C026P.h1LA: Nivolumab Biosimilar, Human IgG1 L234A L235A P329G (LALAPG) Fc Silent Mutant

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PRODUCT SPECIFICATIONS

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Product Name	Nivolumab Biosimilar, Human IgG1 L234A L235A P329G (LALAPG) Fc Silent Mutant
Supplier Name	Syd Labs, Inc.
Brand Name	Syd Labs
Synonyms	programmed cell death protein 1, PD1, CD279, cluster of differentiation 279
Summary	Recombinant Humanized IgG4 Monoclonal Antibody.
Isotype	Human IgG1 LALAPG Fc Silent Mutant
Source/Host	The anti-human programmed cell death protein 1 (PD-1) monoclonal antibody nivolumab biosimilar was produced in the nivolumab biosimilar CHO stable cell line.
Specificity/Sensitivity	The in vivo grade nivolumab biosimilar specifically binds to PD-1, antagonizing its interaction with its known ligands PD-L1 and PD-L2.
Applications	ELISA, neutralization, functional assays such as bioanalytical PK and ADA assays, and those assays for studying biological pathways affected by nivolumab.
Form Of Antibody	0.2 μM filtered solution, pH 6.0, no stabilizers or preservatives.
Endotoxin	< 1 EU per 1 mg of the protein by the LAL method.
Purity	>95% by SDS-PAGE under reducing conditions and HPLC.
Shipping	The Nivolumab Biosimilar, Human IgG1 L234A L235A P329G (LALAPG) Fc Silent Mutant is shipped with ice pack. Upon receipt, store it immediately at the temperature recommended below.
Stability & Storage	Use a manual defrost freezer and avoid repeated freeze-thaw cycles. 12 months from date of receipt, -20 to -70°C as supplied. 1 month from date of receipt, 2 to 8°C as supplied.
Note	The research grade Nivolumab biosimilar protein is for research use only (RUO). Recombinant human IgG4 isotype controls are available. Condition of sample preparation and optimal sample dilution should be determined experimentally by the investigator.

REFERENCES & BACKGROUND

What is Nivolumab biosimilar research grade? Nivolumab is a humanized IgG4 antibody targeting the immune checkpoint programmed death receptor-1 (PD-1). This antibody was produced entirely in mice and grafted onto human kappa and IgG4 Fc region with the mutation S228P for additional stability and reduced variability. Nivolumab Biosimilar uses the same protein sequences as the therapeutic antibody nivolumab.

PD-L1 and PD-L2 (B7-DC or CD273, programmed cell death ligand 2) are the two ligands for the receptor PD-1 (CD279, programmed cell death protein 1).

Nivolumab blocks PD-1 inhibitory signalling to T-cells. It has a long duration of action as it is administered every 2-4 weeks. Patients should be counselled regarding the risk of immune-mediated adverse effects, infusion-related adverse effects, complications of allogenic hematopoietic stem cell transplants, embryo-fetal toxicity.

The ligands PD-L1 and PD-L2 bind to the PD-1 receptor on T-cells, inhibiting the action of these cells. Tumor cells express PD-L1 and PD-L2. Nivolumab binds to PD-1, preventing PD-L1 and PD-L2 from inhibiting the action of T-cells, restoring a patient's tumor-specific T-cell response.