPKGSLKLSCAASGFTFNMYAMNWVRQAPGQG LEWVARIRSKSNNYATYYADSVKDRFIISRDDSESMVYLQMSNLRA ADTAMYYCVRHLRAMDYWGQGTSVTVSS	Y0188-4 VH
248	EVQLVESGGGLVQPKGSLKLSCAASGFSFNMYAMNWVRQAPGKG LEWVARIRTKSNHYSTYYADSVKDRFTISRDDSASMFYLQMNNLK TEDTAMYFCVRHLRAMDYWGQGTSVTVSS	Y0188-6 VH
249	EVQLIESGGGLVQPKGSLKLSCAASGFTFNMYAMDWVRQAPGKGL EWVARIRSKGSNFETNYADSVKDRFTISRDDSQSMVYLQMNNLKT EDTAMYYCVRHRGGAWFAYWGQGTLVTVSA	Y0188-8 VH
250	EVQLVESGGGLVRPKGSLKLSCAASGFSFNTYAMNWVRQAPGKGL EWIVWIRSKSHNYATYYADSVKDRFTISRDDSESMLYLQMNNLKT EDTAMYYCVRHLRAMDYWGQGTSVTVSS	Y0188-9 VH

251	EVRLVESGGGLVQPKGSLKLSCEASGFSFNMYAMNWVRQAPGKG LEWITHIRSKSNNYATYYADSVKDRFIISRDDSESMVYLQMNNLKT EDTAMYYCVRLLRALDYWGQGTSVTVSS	Y0188-10 VH
252	EVQLVESGGGLVQPKGSLKLSCAASGFTFNMYGMHWVRQAPGKG LEWVAHIRSKSSNYATYYADSVKDRLTISRDDSQSMLYLQMNNLK TEDTAMYYCVRWFRAMDYWGQGTSVTVSS	Y0188-14 VH
253	EVQLVESGGGLVKPGGSLRLSCAASGFTFSMYGMHWVRQAPGKG LEWVGHIRSKSSNYATYYADSVKDRFTISRDDSKNTLYLQMNSLKT EDTAVYYCTTWFRAMDYWGQGTLVTVSS	HV3-15-14 VH
254	EVQLVESGGGLVQPGGSLRLSCAASGFTFSMYGMHWVRQAPGKG LEWVSHIRSKSSNYATYYADSVKDRFTISRDNAKNSLYLQMNSLRA EDTAVYYCARWFRAMDYWGQGTLVTVSS	HV3-48-14 VH
255	EVQLVESGGGLVQPGGSLKLSCAASGFTFSMYGMHWVRQASGKG LEWVGHIRSKSSNYATYYADSVKDRFTISRDDSKNTAYLQMNSLK TEDTAVYYCTRWFRAMDYWGQGTLVTVSS	HV3-73*2-14 VH
256	EVQLVESGGGLVQPGGSLRLSCAASGFTFSMYGMHWVRQAPGKG LEWVGHIRSKSSNYATYYADSVKDRFTISRDDSKNSLYLQMNSLKT EDTAVYYCARWFRAMDYWGQGTLVTVSS	HV3-72-14 VH
257	EVQLVESGGGLVQPGGSLRLSCAASGFTFSMYGMHWVRQAPGKG LEWVSHIRSKSSNYATYYADSVKDRFTISRDNAKNSLYLQMNSLRA EDTAVYYCARWFRAMDYWGQGTLVTVSS	Y01-14 VH
258	EVQLVESGGGLEQPGGSLRLSCAGSGFTFRMYGMHWVRQAPGKG LEWVSHIRSKSSNYATYYADSVKDRFTISRDNSKNTLYLQMNSLRA EDTAVYYCAKWFRAMDYWGQGTTVTVSS	162-14 VH
259	EVQLVESGGGLVQPGGSLKLSCAASGFTFSMYGMHWVRQASGKG LEWVGHIRSKSSNYATYYADSVKDRFTISRDDSKNTAYLQMNSLK TEDTAVYYCTRWFRAMDYWGQGTTVTVSS	VH73-14 VH
260	DIVMTQSHKFMSTSVGDRVSITCKASQDVSTAVAWYQEKPGQSPK LLIYWASTRHTGVPDRFTGSGSGTDYTLTISSVQAEDLALYYCQQH YSTPLTFGAGTKLELK	Y0188-1 VL
261	DIVVTQSPASLAVSLGQRATISCRASKSVSTSGYSYMHWYQQKPGQ PPKLLIYLASNLESGVPARFSGSGSGTDFTLNIHPVEEEDVAIYYCQH SRELPLTFGAGTKLELK	Y0188-2 VL
262	DIQMTQSPSSLSASLGERVSLTCRASQEISGYLSWLQQKPDGTIKRLI YAASTLDSGVPKRFSGSRSGSDYSLTISSLESEDFADYYCLQYGSYP YTFGGGTKLEIK	Y0188-3 VL
263	DIVLTQSPASLTVSLGQRATISCRASKSVSTSGYSYMHWYQQKPGQ PPKLLIYLASNLESGVPARFSGSGSGTDFTLNIHPVEEEDAATYYCQ HSRELPITFGSGTKLEIK	Y0188-4 VL
264	DIVLTQSPASLVVSLGQRATISCRASQSVSTSGYSYMHWYQQKPGQ PPKLLIYLASNVQSGVPARFSGSGSGTDFTLNIHPVEEEDVATYYCH HNRDLPFTFGSGTKLEIK	Y0188-6 VL
265	DIVVTQSPASLAVSLGQRATISCRASKSVSTSGYSYMHWYQQKPGQ PPKLLIYLASNLESGVPARFSGSGSGTDFTLNIHPVEEEDVAIYYCQH SRELPLTFGAGTKLELK	Y0188-8 VL
266	DIVLTQSPASLAVSLGQRATISCRASKSVSASGYSYMHWYQQKPGQ PPKLLIYLASNLQSGVPARFSGSGSGTDFTLNIHPVEEEDAATYYCQ	Y0188-9 VL

	HSRELPPTFGGGTKLEIK	
267	DIVLTQSPASLAVFLGQRATISCRASKSVSTSGYSYMHWYQQKAGQ PPKLLIYLASNLESGVPARFSGSGSGTDFTLNIHPVEEEDAATYYCH HSRELPITFGSGTKLEMK	Y0188-10 VL
268	DIVMTQSHKFMSTSVGDRVSITCKASQDVSTAVAWYQEKPGQSPK LLIYWASTRHTGVPDRFTGSGSGTDYTLTISSVQAEDLALYYCQQH YSTPLTFGAGTKLELK	Y0188-14 VL
269	EIVLTQSPGTLSLSPGERATLSCKASQDVSTAVAWYQQKPGQAPRL LIYWASTRHTGIPDRFSGSGSGTDFTLTISRLEPEDFAVYYCQQHYS TPLTFGQGTKVEIK	Y01-14 VL
270	DIVMTQSPLSLPVTPGEPASISCKASQDVSTAVAWYLQKSGQSPQLL IYWASTRHTGVPDRFSGSGSGTDFTLKISRVEAEDVGFYYCQQHYS TPLTFGQGTKLEIK	164-14 VL
271	DIVMTQSPDSLAVSLGERATINCKASQDVSTAVAWYQQKPGQPPK LLIYWASTRHTGVPDRFSGSGSGTDFTLTISSLQAEDVAVYYCQQH YSTPLTFGGGTKVEIK	KV4-14 VL
272	DIQMTQSPSSLSASVGDRVTITCKASQDVSTAVAWYQQKPGKVPKL LIYWASTRHTGVPSRFSGSGSGTDFTLTISSLQPEDVATYYCQQHYS TPLTFGGGTKVEIK	KV1-27-14 VL
273	DIQLTQSPSFLSASVGDRVTITCKASQDVSTAVAWYQQKPGKAPKL LIYWASTRHTGVPSRFSGSGSGTEFTLTISSLQPEDFATYYCQQHYS TPLTFGGGTKVEIK	KV1-9-14 VL
274	DIQMTQSPSSLSASVGDRVTITCKASQDVSTAVAWYQQKPGKAPKL LLYWASTRHTGVPSRFSGSGSGTDYTLTISSLQPEDFATYYCQQHYS TPLTFGGGTKVEIK	KV1-NL1-14 VL
275	AIRMTQSPFSLSASVGDRVTITCKASQDVSTAVAWYQQKPAKAPKL FIYWASTRHTGVPSRFSGSGSGTDYTLTISSLQPEDFATYYCQQHYS TPLTFGGGTKVEIK	KV1D-43-14 VL

實例

【0126】 提出以下實例以便向一般熟習此項技術者提供如何製造及使用本發明之方法及組成物的完整揭示內容及描述，且不意欲限制本發明人視為本發明之內容的範疇。已努力確保關於所用數字(例如量、溫度等)之準確性，但應考慮到一些實驗誤差及偏差。除非另外指明，否則份數為重量份，分子量為平均分子量，溫度以攝氏度計，且壓力為大氣壓或接近大氣壓。

實例 1：用 PEG3350 或泊洛沙姆 188 防止含有脂肪酶之調配物中的顆粒形

成

【0127】 不意欲受理論束縛，咸信在倉鼠、大鼠、小鼠、人類及牛中高度保守之推定磷脂酶B樣2 (PLBL2)在某些過程中與某些細胞株中產生之一些類別的所關注蛋白質共純化，且具有負責水解聚山梨醇酯20及80之酯酶活性。作為經由純化方法(例如美國專利案第10,342,876號中所述)移除脂肪酶之替代方案，使用替代性界面活性劑製備IL-4R抗體之調配物，且隨時間推移量測顆粒形成。濃度為150 mg/mL mAb1之包含SEQ ID NO: 1/2之HCVR/LCVR胺基酸序列對的抗IL-4R抗體與20 mM組胺酸、12.5 mM乙酸鈉、25 mM精胺酸-HCl、5% w/v蔗糖及不同濃度之PEG3350或泊洛沙姆188一起調配，pH為5.9。將調配物在5℃下儲存於注射器中長達 36 個月，藉由顯微術定期量測調配物中存在之顆粒(≥10 μm及≥25 μm)數目。

