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*
1.	**АЗАЦИТИДИН САНДОЗ®**	порошок для суспензії для ін'єкцій, 100 мг; по 1 флакону з порошком у картонній коробці	Сандоз Фармасьютікалз д.д.	Словенія	випуск серії: Лек Фармацевтична компанія д.д., Словенія; випуск серії: Салютас Фарма ГмбХ, Німеччина; виробництво нерозфасованого продукту, первинне та вторинне пакування, тестування: МСН Лабораторіс Прайват Лімітед, Індія; тестування: Фармадокс Хелскер Лтд, Мальта	Словенія/ Німеччина/ Індія/ Мальта	**Type IA - B.I.b.1.c - Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent used in the manufacturing process of the active substance - Specific optical rotation** The Specification for Specific optical rotation for active substance is included for better quality requirment. Consequence change has been made to DPM specification and analytical procedure same as made in DSM specification and analytical procedure. **Type IA - B.I.b.1.d - Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent used in the manufacturing process of the active substance - Heavy metals** The risk assessment for the elemental impurities as per ICH Q3D was performed and accordingly the Heavy metals test has been removed. Consequence change has been made to DPM specification and analytical procedure same as made in DSM specification and analytical procedure. **Type IA - B.I.b.1.b - Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent**	*ра рецептом*	UA/19561/01/01

№ п/п	Назва лікарського засобу	Форма випуску (лікарська форма, упаковка)	Заявник	Країна	Виробник	Країна	Реєстраційна процедура	Умови відпуску	Номер реєстраційного посвідчення
							used in the manufacturing process of the active substance - Related substances by HPLC Based on the available drug substabce barches trend data, specification limits has been tightened. Consequence change has been made to DPM specification and analytical procedure same as made in DSM specification and analytical procedure. **Type IA - B.I.b.1.b - Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent used in the manufacturing process of the active substance - Bacterial Endotoxin** Based on the available drug substabce barches trend data, specification limits has been tightened. Consequence change has been made to DPM specification and analytical procedure same as made in DSM specification and analytical procedure. **Type IA - B.I.b.2.a - Change in the test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Assay by HPLC** In the test procedure for Assay by HPLC the note for Solution and Mobile Phase stability is included based on analytical method validation date. Consequence change has been made to DPM specification and analytical procedure same as made in DSM specification and analytical procedure.		

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							Type IA - B.I.b.1.b - Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent used in the manufacturing process of the active substance - Tetra acetyl ribofuranose content by GC Based on the available drug substabce barches trend data, specification limits has been tightened. Consequence change has been made to DPM specification and analytical procedure same as made in DSM specification and analytical procedure. **Type IA - B.I.b.2.a - Change in the test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Water content by KFR** The test procedure for determination of water content for active substance is updated from manural instrument method to automated instrument method as per current practice. However, there is no change in the testing procedure of water determination. Consequence change has been made to DPM specification and analytical procedure same as made in DSM specification and analytical procedure. **Type IA - B.I.b.2.a - Change in the test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Related substances by HPLC** In the test procedure for related		

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							substances by HPLC the note for Solution and Mobile Phase stability is included based on analytical method validation date. Consequence change has been made to DPM specification and analytical procedure same as made in DSM specification and analytical procedure. **Type IA - B.I.b.2.a - Change in the test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Tetra acetyl** ribofuranose content by GC In the test procedure for Tetra acetyl ribofuranose content by GC the note for Solution and Mobile Phase stability is included based on analytical method validation date. Consequence change has been made to DPM specification and analytical procedure same as made in DSM specification and analytical procedure. **Type IA - B.I.b.2.a - Change in the test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Limit of 1-β-D-ribofuranosyl-3-gunylurea by HPLC** In the test procedure for Limit of 1-β-D-ribofuranosyl-3-gunylurea by HPLC the note for Solution and Mobile Phase stability is included based on analytical method validation date. Consequence change has been made to DPM specification and analytical procedure same as made in DSM specification and		

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							analytical procedure. **Type IA - B.I.b.2.a - Change in the test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Assay by HPLC** Note with respect to standard solution and sample solution preparation has been included for additional precaution. Similarity factor for the standard solution has been included. Order of injections has been updated. **Type IA - B.I.b.2.a - Change in the test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Residual solvents by GC (Method-I)** Note with respect to standard solution and sample solution preparation has been included for additional precaution. Similarity factor for the standard solution has been included. Order of injections has been updated. **Type IA - B.I.b.2.a - Change in the test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Residual solvents by GC (Method-II)** Note with respect to standard stock solution preparation-1 & 2 has been included for better clarity. Note with respect to standard solution and sample solution		

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							preparation has been included for additional precaution. Similarity factor for the standard solution has been included. Order of injections has been updated.		
2.	**АЗАЦИТИДИН САНДОЗ®**	порошок для суспензії для ін'єкцій, 100 мг; по 1 флакону з порошком у картонній коробці	Сандоз Фармасьютікалз д.д.	Словенія	випуск серії: Лек Фармацевтична компанія д.д., Словенія; випуск серії: Салютас Фарма ГмбХ, Німеччина; виробництво нерозфасованого продукту, первинне та вторинне пакування, тестування: МСН Лабораторіс Прайват Лімітед, Індія; тестування: Фармадокс Хелскер Лтд, Мальта	Словенія/ Німеччина/ Індія/ Мальта	**Type IA: B.II.b.3 - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product** a) Minor change in the manufacturing process Minor changes in the manufacturing process were necessary to conducty the scale up. **Type II: B.II.b.4 - Change in the batch size (including batch size ranges) of the finished product** d) The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes Scale up from 63.90 Kg (Equivalent to 65.0 L/4248 vials) to 181.8 Kg (Equivalent to 185.0 L/12091 vials) to increase commercial capacity.	*за рецептом*	UA/19561/01/01