الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Policy Guidance for Lot Release of Biological Products

Version 1.1

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Drug Sector
Saudi Food & Drug Authority
Kingdom of Saudi Arabia

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Document Control

Version	Date	Author(s)	Comments
1.0	01/09/2008	Registration Department	Published for comments
1.1	01/09/2010	Product Evaluation and Standards Setting Department	Final

Foreword

The policy guidance for lot release of Biological products provides assistance to industry, health care professionals and testing laboratories with respect to the official lot release program of the Saudi Food and Drug Authority (SFDA).

This policy guidance will also assist and provide guidance to staff involved in the assessment of Marketing Authorization of Biological products Applications.

Alternative approaches may be acceptable provided they are supported by scientific justification.

It should be noted that the SFDA has the right to request any biological product / lot or batch to be subjected to a lot release within the context of this policy.

It is the responsibility of SFDA to ensure that the products available in the Kingdom of Saudi Arabia adequately meet the requirements of safety, efficacy and quality.

In the interest of harmonization SFDA may consider lot/batch be released without performing lot release testing if such tests have been performed by well established regulatory authorities or WHO.

This policy guidance should be read in conjunction with the relevant section of other applicable guidances.

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1. Background

Biological products include a wide range of medicinal products, such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues and biosimilars. Unlike the common "small molecules" products, they generally exhibit high molecular complexity and may be quite sensitive to manufacturing process changes.

Due to these complexities, Biological products are regulated differently than other pharmaceutical drug products by well-established regulatory authorities, e.g. US, EU, Canada, Australia, etc. Because of the risk associated, the following two additional measures of safety, efficacy and quality are associated:

(a) A lot-to-lot release; and
(b) On-site GMP evaluation before authorization

2. Responsibility

This policy guidance is applicable to all Biological products regulated by SFDA. It is the responsibility of the manufacturer to comply with the requirements of Biological products marketed in the Kingdom of Saudi Arabia.

3. Policy Objective

The objective of this policy guidance is to clarify and outline the lot release testing program for Biological products prior to their release for sale in the Kingdom of Saudi Arabia by the Saudi Food and Drug Authority (SFDA).

The proposed program is in line with other well-established international authorities.

It is expected that this program will enhance SFDA's ability to maximize the safety, efficacy and quality of Biological products authorized for sale in the Kingdom of Saudi Arabia.

4. Policy Statement

Each lot of a Biological products is subject to the lot release program before marketing in the Kingdom of Saudi Arabia. This risk-based lot release program covers both pre- and post-market stages. The assessment and testing of Biological products is based on the degree of risk associated with the product.

The graduated risk-based approach to testing and oversight allows SFDA to focus on ongoing testing on product for which enhanced surveillance is needed, but are not limited to, the nature of the product, the target population, the manufacturer's production and testing history and the requirements of other international regulatory jurisdictions.

The lot release program requires close communication with the manufacturer in order to ensure that the program is efficient and effective.

5. Grouping of Products

For the purpose of this policy guidance, all Biological products are divided into two groups:

(a) Products under the Pre-Approval Stage
(b) Products under Post-Approval Stage

Products under Pre-Approval Stage

This group includes products that are under assessment as clinical trial applications, new drug applications and their supplements (SNDA). This group is divided into two sub-groups.

Routine Testing for Clinical Trial Application (CTA)

The clinical trial material for prophylactic vaccines is subject to lot release by SFDA prior to their use. Protocols of tests, standards and samples are required to be submitted.

Consistency Testing (NDA and SNDA)

During the assessment, samples from at least three consecutively manufactured lots are required to be tested by SFDA as part of the lot release program. The lots will be released for sale once marketing authorization is given.

Products under Post-Approval Stage

Those are products which have a marketing authorization given by SFDA. For the purpose of the lot release program, this group of products is divided into three categories based on risk, level of assessment and other factors such as:

- Indication of product
- Complexity of product and process
- Production history and compliance and complaints
- Lot failure, recalls, adverse effect

6. Categorization

Some of the factors required to be considered for the categorization of products subject for the lot release program include:

(a) Indication of the product, such as life-threatening, duration of treatment, target population, etc.
(b) Complexity of the product and process, such as complexity of drug substance, drug product, testing methods and manufacturing process, etc.
(c) Production history, compliance and complaints such as consistency of manufacturing, reprocessing, GMP compliance
(d) Lot failure, recalls, adverse effects such as rate of re-test, product recalls and withdrawals, safety profile, etc.

4.2.1 Category I

Category I products require the highest level of monitoring after marketing authorization. These products require a formal lot release from SFDA. Protocols of tests and samples are required.

Consideration may be given for expedited release in case of shortage.

4.2.2 Category II

Category II products require a moderate level of monitoring after marketing authorization. At the discretion of SFDA, these products will require periodic testing. Protocols of tests and samples are required.

Performance Target for testing is 4-6 weeks.

4.2.3 Category III

Category III products do not require lot release testing. However, the manufacturer is required to notify when a lot is to be marketed in the Kingdom of Saudi Arabia. At the discretion of SFDA, they may undergo periodic testing.

4.2.4 Special Consideration

If a product lot is approved through a lot-release program of well-established or recognized regulatory authorities, e.g. US, EU, Canada, and if such a lot is offered for

marketing in the Kingdom of Saudi Arabia, the lot will be exempted from SFDA lot release program, provided evidence of testing is submitted.

7. Annual Update

SFDA expects that all manufacturers/distributors of Biological products provide an annual update. This report is submitted yearly and should include the following information:

- Information on drug substance
- Information on drug product
- Information on test results of drug substance and drug product
- Information on manufacturing facility
- Adverse recall reports
- Recalls, product complaints
- Any changes from the previous Marketing Authorization information

8. Acronyms

NDA	New Drug Application
CTA	Clinical Trial Application
SNDA	Supplemental New Drug Application
COA	Certificate of Analysis
SFDA	Saudi Food and Drug Authority
GMP	Good Manufacturing Practice