【0128】 如圖1中所示，歷經36個月之觀察期，在調配物中鑑別出極少≥10 μm或≥25 μm之顆粒。此外，歷經儲存期，在含有PEG3350或泊洛沙姆188之不同調配物中未觀察到亞可見顆粒數目之明顯差異或變化。此實驗表明，低濃度之PEG3350或泊洛沙姆188可防止顆粒在長期儲存期間形成。

實例2：含有PEG3350或泊洛沙姆188之調配物的攪拌應力穩定性

【0129】 測試含有不同濃度之界面活性劑 PEG3350 或泊洛沙姆 188 之IL-4R抗體調配物的攪拌應力穩定性。濃度為150 mg/mL之包含SEQ ID NO: 1/2之HCVR/LCVR胺基酸序列對的抗IL-4R抗體與20 mM組胺酸、12.5 mM乙酸鈉、25 mM精胺酸-HCl、5% w/v蔗糖及不同濃度之PEG3350或泊洛沙姆188一起調配，pH為5.9。將調配物儲存於玻璃小瓶中，且藉由渦旋(速度設置＝4)攪拌30分鐘、60分鐘或120分鐘。隨後藉由尺寸排阻超高效液相層析(SE-UPLC)測定高分子量(HMW)物種之百分比。

【0130】 如圖 2A 中所示，用至少 0.01% (w/v) PEG3350 調配抗體防止因攪拌所致的 HMW 物種(藉由 SE-UHPLC 定量)之可觀測增加。較低量的 PEG3350 (0.001%或 0.005%)不足以防止 HMW 的形成。類似地，如圖 2B 中所示，用至少 0.01% (w/v)泊洛沙姆 188 調配抗體防止 HMW 物種之可觀測增加，但用較低量之泊洛沙姆 188 (0.001%或 0.005%)觀察到 HMW 物種。

實例 3：含有 PEG3350 或泊洛沙姆 188 之調配物的熱應力穩定性

【0131】 測試含有 PEG3350 或泊洛沙姆 188 之 IL-4R 抗體調配物的熱應力穩定性，且與含有聚山梨醇酯之各種 IL-4R 抗體調配物進行比較。濃度為 150 mg/mL 之包含 SEQ ID NO: 1/2 之 HCVR/LCVR 胺基酸序列對的抗 IL-4R 抗體與 20 mM 組胺酸、12.5 mM 乙酸鈉、25 mM 精胺酸-HCl、5% w/v 蔗糖及不同濃度之聚山梨醇酯 20、聚山梨醇酯 80、PEG3350 或泊洛沙姆 188 一起調配，pH 為 5.9。此等調配物經受熱應力(45℃)持續長達 56 天之時間段，且在 7 天、14 天、28 天、42 天及 56 天藉由尺寸排阻超高效液相層析(SE-UPLC)測定高分子量(HMW)物種之百分比。

【0132】 如圖 3 中所示，包含濃度為 0.01%或 0.02%之 PEG3350 或泊洛沙姆 188 的抗體調配物顯示出與含有較低量之聚山梨醇酯(至多 0.1% w/v)的抗體調配物相似的熱穩定性。截至 28 天，含有 PEG3350 或泊洛沙姆 188 之調配物顯示出比包含 0.2%聚山梨醇酯 20 之對照調配物更低的 HMW 物種百分比。

實例 4：含有不同濃度之泊洛沙姆 188 或 PEG3350 之調配物的熱應力穩定性

【0133】 在熱應力條件(45℃)下測試含有不同濃度之泊洛沙姆 188 或 PEG3350 之 IL-4R 抗體調配物的熱應力穩定性長達 3 個月。濃度為 150 mg/mL

之包含 SEQ ID NO: 1/2 之 HCVR/LCVR 胺基酸序列對的抗 IL-4R 抗體與 20 mM 組胺酸、12.5 mM 乙酸鈉、25 mM 精胺酸-HCl、5% w/v 蔗糖及界面活性劑[0.2% w/v 之聚山梨醇酯 80，0.01%、0.1%或 0.5% w/v 之泊洛沙姆 188，或 0.01%、0.1%或 0.5% w/v 之 PEG3350]一起調配，pH 為 5.9。此等調配物在 45℃下儲存於玻璃小瓶中 1、2 或 3 個月。藉由逆相超高效液相層析(RP-UPLC)測定所回收藥品(抗體)之百分比。藉由尺寸排阻超高效液相層析(SE-UPLC)測定高分子量(HMW)物種之百分比。藉由陽離子交換超高效液相層析(CEX-UPLC)量測電荷變異體物種之形成。使用微流成像(MFI)來量測亞可見顆粒。

【0134】 表 2 顯示含有 0.2% (w/v)聚山梨醇酯 80 之調配物在 0、1 及 3 個月時的穩定性資料。表 3、4 及 5 分別顯示含有 0.01%、0.1%及 0.5%泊洛沙姆 188 之調配物的穩定性資料。表 6、7 及 8 分別顯示含有 0.01%、0.1%及 0.5% PEG3350 之調配物的穩定性資料。如表 3 及表 6 中所示，即使最低測試濃度之泊洛沙姆 188 及 PEG3350 (0.01%)仍提供與 0.2%聚山梨醇酯 80 相似程度的保護。0.01%泊洛沙姆 188 調配物表現出與 0.1%及 0.5%泊洛沙姆 188 相似的穩定性特徵(參見表 3 至 5)。0.01% PEG3350 調配物表現出與 0.1%及 0.5% PEG3350 相似的穩定性特徵(參見表 6 至 8)。

表 2：具有 0.2% (w/v)聚山梨醇酯 80 之調配物的穩定性資料

試驗		在 45℃下之儲存時長(月)		
		0	1	3
藉由 RP-UPLC 回收之抗體的%		100	98	94
藉由 SE-UPLC 測定之純度	% HMW	2.1	10.3	26.6
	%主要	97.2	88.7	70.7
	% LMW	0.7	1.0	2.7
藉由 CEX-UPLC 之電荷變異體分析	%酸性	27.7	53.7	86.9
	%主要	62.5	41.0	9.5
	%鹼性	9.9	5.3	3.6
MFI (顆粒數/mL)	2-10 μm	125	1428	377
	≥10 μm	23	29	19

	≥25 μm	4	2	4

表 3：具有 0.01% (w/v)泊洛沙姆 188 之調配物的穩定性資料

試驗		在 45℃下之儲存時長(月)		
		0	1	3
藉由 RP-UPLC 回收之抗體的%		100	100	98
藉由 SE-UPLC 測定之純度	% HMW	2.1	9.1	23.7
	%主要	97.2	90.0	73.5
	% LMW	0.7	0.9	2.7
藉由 CEX-UPLC 之電荷變異體分析	%酸性	28.4	51.7	86.6
	%主要	62.1	43.1	8.9
	%鹼性	9.5	5.3	4.5
MFI (顆粒數/mL)	2-10 μm	79	142	396
	≥10 μm	17	17	8
	≥25 μm	0	6	0

表 4：具有 0.1% (w/v)泊洛沙姆 188 之調配物的穩定性資料

試驗		在 45℃下之儲存時長(月)		
		0	1	3
藉由 RP-UPLC 回收之抗體的%		100	99	100
藉由 SE-UPLC 測定之純度	% HMW	2.1	9.1	23.7
	%主要	97.3	90.0	73.6
	% LMW	0.6	0.9	2.8
藉由 CEX-UPLC 之電荷變異體分析	%酸性	28.1	51.9	84.0
	%主要	62.1	46.2	8.7
	%鹼性	9.8	1.9	7.4
MFI (顆粒數/mL)	2-10 μm	69	540	811
	≥10 μm	0	17	25
	≥25 μm	0	0	0

表 5：具有 0.5% (w/v)泊洛沙姆 188 之調配物的穩定性資料

試驗		在 45℃下之儲存時長(月)		
		0	1	3
藉由 RP-UPLC 回收之抗體的%		100	100	100
藉由 SE-UPLC 測定之純度	% HMW	2.1	9.1	24.2
	%主要	97.3	90.0	73.1
	% LMW	0.6	0.9	2.7
藉由 CEX-UPLC 之電荷變異體分析	%酸性	29.5	50.8	86.6
	%主要	61.5	44.5	9.0
	%鹼性	9.1	4.8	4.4
MFI (顆粒數/mL)	2-10 μm	179	805	1887

	≥10 μm	10	8	307
	≥25 μm	0	2	61

表 6：具有 0.01% (w/v) PEG3350 之調配物的穩定性資料

試驗		在 45℃下之儲存時長(月)		
		0	1	3
藉由 RP-UPLC 回收之抗體的%		100	102	100
藉由 SE-UPLC 測定之純度	% HMW	2.1	9.3	23.6
	%主要	97.4	89.9	73.6
	% LMW	0.6	0.9	2.7
藉由 CEX-UPLC 之電荷變異體分析	%酸性	29.4	51.6	86.4
	%主要	62.2	46.1	11.9
	%鹼性	8.5	2.4	1.8
MFI (顆粒數/mL)	2-10 μm	42	494	2085
	≥10 μm	6	15	206
	≥25 μm	0	6	40

表 7：具有 0.1% (w/v) PEG3350 之調配物的穩定性資料

試驗		在 45℃下之儲存時長(月)		
		0	1	3
藉由 RP-UPLC 回收之抗體的%		100	97	92
藉由 SE-UPLC 測定之純度	% HMW	2.1	9.3	22.4
	%主要	97.4	89.8	74.9
	% LMW	0.6	0.9	2.8
藉由 CEX-UPLC 之電荷變異體分析	%酸性	32.1	51.0	85.7
	%主要	60.6	45.6	10.9
	%鹼性	7.4	3.4	3.5
MFI (顆粒數/mL)	2-10 μm	94	313	2058
	≥10 μm	2	15	159
	≥25 μm	0	4	21

