FOOD AND DRUGS AUTHORITY GHANA

GUIDELINES FOR BATCH RELEASE OF VACCINES

HEPATITS A (VIROSOMAL) VACCINE

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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).

2 Sampling and tests to be performed by the Control Laboratory

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

The Control Laboratory should perform the following tests:

- *in vivo* assay may be done on the final bulk or on a lot of finished product derived from it
- *in vitro* assay to determine the antigen content must be done on the final 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 presentation of the protocol data. Results of the tests are required (pass or fail is not sufficient, results of re-test 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: ……

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

3.2.1.1. For the Influenza component
Refer to starting materials in the current guideline for Food and Drugs Authority Batch Release of Influenza Vaccine.
Virus seed lot : refer to section 3.2.1

3.2.1.2. For the Hepatitis A component

Refer to starting materials in the current guideline for Food and Drug Authority Batch Release of Hepatitis A Vaccine (Inactivated, Adsorbed).

- Virus seed lots : refer to section 3.2.1.1
- Cell substrate for virus propagation : refer to section 3.2.1.2
- Control cell cultures : refer to section 3.2.1.3

3.2.2 Intermediate stages

3.2.2.1. For the Influenza component

Refer to intermediate stages in the current guideline for Food and Drug Authority Batch Release of Influenza Vaccine.

- Monovalent virus pool : refer to section 3.2.2.1

3.2.2.2. For the Hepatitis A component

Refer to intermediate stages in the guideline for Food and Drug Authority Batch Release of Hepatitis A Vaccine (Inactivated, Adsorbed) .

- Single Harvests : refer to section 3.2.2.1
- Purified harvests : refer to section 3.2.2.2
- Inactivated purified harvest : refer to section 3.2.2.3

3.2.2.3. Preparation of Virosomes:

Haemagglutinin content
Method: ……
Reference preparation: ……
Specification: ……
Date: ……
Result: ……

Phospholipid content
Method: ……
Specification: ……
Date: ……
Result: ……

Ratio of phospholipid to haemagglutinin
Method: ……
Specification: ……
Date: ……
Result: ……

Residual chemicals
Method: ……
Specification: ……
Date: ……
Result: ……

3.2.2.4 Final bulk vaccine

Batch number: ……

Volumes and batch numbers of all components
used during formulation: ……

Pooling date: ……

Date of manufacture: ……

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

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

Abnormal toxicity
Method: ……
Date test on: ……
Date test off: ……
Result: ……

Pyrogens
Method: ……
Date test on: ……
Date test off: ……
Result: ……

pH
Method: ……
Specification: ……
Date: ……
Result: ……

Protein content
Method: ……
Specification: ……
Date: ……
Result: ……

Phospholipid content
Method: ……
Specification: ……
Date: ……
Result: ……

Haemagglutinin content
Method: ……
Reference preparation: ……
Specification: ……
Date: ……
Result ……

Hepatitis A antigen content
Method: .....
Specification: .....
Date: .....
Result: .....

Preservative content
Method: .....
Specification: .....
Date: .....
Result: .....

Free formaldehyde content
Method: .....
Specification: .....
Date: .....
Result: .....

Residual BSA
Method: .....
Specification: .....
Date: .....
Result: .....

Residual Ovalbumin
Method: .....
Specification: .....
Date: .....
Result: .....

Residual Chemicals
Method: .....
Specification: .....
Date: .....
Result: .....

Endotoxin
Method: .....
Specification: .....
Date: .....
Result: .....

Virosome Size
Method: .....
Specification: .....
Date: .....
Result: .....

In vivo assay (if applicable)

Species, strain, sex and weight specifications: ……

Dates of immunisation, bleeding and measure of antibodies: ……

Batch number of reference vaccine: ……

Vaccine doses (dilutions): ……

Specification: ……

Date (s) of assay (s): ……

Number of animals responding to each dose: ……

ED_{50} of reference and test vaccine: ……

Potency of test vaccine vs. reference vaccine with 95% fiducial limits: ……

Validity criteria (linearity, parallelism, precision, ED_{50} between highest and lowest response): ……

3.3 Batch of finished product (final lot)

Batch number: ……

Date of filling: ……

Type of container: ……

Number of containers after inspection: ……

Filling Volume: …….

Tests for free formaldehyde, preservative content and in vivo potency, performed on the final bulk vaccine with satisfactory results do not have to be repeated on the final lot

Appearance

Method: ……

Specification: ……

Date: ……

Result: ……

Identification

Method: ……

Specification: ……

Date: ……

Result: ……

pH

Method: ……

Specification: ……

Date: ……

Result: ……

Extractable Volume
Method: ……
Specification: ……
Date: ……
Result: ……

Preservative content
Method: ……
Specification: ……
Date: ……
Result: ……

Free formaldehyde content
Method: ……
Specification: ……
Date: ……
Result: ……

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

Endotoxin
Method: ……
Specification: ……
Date: ……
Result: ……

In vivo assay (if not performed on the final bulk)
Species, strain, sex and weight specifications: ……
Dates of immunisation, bleeding and measure of antibodies: ……
Batch number of reference vaccine: ……
Vaccine doses (dilutions): ……
Specification: ……
Date(s) of assay(s): ……
Number of animals responding to each dose: ……
ED_{50} of reference and test vaccine: ……
Potency of test vaccine vs. reference vaccine
with 95% fiducial limits: ……
validity criteria (linearity, parallelism, precision,
ED_{50} between highest and lowest response): ……

In vitro assay (where applicable)

Method: ……

Reference preparation: ……

Specification: ……

Validity criteria (linearity, parallelism): ……

Date test on: ……

Date test off: ……

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: _____