

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

(19) World Intellectual Property
Organization
International Bureau

(43) International Publication Date
27 March 2025 (27.03.2025)



(10) International Publication Number
WO 2025/064286 A1

(51) International Patent Classification:

A61K 9/20 (2006.01) *A61K 31/502* (2006.01)
A61K 9/28 (2006.01) *A61P 35/00* (2006.01)
A61K 9/48 (2006.01)

(21) International Application Number:

PCT/US2024/046336

(22) International Filing Date:

12 September 2024 (12.09.2024)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/583,775 19 September 2023 (19.09.2023) US

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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, MU, 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, SC, 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).

Published:

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

(54) Title: STABLE 4-(AMINOMETHYL)-6-(PHENYLPYRAZOLYL)PHTHALAZINONE COMPOSITIONS AND PROCESSES FOR PREPARATION THEREOF

(57) Abstract: A granulated composition of 2-(4-(4-(aminomethyl)-1-oxo-1,2-dihydrophthalazin-6-yl)-1-methyl-1H-pyrazol-5-yl)-4-chloro-6-cyclopropoxy-3-fluorobenzonitrile comprising: a crystalline form of said compound comprising a first chiral crystalline form present in an amount of at least 85 wt%, based on the weight of the crystalline form; and a filler. A method of making said composition, method comprising: providing a crystalline form of 2-(4-(4-(aminomethyl)-1-oxo-1,2-dihydrophthalazin-6-yl)-1-methyl-1H-pyrazol-5-yl)-4-chloro-6-cyclopropoxy-3-fluorobenzonitrile comprising at least 95 wt% of a first chiral crystalline form; providing a filler; mixing the crystalline form and the filler in a weight ratio of at least 1: 10; subjecting the mixture to a granulating method selected from fluid bed granulation, high or low shear granulation, and dry granulation to provide a granulated composition; wherein the granulated composition has no more than 10 wt % of an amorphous form of 2-(4-(4-(aminomethyl)-1-oxo-1,2-dihydrophthalazin-6-yl)-1-methyl-1H-pyrazol-5-yl)-4-chloro-6-cyclopropoxy-3-fluorobenzonitrile; and wherein the granulated composition has no more than 5 wt% of a second chiral form of 2-(4-(4-(aminomethyl)-1-oxo-1,2-dihydrophthalazin-6-yl)-1-methyl-1H-pyrazol-5-yl)-4-chloro-6-cyclopropoxy-3-fluorobenzonitrile.

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