FOOD AND DRUGS AUTHORITY GHANA

GUIDELINES FOR BATCH RELEASE OF VACCINES

BCG VACCINE

FDA/SMC/BPU/BR-BCG/2013/04

1 Introduction

These guidelines outline the minimum Ghana Food and Drugs Authority Batch Release requirements for the registration of immunological products.

All general and specific monographs relevant to the product apply (Refer to section 112 of the Ghana Public Health Act 851).

The number of samples (in final containers) used for batch release laboratory tests should be statistically justified.

2 Sampling and tests to be performed by the Control Laboratory

The control laboratory should perform the following tests:

- Identity
- count of viable units (potency assay)
- Test for virulent mycobacteria: on every new working seed lot
- Excessive dermal reactivity: on every new working seed lot

3 Protocol submission

A model protocol is given below. The protocol for a specific product may differ in detail but it is essential that all relevant details demonstrating compliance with the registration requirement and the official monograph should be given. WHO requirements may also serve as the model for the content and the presentation of the protocol data. Results of tests are required (pass or fail is not sufficient, results of re-tests if applicable should be given).

Sufficient detail should be supplied to allow re-calculation of test values. Specifications for each test and dates when they were performed should also be included. Results of qualification tests on reference materials should be given for each new in-house reference material.

3.1 Summary information on the final lot of finished product

Proprietary, Commercial or Trade name: ……..

International Non-Proprietary Name (INN): ……..

Common name of product : ……...

Batch number(s): ……..

Finished product (final lot): ……..
Final bulk : ……...

Type of container: ……...

Total Number of containers in this batch: ……..

Number of doses per container: ……...

Composition/Volume of single human dose: ……..

Date of expiry: ……..

Storage temperature: ……...

Name and address of manufacturer (s): ……..

Name and address of registration holder if different: ……...

Human Albumin used in the production (if applicable): ……..

-Lot number: ……...

- Manufacturer: ……...

(if this batch has been tested and released by a contracted
Laboratory, the release certificate should be provided): ……..

3.2 Production information

Site of manufacture: ……...

Date of manufacture: ……..

Summary information scheme on batch specific production data including dates of different production stages, identification numbers and blending scheme.

3.2.1 Starting materials

The information requested below is to be presented on each submission. Full details on Master seed-lots and working seed-lot upon first submission only.

Identification and source of starting materials
(particularly any materials of human or animal

Origin e.g. plasma; serum; strain of bacteria; master and working seeds; excipients and preservatives etc.): ……

Preparation date and reference number of seed-lot(s): ……

Date of approval of protocol indicating compliance with the requirements of the relevant monographs and with the conditions of registration: ……

Tests on starting materials (including origin, bacterial purity, identity, biochemical characteristics, absence of virulent mycobacteria, skin reaction test): ……...

Production details, in-process controls and dates of tests: ……

Batch number(s) of intermediates: ……...

Date(s) of manufacture: ……

Volume, storage temperature, storage time and approved storage period: ……

Production details including number and volume of containers inoculated, date of inoculation date of harvest: ……

In-process controls and dates of tests (including identity, impurity content, safety tests sterility): ……...

3.2.2 Final bulk vaccine

Batch number: ……...

Date of manufacture: ……

Nature of substances added to final bulk and final concentration: ……...

Human albumin used in the manufacturing process: ……...

Lot number(s): ……...

Manufacturer: ……...

Date of release by manufacturer: ……...

Stage in the manufacturing process in which this lot (s) is used: ……...

The information on excipients derived from human blood (e.g. albumin) should not be less detailed than the information requested for an active ingredient regarding documentation of starting materials as well as specifications and tests on the final product. Nevertheless, if the batch of albumin has been released by a contracted control laboratory in accordance with the Official Authority Batch Release procedure, the submission of a copy of the batch release certificate is sufficient.

Bacterial concentration
Method: ……...
Specification: ……...
Date: ……...
Result: ……...

Test for sterility
Method: ……...
Media: ……...
Date test on: ……...
Date test off: ……...
Result: ……...

Identification
Method: ……..
Specification: ……...
Date: ……...
Result: ……...

Count of viable units before freeze drying
Method: ……
Specification: ……....
Date: ……....
Result: ……

Test for virulent mycobacteria
Method: ……
Specification: ……
Date: ……
Result: ……

Batch number: ……....
Date of filling: ……
Date of freeze-drying: ……
Type of container: ……

Number of containers after inspection: ……
Filling volume: ……

Moisture content
Method: ……
Specification: ……....
Date: ……
Result: ……

Bacterial concentration
Method: ……
Specification: ……....
Date: ……
Result: ……

Test for virulent mycobacteria (if not done on final bulk)
Method: ……
Specification: ……....
Date: ……
Result: ……

Excessive dermal reactivity
Method: ……
Specification: ……...
Date: ……
Result: ……

Test for sterility
Method: ……
Media: ……...
Volume inoculated: ……...
Date test on: ……...
Date test off: ……...
Result: ……

Identification
Method: ……
Specification: ……..
Date: ……
Result: ……

Count of viable units after freeze drying
Method: ……

Specification: ……...
Date: ……
Result: ……

Mean survival rate
Method: ……
Specification: ……....
Date: ……
Result: ……

Temperature stability
Method: ……
Specification: ……....
Date: ……
Result: ……..

Date of start of period of validity: ……

4. Certification

Certification by qualified person taking the overall responsibility for production and control of the product:

I herewith certify that _____ (name of the product) batch number_____ was manufactured and tested according to the procedures approved by the competent authorities and complies with the quality requirements. This includes that, for any materials derived from ruminants (bovine, ovine, caprine) used in the manufacture and/or formulation of the batch of product specified above, all measures have been taken to demonstrate that the material is free from transmissible spongiform encephalopathy.

Name: _____

Designation: _____

Date: _____

Signature: _____