

GMP REGULATORY INSPECTIONS FOR FARMABIOS SPA

Agency/No. of inspectors and duration	Scope	Key Points
US FDA 1 Inspector / 3 Days 24 th 27 th 28 th Oct 1997	Pre-approval inspection	Satisfactory inspection with no findings (no 483 issued).
US FDA 1 Inspector / 3 Days 27 th 28 th 31 st Jul 2000	Pre-approval inspection	Satisfactory with 2 points on 483 letter, CAPA closed and response accepted
Italian Health Authority (AIFA) 2 Inspector 3 Days 17 th 18 th 19 th Dec 2001	Authorization to production – general GMP inspection	Satisfactory inspection with no critical findings - CAPA closed and response accepted
US FDA 1 Inspector / 3 Days 31 st May 02 nd 1 st Jun 2004	Pre-approval inspection	Satisfactory inspection with no findings (no 483 letter issued).
Italian Health Authority (AIFA) 2 Inspector / 4 Days 22 nd 23 rd 24 th 25 th Nov 2004	Authorization to production – general GMP inspection –	Satisfactory with some key findings (no critical), CAPA closed and response accepted
EDQM + AIFA (Italian Health Authority) 4 Inspector / 3 Days 12 ^{ve} 13 th 14 th Apr 2005	Verifications of conformity to Certificate of suitability for cefuroxime sodium sterile - Authorization to production – general GMP inspection -	Satisfactory with some key findings (no critical), CAPA closed and response accepted
US FDA 2 Inspector / 4 Days 05 th 06 th 07 th 08 th March 2007	Pre-approval inspection	Satisfactory inspection with no findings (no 483 issued).
KFDA (Korea) 2 Inspector / 2 Days 15 th 16 th Nov 2007	Pre-approval inspection	Satisfactory inspection with no critical findings - CAPA closed and response accepted
Italian Health Authority (AIFA) 1 Inspector / 4 Days 21 st - 24 th Oct 2008	Authorization to production – general GMP inspection –	Satisfactory with some key findings (no critical), CAPA closed and response accepted
US FDA 2 Inspector / 4 Days 20 th 21 st 22 nd 23 rd September 2010	Pre-approval inspection (8 ANDAs – steroids)	Satisfactory with 3 points on 483 letter, CAPA closed and response accepted
KFDA (Korea) 2 Inspector / 2 Days 11 th 12 ^{ve} Jul 2011	Pre-approval inspection (clobetasol propionate)	Satisfactory inspection with no critical findings - CAPA closed and response accepted
Italian Health Authority (AIFA) 2 Inspectors / 5 Days 28 th Nov -02 nd Dec 2011	Authorization to production for new antitumorals plant – general GMP inspection	Satisfactory with some key findings (no critical), CAPA closed and response accepted

Agency/No. of inspectors and duration	Scope	Key Points
Italian Health Authority (AIFA) 3 Inspectors / 4 Days 12 th – 15 th March 2013	General GMP inspection	Satisfactory with some key findings (no critical), CAPA closed and response accepted
US FDA 1 Inspector / 5 Days 09 th 10 th 11 th 12 th 13 th December 2013	Pre-approval inspection	Satisfactory inspection with no findings (no 483 issued).
Italian Health Authority (AIFA) 2 Inspectors / 5 Days 26 th – 30 th January 2015	General GMP inspection	Satisfactory with some minor observations (no critical) CAPA closed and response accepted
US FDA 1 Inspector / 5 Days 19 th -23 rd October 2015	Pre-approval inspection (on sterile steroid product)	Satisfactory with points on 483 letter, CAPA closed and response accepted
Italian Health Authority (AIFA) 2 Inspectors / 5 Days 14 th – 18 th March 2016	General GMP inspection	Satisfactory with some key findings (no critical), CAPA closed and response accepted
Italian Health Authority (AIFA) 2 Inspectors / 5 Days 4 th – 7 th April 2017	General GMP inspection	Satisfactory with some key findings (no critical), CAPA plan provided and response accepted
US FDA 1 Inspector / 5 Days 22 nd – 26 th May 2017	Pre-approval inspection (on sterile steroid product)	Satisfactory with points on 483 letter, CAPA plan provided and response accepted
Russian MoH 2 Inspectors / 4 Days 5 th – 8 th March 2018	General GMP inspection	Some key findings (no critical), CAPA plan in progress
Italian Health Authority (AIFA) 2 Inspectors / 5 Days 28 th May – 1 st June 2018	Authorization of a new Warehouse – general GMP inspection	Satisfactory with some key findings (no critical), CAPA plan provided and response awaited