**ПЕРЕЛІК**

**ЛІКАРСЬКИХ ЗАСОБІВ ЩОДО ЯКИХ ЗАВЕРШЕНО РОЗГЛЯД РЕЄСТРАЦІЙНИХ МАТЕРІАЛІВ ПРО ВНЕСЕННЯ ЗМІН ДО РЕЄСТРАЦІЙНИХ МАТЕРІАЛІВ ПРОТЯГОМ ДІЇ РЕЄСТРАЦІЙНОГО ПОСВІДЧЕННЯ НА ЛІКАРСЬКІ ЗАСОБИ, ЯКІ ЗАРЕЄСТРОВАНІ КОМПЕТЕНТНИМИ ОРГАНАМИ СПОЛУЧЕНИХ ШТАТІВ АМЕРИКИ, ШВЕЙЦАРСЬКОЇ КОНФЕДЕРАЦІЇ, ЯПОНІЇ, АВСТРАЛІЇ, КАНАДИ, ЛІКАРСЬКИХ ЗАСОБІВ, ЩО ЗА ЦЕНТРАЛІЗОВАНОЮ ПРОЦЕДУРОЮ ЗАРЕЄСТРОВАНІ КОМПЕТЕНТНИМ ОРГАНОМ ЄВРОПЕЙСЬКОГО СОЮЗУ**

| ***№ п/п*** | ***Назва лікарського засобу*** | ***Форма випуску (лікарська форма, упаковка)*** | ***Заявник*** | ***Країна*** | ***Виробник*** | ***Країна*** | ***Реєстраційна процедура*** | ***Умови відпуску*** | ***Номер реєстраційного посвідчення*** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **КІСКАЛІ** | таблетки, вкриті плівковою оболонкою, по 200 мг, по 21 таблетці у блістері, по 3 блістери у картонній коробці; по 21 таблетці у блістері, по 3 блістери у картонній коробці, по 3 коробки у картонній коробці | Новартіс Фарма АГ | Швейцарія | виробництво:Новартіс Сінгапур Фармасьютікал Меньюфекчерінг Пте. Лтд., Сінгапурчастковий контроль якості, первинне та вторинне пакування:Новартіс Фарма Продакшн ГмбХ, Німеччина частковий контроль якості, первинне та вторинне пакування:Новартіс Фарма Штейн АГ, Швейцаріячастковий контроль:Фарманалітика СА, Швейцаріявипуск серії:Новартіс Фарма ГмбХ, Німеччина | Сінгапур/ Німеччина/ Швейцарія | B.I.a.1.z type IB – Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS – Other variationTo add Raybow (Suzhou) Pharmaceutical Co., Ltd., 18 Tonglian Road, Bixi Subdistrict, Changshu Jiangsu 215537, China, as a site responsible for manufacture and quality control testing of the active substance and quality control testing site of the intermediate B8 (all tests except metals.A.4 type IA – Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipientTo change the name of the site responsible for manufacturing of the intermediate B7 from Suzhou Novartis Pharma Technology Co., Ltd., 18 Tonglian Road, Riverside Industrial Park, ChangshuEconomic Development Zone, 215537, China to Raybow (Suzhou) Pharmaceutical Co., Ltd., 18 Tonglian Road, Bixi Subdistrict, Changshu Jiangsu 215537, China. The site address has been slightly adapted due to the change in street name by the local government with no change in the physical location.B.I.b.1.z type IB – Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variationTo add specification parameters with the corresponding test methods for solvents:- 'Identity by GC' and 'Identity by refractive index' for methyl isobutyl ketone- 'Identity by GC' and 'Identity by refractive index' for methanol (used in manufacture of compoundBIO)- 'Identity by GC' for isopropanol (used in the manufacture of final step of active substance)B.I.b.1.z type IB – Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation- To add specification parameters with the corresponding test methods for reagents:- 'Appearance by Visual Examination', 'Identity by Wet chemistry' and 'Assay by Titration' for hydrochloric acid 31% and sodium hydroxide solution 32%B.I.a.3.a type IA – Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch sizeTo increase the batch size of the intermediate B9 from 120 kg to 240 kg (B7 as input) used in the manufacturing process of the active substance at Raybow (Suzhou) Pharmaceutical Co., Ltd..B.I.a.3.a type IA – Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch sizeTo increase the batch size of the intermediate B10 from 400 kg to 620 (B9 as input) used in the manufacturing process of the active substance at Raybow (Suzhou) Pharmaceutical Co., Ltd..B.I.a.3.a type IA – Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch sizeTo increase the batch size of the active substance from 70 kg to 140 kg (B10 as input) manufactured at Raybow (Suzhou) Pharmaceutical Co., Ltd..B.I.b.2.b type IA – Change in test procedure for AS or starting material/reagent/intermediate - Deletion of a test procedure for the AS or a starting material/reagent/intermediate, if an alternative test procedure is already authorisedTo delete the alternative test procedure 'Identity by IR (ATR)' for the solvent methyl isobutyl ketone used in the manufacturing process of the active substance at Raybow (Suzhou) Pharmaceutical Co., Ltd. Manufacturing site.B.I.b.2.b type IA – Change in test procedure for AS or starting material/reagent/intermediate - Deletion of a test procedure for the AS or a starting material/reagent/intermediate, if an alternative test procedure is already authorisedTo delete the alternative test 'Identity by IR (thin film)' for the solvent isopropanol at Raybow (Suzhou) Pharmaceutical Co., Ltd. manufacturing site.B.I.b.2.b type IA – Change in test procedure for AS or starting material/reagent/intermediate - Deletion of a test procedure for the AS or a starting material/reagent/intermediate, if an alternative test procedure is already authorisedTo delete the alternative test 'Identity by IR (ATR)' for the solvent heptane at Raybow (Suzhou) Pharmaceutical Co., Ltd. manufacturing site.B.I.b.z type IB – Change in control of the AS – Other variationChange in the specifications of the antistatic agent used in step B9 at Raybow (Suzhou) Pharmaceutical Co., Ltd. Manufacturing site.B.I.a.2.a type IA – Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the ASMinor change in the manufacturing process of the intermediate BIO to use 32% sodium hydroxide solution instead of currently approved 30% sodium hydroxide solution at Raybow (Suzhou) Pharmaceutical Co., Ltd. manufacturing site.B.I.b.2.c type IB – Change in test procedure for AS or starting material/reagent/intermediate – Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the ASTo replace the 'Spectroscopic' test method by the 'Colourimetric' test procedure for Iron testing for the reagent sodium chloride at Raybow (Suzhou) Pharmaceutical Co., Ltd. manufacturing site.B.I.b.z type IB – Change in control of the AS – Other variationTo add purified water quality (used in B10 intermediate) at at Raybow (Suzhou) Pharmaceutical Co., Ltd. manufacturing site.B.I.a.1.z type IB – Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS – Other variationTo add Lianhe Chemical Technology (Taizhou) Co., Ltd., No. 3 Donghai, 8th Avenue Toumengang, New District Taizhou Zhejiang 317016, China, as a manufacturing site and quality control site for the intermediate B8 (i.e. steps B8b, B8a and B8). In addition, the following changes have been made:- Minor changes in the manufacturing process of the intermediate B8a for crystallization temperature- Minor changes in the manufacturing process of the intermediate B8 for reaction temperature- Decrease in the batch size of the intermediate B8a from 299 kg to 197 kg (B8b as input)- Decrease in the batch size of the intermediate B8b from 300 kg to 200 kg (B8e as input)- Decrease in the batch size of the intermediate B8 from 412 kg to 271 kg (B8a as input)B.I.b.z type IB – Change in control of the AS – Other variationTo add potable water quality (used in B8b and B8a intermediates) at Lianhe Chemical Technology (Taizhou) Co., Ltd. Manufacturing site. | *за* *рецептом* | UA/18157/01/01 |