



U.S. FDA Inspection History

1994 – Edison Drive Facility

GMP Facility Inspection
January 28 & 31, February 04 & 07

1996 – Edison Drive Facility

Pre-Approval Inspection (PAI): 1 drug substance
May 26, 27, & 28

1998 – Edison Drive Facility

GMP Facility Inspection
May 7, & 8

2001 – Edison Drive Facility

GMP Facility Inspection
September 19 & 20

2003 – Edison Drive Facility

Pre-Approval Inspection (PAI): 2 drug substances
July 18, 21, 22 & 24

2004 – Edison Drive Facility

Pre-Approval Inspection (PAI): 1 drug substance
April 21, 22, 23, 26, & 27
No Form 483 Issued

2005 – Washington Drive and Edison Drive Facilities – kilo laboratories only

Pre-Approval Inspection (PAI): 1 drug substance
GMP Facility Inspection
November 2, 3, 4, 7, & 9

2007 – Washington Drive and Edison Drive Facilities

Pre-Approval Inspection (PAI): 3 drug substances
GMP Facility Inspection
April 27 & 30 May 1, 2, 3, & 4
No Form 483 Issued

2009 – Washington Drive and Edison Drive Facilities

Pre-Approval Inspection (PAI): 1 drug substance
GMP Facility Inspection
July 27, 29, 30, 31 & August 4

2011 – Grant Drive and Washington Drive Facilities

Pre-Approval Inspection (PAI): 1 drug substance
NDA Approval

Korean FDA Inspection History

2004 - Edison Drive Facility

Pre-Approval Inspection (PAI): 1 drug substance

April 21, 22, & 23

No Observations Issued