

For office use only

Date received:

Ref:

BORANG LAPORAN KUALITI PRODUK UBAT / MEDICINAL PRODUCT QUALITY REPORTING FORM

(1) MAKLUMAT PRODUK UBAT / MEDICINAL PRODUCT DETAILS

*Nama produk pada label / Name of product on label: _____

Bahan aktif / Active ingredient: _____ Pengilang / Manufacturer: _____

Saiz pak asal / Original pack size: _____ Jumlah produk terjejas / Quantity of product affected: _____

*Bac / Batch number: _____ Tarikh mansuh / Expiry date: _____

(2) BUTIRAN LAPORAN KUALITI / QUALITY REPORT DESCRIPTION

*Tarikh dan masa isu kualiti dikesan / Date and time quality issue was detected: _____

*Sila beri penerangan ringkas berkaitan isu yang dilaporkan / Please provide brief description about the reported issue:

(3) KETERANGAN LANJUT MENGENAI PRODUK UBAT / ADDITIONAL INFORMATION ON MEDICINAL PRODUCT

Adakah seal pada produk sudah dibuka semasa menerima stok? Ya / Yes Tidak/ No Produk tidak mempunyai seal / Product has no seal
Was the seal on product broken when you received the stock?

Adakah stok produk dengan bac yang sama diperiksa? Ya / Yes Tidak/ No
Were other stocks of the same batch examined?

Jika ya, apa keadaan produk tersebut? / If yes, what is the product condition?

Adakah stok bac yang berlainan juga diperiksa? Ya / Yes Tidak/ No Tidak ada bac lain / No other batches available
Were stocks of a different batch also examined?

Jika ya, apa keadaan produk tersebut? / If yes, what is the product condition?

Kondisi penyimpanan produk/ Storage conditions of product:

Suhu bilik/ Room temperature ($\leq 25^{\circ}\text{C}$)

Suhu rangkaian sejuk/ Cold-chain temperature ($2^{\circ}\text{C}- 8^{\circ}\text{C}$)

Kelembapan/ Humidity ($\leq 60\%$ relative humidity)

Lain-lain/ Others _____

Sampel produk dihantar untuk siasatan lanjut?/ Ya / Yes Tidak/ No
Product sample submitted for further investigation?

(Nota: Jika produk adalah menggunakan rangkaian sejuk- sampel akan dikuarantin di peti sejuk di tempat ianya dikesan /Note: If cold chain product- sample are to be quarantined at the refrigerator at the detected site)

(4) MAKLUMAT PELAPOR / REPORTER DETAILS

*Nama pelapor / Reporter's name: _____

Jawatan / Post: _____ *Tempat bertugas / Place of work: _____

*No. telefon / Tel. no.: _____ E-mel / E-mail: _____

Tandatangan & cop rasmi /

Signature & official cop: _____ Tarikh laporan/ Date of reporting: _____