

 <b>НАНОЛЕК</b>	Запись / Record	7 из / of 8
	<b>ПАСПОРТ КАЧЕСТВА / CERTIFICATE OF ANALYSIS</b> № 40000029557	Код / Code: ЗП-П03-03-001 Версия / Version: 7 Бланк / Form 1

Наименование показателя Parameter	Методы испытания Test methods	Нормы Specification	Результаты испытания Test results
Маркировка Labeling			<p>The following is printed on the carton pack in Russian:</p> <ul style="list-style-type: none"> <li>- trade name (with the warning sign ®);</li> <li>- generic name;</li> <li>- dosage form, including the administration route (text "Solution for intramuscular injection");</li> <li>- dosage, volume, number of doses in one vial (text "1 vial – 1 dose (0.5 mL)");</li> <li>- q-ty of doses in a pack (for the carton pack with 1 vial / 1 dose, the text is "1 vial – 1 dose (0.5 mL)");</li> <li>- logo of the manufacturing company in the form of a graphic element "SANOFL" in Latin letters;</li> <li>- composition for 1 dose, including active substances, their content, and the list of all excipients;</li> <li>- batch No. of the packaged product (text "Batch:");</li> <li>- manufacturing date (text "Manufactured:");</li> <li>- expiry date (text "Expiry date:");</li> <li>- storage conditions (text "Store refrigerated (2 to 8 °C) in the original pack (carton pack) to protect from light. Do not freeze");</li> <li>- dispensing rules;</li> <li>- bar code;</li> <li>- MA number (text "Marketing Authorization: ЛП-002636");</li> <li>- name and country of the manufacturer being the legal entity – Marketing Authorization holder;</li> <li>- warnings: "Sterile"; "Keep out of reach of children"; "Read carefully the PIL before use"; "Dispose (destroy) the not-used vaccine or immunization medical wastes as per the national regulations".</li> </ul> <p>Additionally, technical manufacturing / printing house codes may be printed: graphic, numeric, alphabetical.</p> <p>Additionally, the information for monitoring of the medicinal drugs flow from the manufacturer to the end consumer may be printed. Additionally, the temper evidence may be applied.</p>