表 8：具有 0.5% (w/v) PEG3350 之調配物的穩定性資料

試驗		在 45℃下之儲存時長(月)		
		0	1	3
藉由 RP-UPLC 回收之抗體的%		100	100	98
藉由 SE-UPLC 測定之純度	% HMW	2.1	9.2	23.9
	%主要	97.3	89.8	73.4
	% LMW	0.6	0.9	2.7
藉由 CEX-UPLC 之電荷變異體分析	%酸性	29.7	52.0	83.6
	%主要	62.0	45.7	10.5
	%鹼性	8.4	2.3	6.0

MFI (顆粒數/mL)	2-10 μm	121	1289	2654
	≥10 μm	0	44	279
	≥25 μm	0	25	31

實例 5：含有不同濃度之泊洛沙姆 188 或 PEG3350 之調配物的儲存及應力條件之穩定性資料

【0135】 在 5℃長達 18 個月之儲存條件、加速條件(25℃長達 6 個月)、熱應力條件(45℃長達 2 個月)及攪拌應力條件下測試具有不同濃度之泊洛沙姆 188 或 PEG3350 之 IL-4R 抗體調配物的穩定性。濃度為 150 mg/mL 之包含 SEQ ID NO: 1/2 之 HCVR/LCVR 胺基酸序列對的抗 IL-4R 抗體與 20 mM 組胺酸、12.5 mM 乙酸鈉、25 mM 精胺酸-HCl 及 5% w/v 蔗糖一起在無界面活性劑存在下或在 0.02%、0.04%或 0.1% w/v 之泊洛沙姆 188 或 PEG3350 存在下調配，pH 為 5.9。將此等調配物儲存於 Nuova Ompi 2.25 mL 注射器中。藉由 SE-UPLC 測定 HMW 物種之百分比。藉由 CEX-UPLC 量測電荷變異體物種之形成。使用膜顯微術及/或 MFI 來量測容器中之顆粒數目。

【0136】 表 9 至 11 顯示無界面活性劑之調配物的資料。表 12 至 14、15 至 17 及 18 至 20 分別顯示含有 0.02%、0.04%及 0.1% (w/v)泊洛沙姆 188 之調配物的穩定性資料。表 21 至 23、24 至 26 及 27 至 29 分別顯示含有 0.02%、0.04%及 0.1% (w/v) PEG3350 之調配物的穩定性資料。如表 12、15 及 18 中所示，含有 0.02%、0.04%或 0.1% (w/v)泊洛沙姆之調配物在 5℃下長期儲存(長達 18 個月)後具有顯著較少的顆粒。類似地，如表 21、24 及 27 中所示，含有 0.02%、0.04%或 0.1% PEG3350 之調配物在 5℃下長期儲存(長達 18 個月)後具有顯著較少的顆粒。在 25℃之加速條件或 45℃之熱應力條件下，含有 0.02%、0.04%或 0.1% (w/v)泊洛沙姆 188 或 PEG3350 之調配物相比無界面活性劑之調配物具有顯著較少的亞可見顆粒(參見表 10、13、16、19、22、25 及 28)。

【0137】 調配物在 25℃下經受攪拌應力 24 小時，隨後如下儲存：在 5℃下儲存 6、12 或 18 個月，在 25℃下儲存 6 個月，或在 45℃下儲存 1 或 2 個月。與不含界面活性劑之調配物相比，含有 0.02%、0.04%或 0.1% (w/v)泊洛沙姆 188 或 PEG3350 之調配物在 25℃下攪拌 24 小時後形成的 HMW 物種顯著較少。此外，與不含界面活性劑之調配物相比，含有 0.02%、0.04%或 0.1% (w/v)泊洛沙姆 188 或 PEG3350 之調配物在攪拌 24 小時且隨後在 5℃或 25℃條件下長期儲存時表現出較低的 HMW 物種百分比，表明穩定性得到改善。參見表 11、14、17、20、23、26 及 29。

表 9：無界面活性劑之調配物的儲存穩定性資料(5℃)

試驗		t=0	在 5℃下之儲存時長(月)					
			1	3	6	9	12	18
藉由 SE-UPLC 測定之純度	% HMW	2.1	2.2	2.3	2.6	2.6	2.7	2.9
	%主要	96.8	97.6	97.7	96.5	96.5	96.6	96.3
	% LMW	1.1	0.3	0.0	1.0	0.9	0.7	0.9
藉由 CEX-UPLC 之電荷變異體分析	%酸性	27.1	26.2	25.8	26.4	N/A	26.3	25.7
	%主要	58.7	61.1	61.8	60.4	N/A	60.8	61.9
	%鹼性	14.2	12.7	12.4	13.3	N/A	13.0	12.4
膜顯微術 (顆粒數/容器)[a]	≥ 10 µm	N/A	N/A	N/A	72	N/A	51	120
	≥ 25 µm	N/A	N/A	N/A	11	N/A	30	27
MFI (顆粒數/容器) (應用的縱橫比≤0.85)	2-300µm	13600	N/A	N/A	17782	N/A	15175	38790
	5-300µm	4895	N/A	N/A	6367	N/A	4859	17738
	10-300µm	2491	N/A	N/A	3024	N/A	2044	9521
	25-300µm	533	N/A	N/A	511	N/A	406	2368
	50-300µm	47	N/A	N/A	59	N/A	51	265

[a]顯微術 USP 規格：≥10 µm 尺寸≤3000 個顆粒/容器；≥25 µm 尺寸≤300 個顆粒/容器

HMW = 高分子量；LMW = 低分子量；N/A = 不可用

表 10：無界面活性劑之調配物的加速儲存及熱應力穩定性資料

試驗		t=0	培育時長 在 25℃下(月)			培育時長 在 45℃下(月)		
			1	3	6	0.5	1	2
藉由 SE-UPLC 測定之純度	% HMW	2.1	2.7	3.2	3.8	3.6	4.7	8.3
	%主要	96.8	96.9	96.38	94.9	95.4	93.8	89.3
	% LMW	1.1	0.4	0.0	1.3	1.0	1.5	2.4
藉由 CEX-UPLC 之電荷變異體分析	%酸性	27.1	26.5	28.9	32.3	31.2	37.5	62.5
	%主要	58.7	59.5	57.9	53.8	56.3	50.3	27.0
	%鹼性	14.2	14.1	13.2	13.9	12.5	12.2	10.5
膜顯微術 (顆粒數/容器)[a]	≥ 10 µm	N/A	N/A	N/A	49	N/A	N/A	N/A
	≥ 25 µm	N/A	N/A	N/A	11	N/A	N/A	N/A
MFI (顆粒數/容器) (應用的縱橫比 ≤0.85)	2-300µm	13600	N/A	N/A	19813	N/A	9066	N/A
	5-300µm	4895	N/A	N/A	8827	N/A	2510	N/A
	10-300µm	2491	N/A	N/A	4347	N/A	1117	N/A
	25-300µm	533	N/A	N/A	639	N/A	163	N/A
	50-300µm	47	N/A	N/A	39	N/A	7	N/A

[a]顯微術 USP 規格：≥10 µm 尺寸≤3000 個顆粒/容器；≥25 µm 尺寸≤300 個顆粒/容器

HMW = 高分子量；LMW = 低分子量；N/A = 不可用

表 11：無界面活性劑之調配物的攪拌應力穩定性資料

試驗		t=0	24 小時攪拌*，隨後 在 5℃下儲存(月)				24 小時攪拌*，隨後 在 25℃下儲存(月)	24 小時攪拌*，隨後 在 45℃下儲存(月)	
			T0	6	12	18	6	1	2
藉由 SE-UPLC 測定之純度	% HMW	2.1	9.4	8.5	9.1	7.2	7.9	5.3	8.3
	%主要	96.8	90.6	90.6	90.3	92.0	91.1	93.4	89.5
	% LMW	1.1	0.0	0.9	0.6	0.8	1.0	1.3	2.3
藉由 CEX-UPLC 之電荷變異體分析	%酸性	27.1	26.7	25.8	26.4	26.2	32.4	37.5	61.5
	%主要	58.7	59.8	61.0	60.7	61.8	53.9	49.9	26.8
	%鹼性	14.2	13.5	13.3	13.0	12.1	13.7	12.7	11.7

*在 25℃下攪拌 24 小時，隨後在指定溫度下儲存

HMW = 高分子量；LMW = 低分子量

表 12：具有 0.02% (w/v)泊洛沙姆 188 之調配物的儲存穩定性資料(5℃)

試驗		t=0	在 5℃下之儲存時長(月)					
			1	3	6	9	12	18
藉由 SE-UPLC 測定之純度	% HMW	2.0	2.2	2.3	2.5	2.6	2.7	2.8
	%主要	97.1	97.6	97.7	96.5	96.5	96.6	96.4
	% LMW	0.8	0.2	0.0	1.0	0.9	0.7	0.9
藉由 CEX-UPLC 之電荷變異體分析	%酸性	26.9	27.5	26.4	26.5	N/A	26.1	25.9
	%主要	58.4	59.2	60.5	59.9	N/A	60.3	61.8
	%鹼性	14.8	13.3	13.1	13.6	N/A	13.6	12.3
膜顯微術 (顆粒數/容器)[a]	≥ 10 µm	N/A	N/A	N/A	36	N/A	42	86
	≥ 25 µm	N/A	N/A	N/A	17	N/A	17	21
MFI (顆粒數/容器) (應用的縱橫比 ≤0.85)	2-300µm	27602	N/A	N/A	6120	N/A	14265	9781
	5-300µm	8871	N/A	N/A	992	N/A	3355	1560
	10-300µm	3440	N/A	N/A	277	N/A	1349	622
	25-300µm	294	N/A	N/A	10	N/A	201	43
	50-300µm	11	N/A	N/A	2	N/A	38	2

