

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(10) International Publication Number
WO 2023/156794 A1

(43) International Publication Date
24 August 2023 (24.08.2023)

(51) International Patent Classification:

A61K 9/10 (2006.01) *A61K 47/02* (2006.01)
A61K 9/14 (2006.01) *A61L 2/00* (2006.01)
A61K 31/513 (2006.01)

Published:

— with international search report (Art. 21(3))

(21) International Application Number:

PCT/GB2023/050372

(22) International Filing Date:

20 February 2023 (20.02.2023)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

2202297.4 21 February 2022 (21.02.2022) GB

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(81) Designated States (*unless otherwise indicated, for every
kind of national protection available*): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM,
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE,
KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU,
LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG,
NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS,
RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH,
TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS,
ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every
kind of regional protection available*): ARIPO (BW, CV,
GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ,
TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU,
TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE,
DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU,
LV, MC, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI,
SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN,
GQ, GW, KM, ML, MR, NE, SN, TD, TG).

(54) Title: STERILIZATION PROCESS OF STERILE LIQUID PHARMACEUTICAL COMPOSITION COMPRISING ENSIFENTRINE

(57) Abstract: The present invention relates to a process for producing a sterile liquid pharmaceutical composition suitable for administration by inhalation comprising ensifentrine particles, wherein the process comprises: (a) heating ensifentrine particles at a temperature of from 100C to 220C to obtain sterile ensifentrine particles; and (b) combining the sterile ensifentrine particles with a sterile liquid vehicle to produce the sterile liquid pharmaceutical composition suitable for administration by inhalation. A process for producing an ampule comprising the sterile liquid pharmaceutical composition is also described.

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