

**Content of the Batch Certificate for Investigational Medicinal Products
Referred to in Article 62(1) of Regulation (EU) No 536/2014 and Article
4 of Delegated Regulation 1569 /2017**

INTRODUCTION

This template should be used in conjunction with the Delegated Regulation (EU) No 1569/2017 on Good Manufacturing Practice (GMP) for Investigational Medicinal Products (IMP) for human use and arrangements for inspections that has as its legal basis in the first subparagraph of Article 63(1) of Regulation (EU) No 536/2014 and the detailed Commission guidelines on GMP for IMPs for human use, pursuant to the second subparagraph of Article 63(1) of Regulation (EU) No 536/2014.

Investigational medicinal products may not be used in a clinical trial in a member state of the European Union until the completion of the two-step procedure referred to in the “Guideline on the responsibilities of the sponsor with regard to handling and shipping of investigational medicinal products for human use in accordance with Good Clinical Practice and Good Manufacturing Practice”.

The first step is the certification of each batch by the Qualified Person of the manufacturer or importer in line with Article 62(1) of Regulation (EU) No 536/2014 to ensure that the provisions of 63(1) and 63(3) of Regulation (EU) No 536/2014 and those set out in Article 12 of the Commission Delegated Regulation (EU) No 1569/2017 have been complied with and documented. The second step is the regulatory release by the sponsor for use in a clinical trial.

In order to facilitate the free movement of investigational medicinal products between Member States, a batch certification signed by the Qualified Person should be produced according to article 62(1) of Regulation 536/2014.

The content of these certificates should be in accordance with the format presented below with the intention to harmonise the process of certification of batch release. This format may also be used to certify batches destined for use within the Member State of the manufacturer or importer.

**Content of the Batch Certificate for Investigational Medicinal Products
Referred to in Article 62(1) of Regulation (EU) No 536/2014 and Article 4
of Delegated Regulation 1569/2017**

- (1) Name(s) of product(s)/product identifier(s) as referred to in the clinical trial application, where applicable.
- (2) EudraCT No(s) and sponsor protocol code number, when available.
- (3) Strength

Identity (name) and amount per unit dose for all active substance(s) for each IMP (including placebo). The manner in which this information is provided should ensure that the blinding is maintained.

- (4) Dosage form (pharmaceutical form)
- (5) Package size (contents of container) and type (e.g. vials, bottles, blisters).
- (6) Lot/batch number
- (7) Expiry/retest/use by date
- (8) Name and address of manufacturer where the Qualified Person issuing the certificate is located.
- (9) Manufacturing Authorisation number for the site listed under item 8.
- (10) Comments/remarks
- (11) Any additional information considered relevant by the QP.
- (12) Certification statement.
- (13) “I hereby certify that this batch complies with the requirements of Article 62(1) of Regulation (EU) No 536/2014 and article 4 of Delegated Regulation 1569/2017“
- (14) Name of the QP signing the certificate
- (15) Signature
- (16) Date of signature