[a]顯微術 USP 規格：≥10 µm 尺寸≤3000 個顆粒/容器；≥25 µm 尺寸≤300 個顆粒/容器

HMW = 高分子量；LMW = 低分子量；N/A = 不可用

表 13：具有 0.02% (w/v)泊洛沙姆 188 之調配物的加速儲存及熱應力穩定性資料

試驗		t=0	培育時長 在 25℃下(月)			培育時長 在 45℃下(月)		
			1	3	6	0.5	1	2
視覺外觀								
藉由 SE-UPLC 測定之純度	% HMW	2.0	2.7	3.1	3.8	3.8	4.8	8.2
	%主要	97.1	97.1	96.9	95.1	95.1	93.8	89.1
	% LMW	0.8	0.3	0.0	1.2	1.1	1.4	2.6
藉由 CEX-UPLC 之電荷變異體分析	%酸性	26.9	26.8	29.2	32.1	31.5	37.9	60.0
	%主要	58.4	59.0	55.4	54.3	55.3	49.1	26.6
	%鹼性	14.8	14.2	15.4	13.6	13.3	13.0	13.4
膜顯微術 (顆粒數/容器)[a]	≥ 10 µm	N/A	N/A	N/A	36	N/A	N/A	N/A
	≥ 25 µm	N/A	N/A	N/A	13	N/A	N/A	N/A
MFI (顆粒數/容器) (應用的縱橫比 ≤0.85)	2-300µm	27602	N/A	N/A	5786	N/A	4584	N/A
	5-300µm	8871	N/A	N/A	457	N/A	455	N/A
	10-300µm	3440	N/A	N/A	198	N/A	209	N/A
	25-300µm	294	N/A	N/A	10	N/A	14	N/A
	50-300µm	11	N/A	N/A	2	N/A	0	N/A

[a]顯微術 USP 規格：≥10 µm 尺寸≤3000 個顆粒/容器；≥25 µm 尺寸≤300 個顆粒/容器

HMW = 高分子量；LMW = 低分子量；N/A = 不可用

表 14：具有 0.02% (w/v)泊洛沙姆 188 之調配物的攪拌應力穩定性資料

試驗		t=0	24 小時攪拌*，隨後在 5℃下儲存(月)				24 小時攪拌*，隨後在 25℃下儲存(月)	24 小時攪拌*，隨後在 45℃下儲存(月)	
			T0	6	12	18	6	1	2
藉由 SE-UPLC 測定之純度	% HMW	2.0	4.1	3.0	3.0	3.0	3.9	4.9	8.3
	%主要	97.1	95.7	96.1	96.3	95.9	95.0	93.8	89.3
	% LMW	0.8	0.1	0.9	0.7	0.9	1.2	1.4	2.5
藉由 CEX-UPLC 之電荷變異體分析	%酸性	26.9	26.7	26.0	26.2	25.8	32.5	37.4	59.4
	%主要	58.4	59.3	60.8	60.1	61.6	53.6	48.9	26.9
	%鹼性	14.8	14.0	13.3	13.8	12.6	13.9	13.7	13.7

*在 25℃下攪拌 24 小時，隨後在指定溫度下儲存

HMW = 高分子量；LMW = 低分子量；N/A = 不可用

表 15：具有 0.04% (w/v)泊洛沙姆 188 之調配物的儲存穩定性資料(5℃)

試驗		t=0	在 5℃下之儲存時長(月)					
			1	3	6	9	12	18
藉由 SE-UPLC 測定之純度	% HMW	2.1	2.2	2.3	2.6	2.6	2.7	2.8
	%主要	97.1	97.6	97.7	96.5	96.5	96.6	96.3
	% LMW	0.8	0.2	0.0	1.0	0.9	0.7	0.8
藉由 CEX-UPLC 之電荷變異體分析	%酸性	26.9	27.7	26.4	26.1	N/A	25.9	25.6
	%主要	58.3	59.0	60.3	59.4	N/A	60.8	62.0
	%鹼性	14.8	13.4	13.3	14.5	N/A	13.3	12.4
膜顯微術 (顆粒數/容器)[a]	≥ 10 µm	N/A	N/A	N/A	34	N/A	25	40
	≥ 25 µm	N/A	N/A	N/A	2	N/A	8	4
MFI (顆粒數/容器) (應用的縱橫比 ≤0.85)	2-300µm	7067	N/A	N/A	2747	N/A	15777	19227
	5-300µm	772	N/A	N/A	171	N/A	1698	2034
	10-300µm	289	N/A	N/A	54	N/A	734	720
	25-300µm	8	N/A	N/A	5	N/A	33	23
	50-300µm	0	N/A	N/A	0	N/A	3	0

[a]顯微術 USP 規格：≥10 µm 尺寸≤3000 個顆粒/容器；≥25 µm 尺寸≤300 個顆粒/容器

HMW = 高分子量；LMW = 低分子量；N/A = 不可用

表 16：具有 0.04% (w/v)泊洛沙姆 188 之調配物的加速儲存及熱應力穩定性資料

試驗		t=0	培育時長 在 25℃下(月)			培育時長 在 45℃下(月)		
			1	3	6	0.5	1	2
藉由 SE-UPLC 測定之純度	% HMW	2.1	2.7	2.9	3.8	3.8	4.8	8.7
	%主要	97.1	97.2	97.1	95.0	95.2	93.7	89.0
	% LMW	0.8	0.1	0.0	1.1	1.0	1.5	2.3
藉由 CEX-UPLC 之電荷變異體分析	%酸性	26.9	26.4	29.5	32.3	31.3	37.8	60.3
	%主要	58.3	57.9	54.8	54.1	55.6	48.5	24.2
	%鹼性	14.8	15.6	15.8	13.6	13.0	13.8	15.5
膜顯微術 (顆粒數/容器)[a]	≥ 10 µm	N/A	N/A	N/A	15	N/A	N/A	N/A
	≥ 25 µm	N/A	N/A	N/A	0	N/A	N/A	N/A
MFI (顆粒數/容器) (應用的縱橫比 ≤0.85)	2-300µm	7067	N/A	N/A	7042	N/A	7510	N/A
	5-300µm	772	N/A	N/A	550	N/A	377	N/A
	10-300µm	289	N/A	N/A	253	N/A	98	N/A
	25-300µm	8	N/A	N/A	5	N/A	3	N/A
	50-300µm	0	N/A	N/A	2	N/A	0	N/A

[a]顯微術 USP 規格：≥10 µm 尺寸≤3000 個顆粒/容器；≥25 µm 尺寸≤300 個顆粒/容器

HMW = 高分子量；LMW = 低分子量；N/A = 不可用

表 17：具有 0.04% (w/v)泊洛沙姆 188 之調配物的攪拌應力穩定性資料

試驗		t=0	24 小時攪拌*，隨後 在 5℃下儲存(月)				24 小時攪拌*，隨後 在 25℃下儲存(月)	24 小時攪拌*，隨後 在 45℃下儲存(月)	
			T0	6	12	18	6	1	2
藉由 SE-UPLC 測定之純度	% HMW	2.1	2.0	2.6	2.8	2.9	3.9	5.0	8.8
	%主要	97.1	95.2	96.5	96.5	96.2	95.0	93.7	89.0
	% LMW	0.8	2.7	0.1	0.7	0.9	1.2	1.3	2.3
藉由 CEX-UPLC 之電荷變異體分析	%酸性	26.9	26.9	26.3	26.4	26.3	32.3	38.0	60.2
	%主要	58.3	58.3	60.0	59.9	61.2	54.3	48.3	25.4
	%鹼性	14.8	14.8	13.7	13.7	12.6	13.4	13.8	14.4

*在 25℃下攪拌 24 小時，隨後在指定溫度下儲存

HMW = 高分子量；LMW = 低分子量

表 18：具有 0.1% (w/v)泊洛沙姆 188 之調配物的儲存穩定性資料(5℃)

試驗		t=0	在 5℃下之儲存時長(月)					
			1	3	6	9	12	18
藉由 SE-UPLC 測定之純度	% HMW	2.1	2.2	2.3	2.6	2.6	2.7	2.9
	%主要	97.0	97.6	97.8	96.5	96.5	96.6	96.3
	% LMW	1.0	0.2	0.0	0.9	0.9	0.7	0.9
藉由 CEX-UPLC 之電荷變異體分析	%酸性	27.0	27.6	26.2	26.0	N/A	26.3	25.3
	%主要	58.2	59.1	59.9	59.8	N/A	60.7	62.3
	%鹼性	14.8	13.3	14.0	14.2	N/A	13.0	12.4
膜顯微術 (顆粒數/容器)[a]	≥ 10 μm	N/A	N/A	N/A	84	N/A	34	114
	≥ 25 μm	N/A	N/A	N/A	19	N/A	4	30
MFI (顆粒數/容器) (應用的縱橫比≤0.85)	2-300μm	3424	N/A	N/A	3325	N/A	6985	18856
	5-300μm	215	N/A	N/A	217	N/A	426	1802
	10-300μm	119	N/A	N/A	131	N/A	204	894
	25-300μm	5	N/A	N/A	3	N/A	8	16
	50-300μm	0	N/A	N/A	2	N/A	3	3

