

Identity Test Results Memo, May 6, 2010 - MenHibrix

MEMORANDUM

Date: 06 May, 2010
To: STN # 125363
From: Manju Joshi, HFM-407

Through: Rajesh K. Gupta, HFM-407
William McCormick, HFM-407

Subject: Identity Test results on Final Container, STN 125363: MenHiberix® (Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine: Hib-MenCY-TT), GlaxoSmithKline Biologicals

CC: Joseph Temenak, HFM-481
David Staten, HFM-475

GSK submitted (b)(4) lots of combined Hib-MenCY-TT conjugate vaccine (final container) for testing in support of the Biologics License Application (BLA). Identity test for MenC-TT and MenY-TT conjugates was performed using a method adopted from the manufacturer's method [SOP 9000010628: Translation of procedure 9000003114-version 07: Identity (PSC-TT and PSY-TT) in conjugated (b)(4) and final containers by (b)(4)] and for Hib-TT conjugate was performed using a method adopted from the manufacturer's method (SOP 9000007241: Translation of procedure 9000001118-version 06: Determination of the conjugate (PSTT) of *Haemophilus influenzae* type B by (b)(4)-). Below are results of identity test performed at CBER.

Product	Lot Number	Identity Test Results		
		Hib-TT	MenC-TT	MenY-TT
Hib-MenCY-TT	----(b)(4)----	Positive	Positive	Positive
Hib-MenCY-TT	----(b)(4)----	Positive	Positive	Positive
Hib-MenCY-TT	----(b)(4)----	Positive	Positive	Positive

The results for all the lots tested meet specifications for the identity test.