

CpG 7909 Adjuvant

Catalog No. NR-52393

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Product Description:

CpG 7909 oligodeoxynucleotide is an immunostimulatory, toll-like receptor 9 (TLR9) agonist used as an adjuvant for screening with different vaccine antigens. This 24-mer B-Class CpG oligodeoxynucleotide has been used to augment the immunogenicity of several developmental and commercial vaccines. CpG 7909 was manufactured at Avecia through a contract with Emergent BioSolutions.

Note: Except for Concentration and Final Product, all tests were performed on the deposited bulk material (Avecia lot 100000) on 27MAR2019, prior to deposition and vialing on 06NOV2020 in nuclease-free water (Ambion® Am9937).

Lot: 70040420

Manufacturing Date: SEP2015

TEST	SPECIFICATIONS	RESULTS
Appearance	White to off-white powder or cake	White powder
Identification Molecular weight (MW) of free acid by MALDI-TOF mass spectrometry Sequence confirmation by digest and MALDI-TOF	Theoretical MW: 7698.2 ± 8.0 daltons Sequence confirmed	Actual MW: 7697 daltons Sequence confirmed
Purity Reversed-Phase Ion-Pair (RP-IP) UPLC Oligonucleotide main peak Impurities (> 0.20% area LOQ) N-1 N+CNE Any other single impurity Ion-Exchange (IEX) HPLC Oligonucleotide main peak Impurities (> 0.5% area LOQ) PO (type B) Any other single impurity	≥ 87% ≤ 5.0% ≤ 3.0% ≤ 3.0% ≥ 92% ≤ 4.0% ≤ 2.0%	94% < LOQ (RRT 0.913) 1.0% (RRT 1.153) None reportable 95% 3.5% (RRT 0.916) None reportable
Impurity Profile by LCMS (N-1) PS (phosphorothioate) Depurination	Report results Report results	0.46% < LOQ (0.5%)
Assay by RP-IP UPLC	85.0% to 105.0%	98.3%
Concentration	Report results	100 mg per mL
Final Product Amount per vial Volume per vial	Report results Report results	50 mg 0.5 mL
Sodium Content (w/w)	≤ 7.4%	6.3%
Moisture Content (w/w; bulk moisture)	≤ 15.0%	11.7%
pH of 5% Aqueous Solution (w/v)	Report results	6.9
Heavy Metals Silver (Ag) Arsenic (As) Bismuth (Bi)	Total ≤ 20 ppm Report results Report results Report results	Total ≤ 20 ppm < 1 ppm < 2.5 ppm < 1 ppm

Certificate of Analysis for NR-52393

TEST	SPECIFICATIONS	RESULTS
Cadmium (Cd)	Report results	< 2.5 ppm
Copper (Cu)	Report results	< 1 ppm
Mercury (Hg)	Report results	< 2.5 ppm
Lead (Pb)	Report results	< 2.5 ppm
Molybdenum (Mo)	Report results	< 2.5 ppm
Antimony (Sb)	Report results	< 1 ppm
Tin (Sn)	Report results	< 1 ppm
Platinum (Pt)	Report results	< 2.5 ppm
Heavy Metals		
Chromium (Cr)	Report results	< 2.5 ppm
Iron (Fe)	Report results	< 20 ppm
Manganese (Mn)	Report results	< 2.5 ppm
Nickel (Ni)	Report results	< 2.5 ppm
Titanium (Ti)	Report results	< 3 ppm
Residual Solvents		
Acetonitrile	≤ 410 ppm	< 100 ppm
Toluene	≤ 890 ppm	< 100 ppm
Pyridine	≤ 200 ppm	< 100 ppm
<i>tert</i> -Butylamine	≤ 100 ppm	< 100 ppm
Bacterial Endotoxins	≤ 2.0 EU per mg	< 0.700 EU per mg
Microbial Limits		
Total aerobic plate counts	≤ 100 CFU per g	< 20 CFU per g
Total yeast and molds	≤ 100 CFU per g	< 20 CFU per g

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18 NOV 2020

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