[a]顯微術 USP 規格：≥10 μm 尺寸≤3000 個顆粒/容器；≥25 μm 尺寸≤300 個顆粒/容器

HMW = 高分子量；LMW = 低分子量；N/A = 不可用

表 19：具有 0.1% (w/v)泊洛沙姆 188 之調配物的加速儲存及熱應力穩定性資料

試驗		t=0	培育時長 在 25℃下(月)			培育時長 在 45℃下(月)		
			1	3	6	0.5	1	2
藉由 SE-UPLC 測定之純度	% HMW	2.1	2.7	3.0	3.8	3.8	4.7	8.3
	%主要	97.0	97.2	97.0	95.0	95.2	94.0	89.4
	% LMW	1.0	0.1	0.0	1.2	1.0	1.3	2.3
藉由 CEX-UPLC 之電荷變異體分析	%酸性	27.0	27.6	29.5	32.3	31.4	37.8	59.4
	%主要	58.2	57.8	54.3	53.8	54.9	49.0	25.9
	%鹼性	14.8	14.6	16.3	13.9	13.7	13.3	14.7
膜顯微術 (顆粒數/容器)[a]	≥ 10 μm	N/A	N/A	N/A	38	N/A	N/A	N/A
	≥ 25 μm	N/A	N/A	N/A	8	N/A	N/A	N/A
MFI (顆粒數/容器) (應用的縱橫比≤0.85)	2-300μm	3424	N/A	N/A	18633	N/A	7812	N/A
	5-300μm	215	N/A	N/A	1410	N/A	465	N/A
	10-300μm	119	N/A	N/A	650	N/A	204	N/A
	25-300μm	5	N/A	N/A	29	N/A	5	N/A
	50-300μm	0	N/A	N/A	0	N/A	0	N/A

[a]顯微術 USP 規格：≥10 μm 尺寸≤3000 個顆粒/容器；≥25 μm 尺寸≤300 個顆粒/容器

HMW = 高分子量；LMW = 低分子量；N/A = 不可用

表 20：具有 0.1% (w/v)泊洛沙姆 188 之調配物的攪拌應力穩定性資料

試驗		t=0	24 小時攪拌*，隨後在 5℃下儲存(月)				24 小時攪拌*，隨後在 25℃下儲存(月)	24 小時攪拌*，隨後在 45℃下儲存(月)	
			T0	6	12	18	6	1	2
藉由 SE-UPLC 測定之純度	% HMW	2.1	2.1	2.6	2.8	2.9	3.9	4.9	8.4
	%主要	97.0	97.8	96.4	96.5	96.3	95.0	93.8	89.2
	% LMW	1.0	0.1	1.0	0.7	0.9	1.2	1.3	2.4
藉由 CEX-UPLC 之電荷變異體分析	%酸性	27.0	26.8	26.6	26.4	26.4	32.3	38.1	58.9
	%主要	58.2	58.0	60.0	60.3	60.6	54.0	47.5	26.6
	%鹼性	14.8	15.2	13.4	13.4	13.0	13.7	14.4	14.5

*在 25℃下攪拌 24 小時，隨後在指定溫度下儲存

HMW = 高分子量；LMW = 低分子量

表 21：具有 0.02% (w/v) PEG3350 之調配物的儲存穩定性資料(5℃)

試驗		t=0	在 5℃下之儲存時長(月)					
			1	3	6	9	12	18
藉由 SE-UPLC 測定之純度	% HMW	2.0	2.2	2.3	2.5	2.7	2.7	2.8
	%主要	97.1	97.8	97.7	96.5	96.5	96.6	96.3
	% LMW	0.9	0.0	0.0	0.9	0.9	0.7	0.9
藉由 CEX-UPLC 之電荷變異體分析	%酸性	26.9	25.7	25.9	25.9	N/A	26.1	26.0
	%主要	58.5	61.3	60.4	60.7	N/A	60.5	61.8
	%鹼性	14.6	13.0	13.7	13.5	N/A	13.3	12.2
膜顯微術(顆粒數/容器)[a]	≥ 10 μm	N/A	N/A	N/A	15	N/A	23	25
	≥ 25 μm	N/A	N/A	N/A	0	N/A	6	8
MFI (顆粒數/容器)(應用的縱橫比≤0.85)	2-300μm	15027	N/A	N/A	10791	N/A	23589	22239
	5-300μm	6840	N/A	N/A	2297	N/A	8189	6644
	10-300μm	3540	N/A	N/A	1021	N/A	3571	2581
	25-300μm	612	N/A	N/A	144	N/A	444	386
	50-300μm	18	N/A	N/A	8	N/A	18	51

[a]顯微術 USP 規格：≥10 μm 尺寸≤3000 個顆粒/容器；≥25 μm 尺寸≤300 個顆粒/容器

HMW = 高分子量；LMW = 低分子量；N/A = 不可用

表 22：具有 0.02% (w/v) PEG3350 之調配物的加速儲存及熱應力穩定性資料

試驗		t=0	培育時長 在 25℃下(月)			培育時長 在 45℃下(月)		
			1	3	6	0.5	1	2
藉由 SE-UPLC 測定之純度	% HMW	2.0	2.6	3.1	3.8	3.7	4.9	8.6
	%主要	97.1	97.1	96.9	95.0	95.4	93.8	89.2
	% LMW	0.9	0.3	0.0	1.3	0.9	1.4	2.3
藉由 CEX-UPLC 之電荷變異體分析	%酸性	26.9	27.0	29.4	32.3	31.2	37.5	60.9
	%主要	58.5	58.6	55.3	53.8	56.3	50.0	25.7
	%鹼性	14.6	14.4	15.3	13.9	12.5	12.5	13.4
膜顯微術 (顆粒數/容器)[a]	≥ 10 µm	N/A	N/A	N/A	49	N/A	N/A	N/A
	≥ 25 µm	N/A	N/A	N/A	15	N/A	N/A	N/A
MFI (顆粒數/容器) (應用的縱橫比 ≤0.85)	2-300µm	15027	N/A	N/A	6011	N/A	9876	N/A
	5-300µm	6840	N/A	N/A	2448	N/A	1077	N/A
	10-300µm	3540	N/A	N/A	10334	N/A	432	N/A
	25-300µm	612	N/A	N/A	70	N/A	47	N/A
	50-300µm	18	N/A	N/A	3	N/A	2	N/A

[a]顯微術 USP 規格：≥10 µm 尺寸≤3000 個顆粒/容器；≥25 µm 尺寸≤300 個顆粒/容器

HMW = 高分子量；LMW = 低分子量；N/A = 不可用

表 23：具有 0.02% (w/v) PEG3350 之調配物的攪拌應力穩定性資料

試驗		t=0	24 小時攪拌*，隨後在 5℃下儲存(月)				24 小時攪拌*，隨後在 25℃下儲存(月)	24 小時攪拌*，隨後在 45℃下儲存(月)	
			T0	6	12	18	6	1	2
視覺外觀									
藉由 SE-UPLC 測定之純度	% HMW	2.0	2.9	2.9	2.8	2.9	3.9	4.9	8.5
	%主要	97.1	97.1	96.1	96.5	96.2	95.0	93.7	89.1
	% LMW	0.9	0.0	1.0	0.7	0.9	1.1	1.4	2.4
藉由 CEX-UPLC 之電荷變異體分析	%酸性	26.9	26.7	26.0	261	26.1	32.7	37.6	60.3
	%主要	58.5	59.3	60.7	60.4	61.6	54.0	49.6	25.8
	%鹼性	14.6	14.0	13.3	13.6	12.3	13.4	12.8	13.9

*在 25℃下攪拌 24 小時，隨後在指定溫度下儲存

HMW = 高分子量；LMW = 低分子量

表 24：具有 0.04% (w/v) PEG3350 之調配物的儲存穩定性資料(5℃)

試驗		t=0	在 5℃下之儲存時長(月)					
			1	3	6	9	12	18
藉由 SE-UPLC 測定之純度	% HMW	2.1	2.2	2.4	2.6	2.6	2.7	2.9
	%主要	97.0	97.7	97.6	96.4	96.5	96.6	96.3
	% LMW	1.0	0.1	0.0	1.0	0.9	0.7	0.9
藉由 CEX-UPLC 之電荷變異體分析	%酸性	26.8	26.2	25.8	26.4	N/A	26.1	25.2
	%主要	58.2	60.2	61.1	60.4	N/A	60.7	62.7
	%鹼性	14.9	13.7	13.1	13.2	N/A	13.2	12.1
膜顯微術 (顆粒數/容器)[a]	≥ 10 μm	N/A	N/A	N/A	38	N/A	61	42
	≥ 25 μm	N/A	N/A	N/A	11	N/A	19	6
MFI (顆粒數/容器) (應用的縱橫比≤0.85)	2-300μm	43797	N/A	N/A	18903	N/A	16022	22243
	5-300μm	6840	N/A	N/A	5833	N/A	4553	6873
	10-300μm	10262	N/A	N/A	1951	N/A	1881	3082
	25-300μm	940	N/A	N/A	67	N/A	204	367
	50-300μm	16	N/A	N/A	5	N/A	2	15

[a]顯微術 USP 規格：≥10 μm 尺寸≤3000 個顆粒/容器；≥25 μm 尺寸≤300 個顆粒/容器

HMW = 高分子量；LMW = 低分子量；N/A = 不可用

表 25：具有 0.04% (w/v) PEG3350 之調配物的加速儲存及熱應力穩定性資料

試驗		t=0	培育時長 在 25℃下(月)			培育時長 在 45℃下(月)		
			1	3	6	0.5	1	2
藉由 SE-UPLC 測定之純度	% HMW	2.1	2.6	3.0	3.8	3.8	4.6	8.2
	%主要	97.0	97.3	97.0	95.1	95.2	94.0	89.4
	% LMW	1.0	0.1	0.0	1.1	1.0	1.4	2.4
藉由 CEX-UPLC 之電荷變異體分析	%酸性	26.8	27.0	28.8	32.3	31.3	35.3	60.3
	%主要	58.2	58.3	56.0	53.6	55.0	51.1	24.3
	%鹼性	14.9	14.8	15.2	14.1	13.7	13.6	15.4
膜顯微術 (顆粒數/容器)[a]	≥ 10 μm	N/A	N/A	N/A	80	N/A	N/A	N/A
	≥ 25 μm	N/A	N/A	N/A	25	N/A	N/A	N/A
MFI (顆粒數/容器) (應用的縱橫比≤0.85)	2-300μm	43797	N/A	N/A	13611	N/A	5744	N/A
	5-300μm	6840	N/A	N/A	3628	N/A	475	N/A
	10-300μm	10262	N/A	N/A	1581	N/A	188	N/A
	25-300μm	940	N/A	N/A	103	N/A	18	N/A
	50-300μm	16	N/A	N/A	2	N/A	2	N/A

