

# Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 18796 Insp GMP 18796/404880-0002 [H]

## CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER(1),(2)

### Part 1

Issued following an inspection in accordance with :

Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : TEVA PARENTERAL MEDICINES, INC.

Site address : TEVA PARENTERAL MEDICINES, INC., 19 HUGHES, IRVINE, 92618-1902, UNITED STATES

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 15/03/2010, it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

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- (1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.
  - (2) These requirements fulfil the GMP recommendations of WHO.

### Part 2

#### Human Medicinal Products

#### 1. MANUFACTURING OPERATIONS

##### [ 1.1 ] Sterile Products

[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)

[ 1.1.1.2 ] Lyophilisates

[ 1.1.1.4 ] Small volume liquids

[ 1.1.2 ] Terminally Sterilised (processing operations for the following dosage forms)

[ 1.1.2.3 ] Small volume liquids

**[ 1.3 ] Biological medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.5 ] Biotechnology products

[ 1.3.1.6 ] Human or animal extracted products

**[ 1.4 ] Other products or manufacturing activity**

[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:

[ 1.4.2.1 ] Filtration

[ 1.4.2.3 ] Moist heat

**[ 1.6 ] Quality control testing**

[ 1.6.1 ] Microbiological: sterility

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

Any restrictions related to the scope of this certificate:

| <b>Building</b>   | <b>Room Line/equipment</b> | <b>QC Testing</b> | <b>Products</b> |
|---|----------------------------|-------------------|-----------------|
| The inspection covered sterile production activities in building 19 and 21. Visual and automatic Inspection activities in building 13. Warehouse activities in building 23 and 25 and off site at bake parkway. |                            |                   |                 |

08/06/2010 Name and signature of the authorised person of the Competent Authority of United Kingdom  
Confidential  
Medicines and Healthcare products Regulatory Agency  
Tel : Confidential