

afluria[®] Influenza Virus Vaccine, 2010-2011 Formula

Catalog No. NR-31798

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Product Description: NR-31798 is an inactivated split viron influenza virus vaccine prepared from influenza viruses A/California/07/2009 NYMC X-181 (H1N1)pdm09, A/Victoria/210/2009 NYMC X-187 (H3N2) (an A/Perth/16/2009-like virus) and B/Brisbane/60/2008 that were predicted to circulate in the United States during the 2010 to 2011 influenza season.

Lot¹: M52208

Manufacturing Date: 2010

TEST	SPECIFICATIONS	RESULTS
Appearance	Report results	Slightly opalescent liquid ²
Hemagglutinin Content A/California/07/2009 NYMC X-181 H1N1)pdm09 A/Victoria/210/2009 NYMC X-187 (H3N2) B/Brisbane/60/2008	15 µg per syringe 15 µg per syringe 15 µg per syringe	15 µg per syringe 15 µg per syringe 15 µg per syringe
Hemagglutinin Concentration A/California/07/2009 NYMC X-181 H1N1)pdm09 A/Victoria/210/2009 NYMC X-187 (H3N2) B/Brisbane/60/2008	30 µg per mL 30 µg per mL 30 µg per mL	30 µg per mL 30 µg per mL 30 µg per mL
Residual Components Sodium taurodeoxycholate Ovalbumin Neomycin sulfate Polymyxin B β-propiolactone	≤ 10 ppm ≤ 1 µg per syringe ≤ 0.2 µg per syringe ≤ 0.03 µg per syringe < 25 ng per syringe	≤ 10 ppm ≤ 1 µg per syringe ≤ 0.2 µg per syringe ≤ 0.03 µg per syringe < 25 ng per syringe

¹NR-31798 contains a pre-filled (0.5 mL) syringe.

²Any sediment present should resuspend upon shaking to form a homogeneous suspension.

Date: 09 MAY 2013

Signature: *Dorothy C. Young*

Title: Technical Manager, BEI Authentication or designee

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