[a]顯微術 USP 規格：≥10 μm 尺寸≤3000 個顆粒/容器；≥25 μm 尺寸≤300 個顆粒/容器

HMW = 高分子量；LMW = 低分子量；N/A = 不可用

表 26：具有 0.04% (w/v) PEG3350 之調配物的攪拌應力穩定性資料

試驗		t=0	24 小時攪拌*，隨後在 5℃下儲存(月)				24 小時攪拌*，隨後在 25℃下儲存(月)	24 小時攪拌*，隨後在 45℃下儲存(月)	
			T0	6	12	18	6	1	2
藉由 SE-UPLC 測定之純度	% HMW	2.1	2.1	2.6	2.7	2.9	3.9	4.8	8.3
	%主要	97.0	97.9	96.4	96.6	96.3	95.0	93.7	89.5
	% LMW	1.0	0.0	1.0	0.7	0.9	1.1	1.5	2.2
藉由 CEX-UPLC 之電荷變異體分析	%酸性	26.8	26.8	26.6	26.3	25.9	32.6	35.8	59.5
	%主要	58.2	57.5	60.0	60.3	61.7	53.7	50.0	26.4
	%鹼性	14.9	15.8	13.5	13.4	12.4	13.6	14.2	14.2

*在 25℃下攪拌 24 小時，隨後在指定溫度下儲存

HMW = 高分子量；LMW = 低分子量

表 27：具有 0.1% (w/v) PEG3350 之調配物的儲存穩定性資料(5℃)

試驗		t=0	在 5℃下之儲存時長(月)					
			1	3	6	9	12	18
藉由 SE-UPLC 測定之純度	% HMW	2.0	2.2	2.3	2.6	2.6	2.7	2.9
	%主要	97.0	97.7	97.7	96.5	96.5	96.6	96.3
	% LMW	0.9	0.2	0.0	0.9	0.9	0.7	0.8
藉由 CEX-UPLC 之電荷變異體分析	%酸性	26.9	27.7	26.5	26.3	N/A	26.3	26.1
	%主要	58.2	59.1	60.0	59.5	N/A	60.4	61.8
	%鹼性	15.0	13.3	13.5	14.2	N/A	13.3	12.1
膜顯微術 (顆粒數/容器)[a]	≥ 10 µm	N/A	N/A	N/A	99	N/A	36	38
	≥ 25 µm	N/A	N/A	N/A	42	N/A	11	11
MFI (顆粒數/容器) (應用的縱橫比 ≤0.85)	2-300µm	12061	N/A	N/A	12946	N/A	8967	11449
	5-300µm	1075	N/A	N/A	1010	N/A	528	638
	10-300µm	445	N/A	N/A	414	N/A	184	200
	25-300µm	13	N/A	N/A	16	N/A	2	7
	50-300µm	0	N/A	N/A	0	N/A	0	0

[a]顯微術 USP 規格：≥10 µm 尺寸≤3000 個顆粒/容器；≥25 µm 尺寸≤300 個顆粒/容器

HMW = 高分子量；LMW = 低分子量；N/A = 不可用

表 28：具有 0.1% (w/v) PEG3350 之調配物的加速儲存及熱應力穩定性資料

試驗		t=0	培育時長 在 25℃下(月)			培育時長 在 45℃下(月)		
			1	3	6	0.5	1	2
藉由 SE-UPLC 測定之純度	% HMW	2.0	2.7	3.0	3.8	3.7	4.8	8.6
	%主要	97.0	97.1	97.0	95.0	95.3	93.7	88.9
	% LMW	0.9	0.2	0.0	1.2	1.0	1.5	2.5
藉由 CEX-UPLC 之電荷變異體分析	%酸性	26.9	27.7	28.7	32.3	31.1	37.6	60.1
	%主要	58.2	57.1	55.5	53.6	55.4	48.5	26.2
	%鹼性	15.0	15.2	15.7	14.1	13.4	13.9	13.7
膜顯微術 (顆粒數/容器)[a]	≥ 10 µm	N/A	N/A	N/A	27	N/A	N/A	N/A
	≥ 25 µm	N/A	N/A	N/A	2	N/A	N/A	N/A
MFI (顆粒數/容器) (應用的縱橫比 ≤0.85)	2-300µm	12061	N/A	N/A	6177	N/A	3701	N/A
	5-300µm	1075	N/A	N/A	430	N/A	297	N/A
	10-300µm	445	N/A	N/A	161	N/A	129	N/A
	25-300µm	13	N/A	N/A	7	N/A	15	N/A
	50-300µm	0	N/A	N/A	2	N/A	0	N/A

[a]顯微術 USP 規格：≥10 µm 尺寸≤3000 個顆粒/容器；≥25 µm 尺寸≤300 個顆粒/容器

HMW = 高分子量；LMW = 低分子量；N/A = 不可用

表 29：具有 0.1% (w/v) PEG3350 之調配物的攪拌應力穩定性資料

試驗		t=0	24 小時攪拌*，隨後 在 5℃下儲存(月)				24 小時攪拌*，隨後 在 25℃下儲存(月)	24 小時攪拌*，隨後 在 45℃下儲存(月)	
			T0	6	12	18	6	1	2
藉由 SE-UPLC 測定之純度	% HMW	2.0	2.1	2.6	2.8	2.9	3.9	5.0	8.8
	%主要	97.0	97.9	96.4	96.5	96.3	95.0	93.7	88.9
	% LMW	0.9	0.0	1.0	0.7	0.9	1.1	1.3	2.3
藉由 CEX-UPLC 之電荷變異體分析	%酸性	26.9	26.7	26.2	27.2	25.5	32.6	37.7	60.6
	%主要	58.2	57.8	60.0	59.3	62.1	53.7	49.7	25.0
	%鹼性	15.0	15.5	13.7	13.5	12.4	13.6	12.7	14.5

*在 25℃下攪拌 24 小時，隨後在指定溫度下儲存

HMW = 高分子量；LMW = 低分子量

【0138】 本發明之範疇不受本文所述之特定實施例限制。實際上，根據前述說明，除本文所述之修改以外，本發明之各種修改對熟習此項技術者而言亦會變得顯而易見。此類修飾意欲屬於隨附申請專利範圍之範疇內。

表 30：自 ST.26 格式化序列表中排除的序列

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7	LGS

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【發明申請專利範圍】

【請求項1】 一種穩定的液體醫藥調配物，其包含：

(i)特異性結合於人類介白素-4 受體 α (hIL-4Rα)之人類抗體；

(ii)一或多種緩衝液；

(iii)熱穩定劑；

(iv)黏度調節劑；及

(v)包含濃度為 0.01% w/v 至 0.19% w/v 之聚乙二醇或泊洛沙姆(poloxamer)的界面活性劑，

其中該調配物之 pH 為 5.7 至 6.1。

【請求項2】 如請求項 1 之穩定的液體醫藥調配物，其中該抗體包含重鏈可變區(HCVR)及輕鏈可變區(LCVR)，該 HCVR 包含分別包含 SEQ ID NO: 3、4 及 5 之胺基酸序列的互補決定區 HCDR1、HCDR2 及 HCDR3，該 LCVR 包含分別包含 SEQ ID NO: 6、7 及 8 之胺基酸序列的互補決定區 LCDR1、LCDR2 及 LCDR3。

【請求項3】 如請求項 2 之穩定的液體醫藥調配物，其中該抗體包含含有 SEQ ID NO: 1 之胺基酸序列的 HCVR 及含有 SEQ ID NO: 2 之胺基酸序列的 LCVR。

【請求項4】 如請求項 1 至 3 中任一項之穩定的液體醫藥調配物，其中該抗體具有人類 IgG 重鏈恆定區。

【請求項5】 如請求項 4 之穩定的液體醫藥調配物，其中該重鏈恆定區屬於同型 IgG1。

【請求項6】 如請求項 4 之穩定的液體醫藥調配物，其中該重鏈恆定區屬於同型 IgG4。

【請求項7】 如請求項 1 至 3 中任一項之穩定的液體醫藥調配物，其中該抗體包含含有 SEQ ID NO: 9 之胺基酸序列的重鏈，及含有 SEQ ID NO: 10 之胺基

酸序列的輕鏈。

【請求項8】 如請求項 1 至 7 中任一項之穩定的液體醫藥調配物，其中該界面活性劑為聚乙二醇。

【請求項9】 如請求項 8 之穩定的液體醫藥調配物，其中該聚乙二醇為 PEG3350。

【請求項10】 如請求項 1 至 7 中任一項之穩定的液體醫藥調配物，其中該界面活性劑為泊洛沙姆。

【請求項11】 如請求項 10 之穩定的液體醫藥調配物，其中該泊洛沙姆為泊洛沙姆 188。

【請求項12】 如請求項 1 至 11 中任一項之穩定的液體醫藥調配物，其中該緩衝液包含乙酸鹽緩衝液及/或組胺酸緩衝液。

【請求項13】 如請求項 12 之穩定的液體醫藥調配物，其中該緩衝液包含濃度為 10 mM 至 15 mM 之乙酸鹽。

【請求項14】 如請求項 13 之穩定的液體醫藥調配物，其中該乙酸鹽以 12.5 mM ± 1.25 mM 之濃度存在。

【請求項15】 如請求項 12 之穩定的液體醫藥調配物，其中該緩衝液包含濃度為 15 mM 至 25 mM 之組胺酸。

【請求項16】 如請求項 15 之穩定的液體醫藥調配物，其中該組胺酸以 20 mM ± 2 mM 之濃度存在。

【請求項17】 如請求項 1 至 16 中任一項之穩定的液體醫藥調配物，其中該熱穩定劑為濃度為 2.5% w/v 至 7.5% w/v 之蔗糖。

【請求項18】 如請求項 17 之穩定的液體醫藥調配物，其中該蔗糖以 5% w/v ± 0.5% w/v 之濃度存在。

【請求項19】 如請求項 1 至 18 中任一項之穩定的液體醫藥調配物，其中該黏度調節劑為濃度為 20 mM 至 80 mM 之精胺酸。

【請求項20】 如請求項 19 之穩定的液體醫藥調配物，其中該精胺酸以 25 mM ± 2.5 mM 之濃度存在。

【請求項21】 如請求項 19 之穩定的液體醫藥調配物，其中該精胺酸以 50 mM ± 2.5 mM 之濃度存在。

【請求項22】 如請求項 19 之穩定的液體醫藥調配物，其中該精胺酸以 75 mM ± 2.5 mM 之濃度存在。

【請求項23】 如請求項 1 至 22 中任一項之穩定的液體醫藥調配物，其中該抗體以至多 200 mg/mL 之濃度存在。

【請求項24】 如請求項 1 至 23 中任一項之穩定的液體醫藥調配物，其中該抗體以 100 mg/mL 至 200 mg/mL 之濃度存在。

【請求項25】 如請求項 24 之穩定的液體醫藥調配物，其中該抗體以 150 mg/mL ± 15 mg/mL 之濃度存在。

【請求項26】 如請求項 24 之穩定的液體醫藥調配物，其中該抗體以 175 mg/mL ± 15 mg/mL 之濃度存在。

【請求項27】 一種穩定的液體醫藥調配物，其包含：

(i)濃度為 150 mg/mL ± 10 mg/mL 之人類抗體，其中該抗體特異性結合於人類介白素-4 受體 α (hIL-4Rα)且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；

(ii)濃度為 12.5 mM ± 1.25 mM 之乙酸鹽；

(iii)濃度為 20 mM ± 2 mM 之組胺酸；

(iv)濃度為 5% w/v ± 0.5% w/v 之蔗糖；

(v)濃度為 25 mM ± 2.5 mM 之精胺酸；及

(vi)包含濃度為 0.01% w/v 至 0.19% w/v 之 PEG3350 或泊洛沙姆 188 的界面活性劑，

其中該調配物之 pH 為 5.9 ± 0.2。

【請求項28】 一種穩定的液體醫藥調配物，其包含：

(i)濃度為 175 mg/mL ± 10 mg/mL 之人類抗體，其中該抗體特異性結合於人類介白素-4 受體 α (hIL-4Rα)且包含含有 SEQ ID NO: 1 之胺基酸序列的重鏈可變區(HCVR)及含有 SEQ ID NO: 2 之胺基酸序列的輕鏈可變區(LCVR)；

(ii)濃度為 12.5 mM ± 1.25 mM 之乙酸鹽；

(iii)濃度為 20 mM ± 2 mM 之組胺酸；

(iv)濃度為 5% w/v ± 0.5% w/v 之蔗糖；

(v)濃度為 25 mM ± 2.5 mM 之精胺酸；及

(vi)包含濃度為 0.01% w/v 至 0.19% w/v 之 PEG3350 或泊洛沙姆 188 的界面活性劑，

其中該調配物之 pH 為 5.9 ± 0.2。

【請求項29】 如請求項 27 或 28 之穩定的液體醫藥調配物，其中該抗體包含含有 SEQ ID NO: 9 之胺基酸序列的重鏈及含有 SEQ ID NO: 10 之胺基酸序列的輕鏈。

【請求項30】 如請求項 1 至 29 中任一項之穩定的液體醫藥調配物，其中該調配物含有磷脂酶蛋白。

【請求項31】 如請求項 1 至 30 中任一項之穩定的液體醫藥調配物，其中該調配物在室溫下藉由渦旋攪拌至多 120 分鐘後，藉由尺寸排阻-超高效液相層析(SE-UPLC)測定，包含不超過 3%的高分子量(HMW)物種。

【請求項32】 如請求項 31 之穩定的液體醫藥調配物，其中該調配物在室溫下藉由渦旋攪拌至多 120 分鐘後，藉由 SE-UPLC 測定，包含不超過 2.5%的高分子量(HMW)物種。

【請求項33】 如請求項 1 至 30 中任一項之穩定的液體醫藥調配物，其中該調配物在 45℃下儲存 30 天後，藉由 SE-UPLC 測定，包含不超過 8%的高分子量(HMW)物種。

【請求項34】 如請求項 1 至 30 中任一項之穩定的液體醫藥調配物，其中該調配物在 45℃下儲存 40 天後，藉由 SE-UPLC 測定，包含不超過 9%的高分子量(HMW)物種。

【請求項35】 如請求項 1 至 30 中任一項之穩定的液體醫藥調配物，其中該調配物在 45℃下儲存 50 天後，藉由 SE-UPLC 測定，包含不超過 11%的高分子量(HMW)物種。

【請求項36】 如請求項 1 至 35 中任一項之穩定的液體醫藥調配物，其中該調配物在 5℃下儲存 6 個月後，藉由顯微術測定，在 2.25 mL 的體積中，直徑≥10 μm 之顆粒不超過 1000 個、不超過 500 個或不超過 150 個，且其中該調配物含有磷脂酶蛋白。

【請求項37】 如請求項 1 至 35 中任一項之穩定的液體醫藥調配物，其中該調配物在 5℃下儲存 36 個月後，藉由顯微術測定，在 2.25 mL 的體積中，直徑≥10 μm 之顆粒不超過 1000 個、不超過 500 個或不超過 150 個，且其中該調配物含有磷脂酶蛋白。

【請求項38】 如請求項 1 至 35 中任一項之穩定的液體醫藥調配物，其中該調配物在 5℃下儲存 6 個月後，藉由顯微術測定，在 2.25 mL 的體積中，直徑≥25 μm 之顆粒不超過 500 個、不超過 250 個或不超過 50 個，且其中該調配物含有磷脂酶蛋白。

【請求項39】 如請求項 1 至 35 中任一項之穩定的液體醫藥調配物，其中該調配物在 5℃下儲存 6 個月後，藉由顯微術測定，在 2.25 mL 的體積中，直徑≥25 μm 之顆粒不超過 500 個、不超過 250 個或不超過 50 個，且其中該調配物含有磷脂酶蛋白。

【請求項40】 如請求項 36 至 39 中任一項之穩定的液體醫藥調配物，其中該磷脂酶蛋白為磷脂酶 B 樣 2 蛋白。

【請求項41】 如請求項 1 至 35 中任一項之穩定的液體醫藥調配物，其中該

調配物在 25℃下攪拌 24 小時後，藉由 SE-UPLC 測定，包含不超過 4%的高分子量(HMW)物種。

【請求項42】 如請求項 1 至 35 中任一項之穩定的液體醫藥調配物，其中該調配物在 25℃下攪拌 24 小時且(i)在 5℃下儲存 6、12 或 18 個月，或(ii)在 25℃下儲存 6 個月後，藉由 SE-UPLC 測定，包含不超過 4%的高分子量(HMW)物種。

【請求項43】 如請求項 1 至 42 中任一項之穩定的液體醫藥調配物，其包含於玻璃小瓶中。

【請求項44】 如請求項 1 至 42 中任一項之穩定的液體醫藥調配物，其包含於注射器中。

【請求項45】 如請求項 44 之穩定的液體醫藥調配物，其中該注射器包含經氟碳塗佈之柱塞。

【請求項46】 如請求項 44 之穩定的液體醫藥調配物，其中該注射器為低鎢注射器。

【請求項47】 如請求項 44 至 46 中任一項之穩定的液體醫藥調配物，其為預填充注射器。

【請求項48】 如請求項 47 之穩定的液體醫藥調配物，其為預填充固定針頭注射器。

【請求項49】 如請求項 1 至 42 中任一項之穩定的液體醫藥調配物，其包含在大容量裝置或推注注射器中。

【請求項50】 一種筆式或自動注射器遞送裝置，其含有如請求項 1 至 42 中任一項之穩定的液體醫藥調配物。

【請求項51】 如請求項 50 之遞送裝置，其為一次性筆式遞送裝置。

【請求項52】 如請求項 50 之遞送裝置，其為可重複使用的筆式遞送裝置。

【請求項53】 一種容器，其含有如請求項 1 至 42 中任一項之穩定的液體醫藥調配物。

【請求項54】 一種套組，其包含(i)含有如請求項 1 至 42 中任一項之穩定的液體醫藥調配物之容器，及(ii)該醫藥調配物之使用標籤。

【請求項55】 如請求項 54 之套組，其中該標籤敍述該醫藥調配物之皮下投予。

【請求項56】 如請求項 54 之套組，其中該標籤敍述該醫藥調配物之靜脈內投予。

【請求項57】 一種單位劑型，其包含如請求項 1 至 42 中任一項之穩定的液體醫藥調配物，其中該抗體以 1 mg 至 500 mg 之量存在。

【請求項58】 如請求項 57 之單位劑型，其中該抗體以約 300 mg 之量存在。

【請求項59】 如請求項 57 之單位劑型，其中該抗體以約 200 mg 之量存在。

【請求項60】 如請求項 57 之單位劑型，其中該抗體以約 100 mg 之量存在。

【請求項61】 如請求項 57 至 60 中任一項之單位劑型，其中該調配物包含於注射器中。

【請求項62】 如請求項 61 之單位劑型，其中該注射器為預填充注射器。

【請求項63】 一種安全系統遞送裝置，其含有如請求項 1 至 42 中任一項之穩定的液體醫藥調配物。

【請求項64】 如請求項 63 之安全系統遞送裝置，其包括經配置藉由人工操作來延伸的安全套管。

【請求項65】 如請求項 63 之安全系統遞送裝置，其包括經配置在注射該穩定的液體醫藥調配物後自動延伸的安全套管。

[發明圖式]

圖1

【表1】

試驗編號	試驗條件				試驗結果	
	溫度(°C)	壓力(MPa)	時間(h)	氣體流量(sccm)	產率(%)	純度(%)
1	25	0.1	1	100	12.5	98.2
2	25	0.1	2	100	23.1	98.5
3	25	0.1	4	100	41.8	98.9
4	25	0.1	8	100	68.4	99.1
5	25	0.1	12	100	82.0	99.3
6	25	0.1	24	100	91.7	99.4
7	25	0.1	48	100	96.3	99.5
8	25	0.1	72	100	97.0	99.5
9	25	0.1	96	100	97.2	99.5
10	25	0.1	120	100	97.3	99.5
11	25	0.1	144	100	97.3	99.5
12	25	0.1	168	100	97.3	99.5
13	25	0.1	192	100	97.3	99.5
14	25	0.1	216	100	97.3	99.5
15	25	0.1	240	100	97.3	99.5
16	25	0.1	264	100	97.3	99.5
17	25	0.1	288	100	97.3	99.5
18	25	0.1	312	100	97.3	99.5
19	25	0.1	336	100	97.3	99.5
20	25	0.1	360	100	97.3	99.5
21	25	0.1	384	100	97.3	99.5
22	25	0.1	408	100	97.3	99.5
23	25	0.1	432	100	97.3	99.5
24	25	0.1	456	100	97.3	99.5
25	25	0.1	480	100	97.3	99.5

【表2】試驗三/密集，最佳條件

試驗編號	試驗條件				試驗結果	
	溫度(°C)	壓力(MPa)	時間(h)	氣體流量(sccm)	產率(%)	純度(%)
1	25	0.1	1	100	12.5	98.2
2	25	0.1	2	100	23.1	98.5
3	25	0.1	4	100	41.8	98.9
4	25	0.1	8	100	68.4	99.1
5	25	0.1	12	100	82.0	99.3
6	25	0.1	24	100	91.7	99.4
7	25	0.1	48	100	96.3	99.5
8	25	0.1	72	100	97.0	99.5
9	25	0.1	96	100	97.2	99.5
10	25	0.1	120	100	97.3	99.5
11	25	0.1	144	100	97.3	99.5
12	25	0.1	168	100	97.3	99.5
13	25	0.1	192	100	97.3	99.5
14	25	0.1	216	100	97.3	99.5
15	25	0.1	240	100	97.3	99.5
16	25	0.1	264	100	97.3	99.5
17	25	0.1	288	100	97.3	99.5
18	25	0.1	312	100	97.3	99.5
19	25	0.1	336	100	97.3	99.5
20	25	0.1	360	100	97.3	99.5
21	25	0.1	384	100	97.3	99.5
22	25	0.1	408	100	97.3	99.5
23	25	0.1	432	100	97.3	99.5
24	25	0.1	456	100	97.3	99.5
25	25	0.1	480	100	97.3	99.5

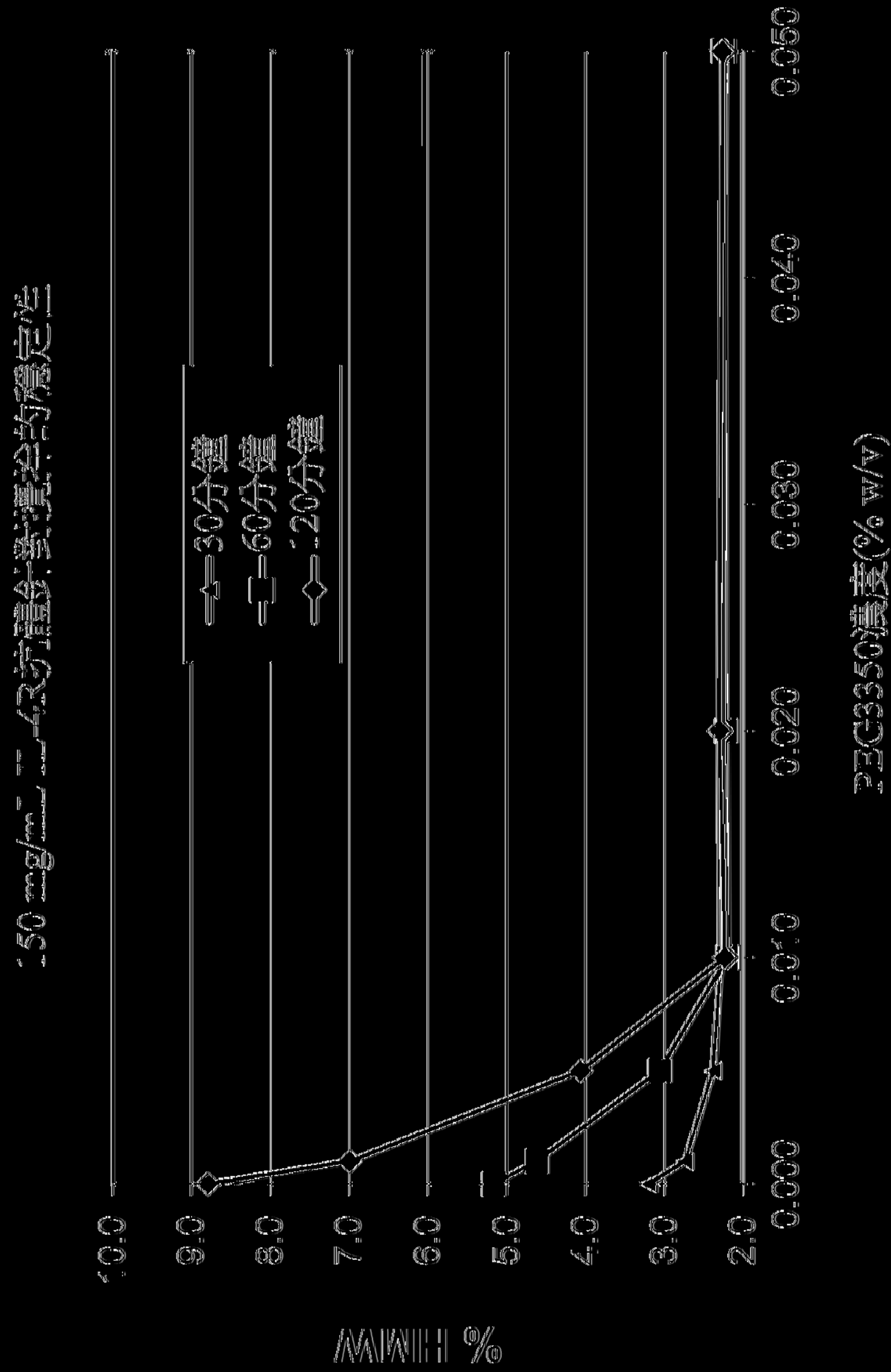

150 mg/mL IL-4R抗體針對攪拌的穩定性
30分鐘
60分鐘
120分鐘
% HMW
10.0
9.0
8.0
7.0
6.0
5.0
4.0
3.0
2.0
0.000
0.010
0.020
0.030
0.040
0.050
PEG3350濃度(% w/v)

圖2A

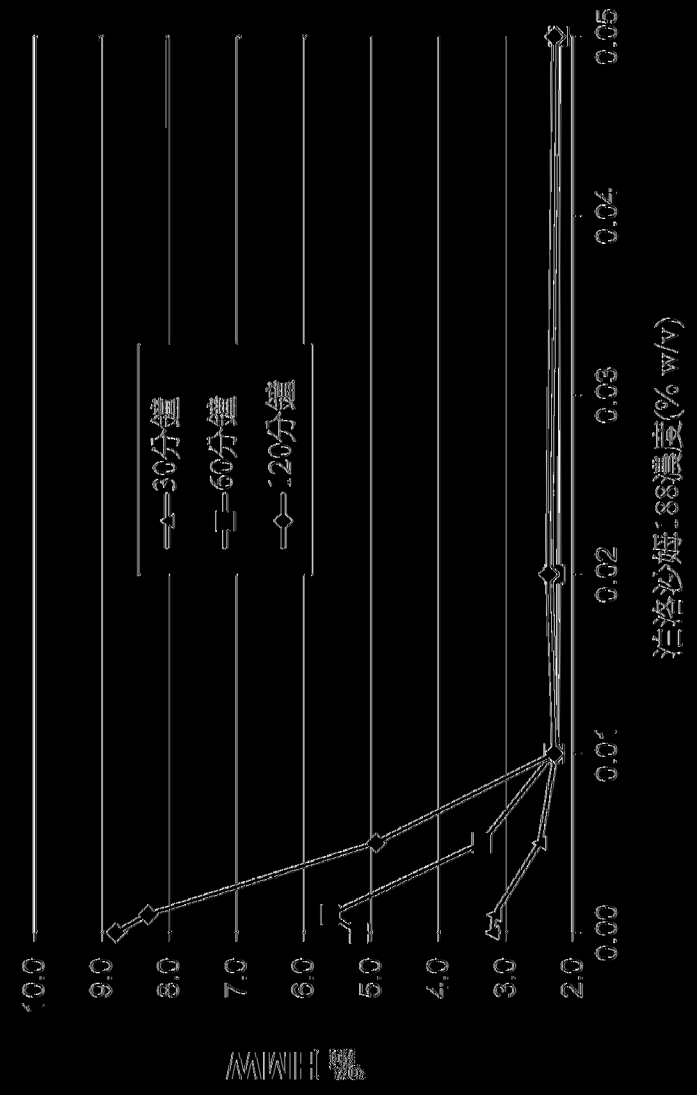

150 mg/mL トラスツズマブ製剤の粘度
30分静置
60分静置
120分静置
粘度(mPa·s)
0.0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1.0
0.00
0.01
0.02
0.03
0.04
0.05
界面活性剤濃度(% w/v)

図23

150 mg/mL 一次方晶之熱重量與光學密度
無水物
0.2% PS-20
0.2% PS-20
0.05% PS-20
0.05% PS-80
0.02% EG350
0.02% EG350
無水物
0.2% PS-20
0.1% PS-20
0.1% PS-80
0.025% PS-80
0.01% EG350
無水物
% HMW (SE-UPLC)
在45°C下的時間(日)
0
10
20
30
40
50
60
0
2
4
6
8
10
12
14

圖3