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# WHO Model NRA/NCL Lot Release Certificate for SARS-CoV-2 (Covid-19) vaccines

This certificate is to be provided by the NRA or NCL of the country where the vaccine has been manufactured, on request by the manufacturer.

Certificate no.:

The following lot(s) of SARS-CoV-2 vaccine produced by [[1]](#footnote-1)

in ,[[2]](#footnote-2) whose numbers appear on the labels of the final containers, meet all national requirements,[[3]](#footnote-3),[[4]](#footnote-4) and comply with WHO good manufacturing practices for pharmaceutical products: main principles;[[5]](#footnote-5) WHO good manufacturing practices for biological products;[[6]](#footnote-6) and the WHO Guidelines for independent lot release of vaccines by regulatory authorities.[[7]](#footnote-7)

The release decision is based on\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[[8]](#footnote-8)

Final lot number:

Number of human doses released in this final lot:

Manufacturing date/Expiry date :

The certificate may also include the following information:

* name and address of manufacturer;
* site(s) of manufacturing;
* trade name and/or common name of product;
* marketing authorization number;
* lot number(s) (including sub-lot numbers and packaging lot numbers if necessary);
* type of container;
* number of doses per container;
* number of containers or lot size;
* date of start of period of validity (for example, manufacturing date);
* storage conditions;
* signature and function of the person authorized to issue the certificate;
* date of issue of certificate.

The Director of the NRA/NCL (or other appropriate authority):

Signature:

Name (typed):

Date:

1. Name of manufacturer. [↑](#footnote-ref-1)
2. Country of origin. [↑](#footnote-ref-2)
3. If any national requirements have not been met, specify which one(s) and indicate why the release of the lot(s) has nevertheless been authorized by the NRA or NCL. [↑](#footnote-ref-3)
4. With the exception of provisions on distribution and transport, which the NRA or NCL may not be in a position to assess. [↑](#footnote-ref-4)
5. WHO Technical Report Series, No. 986, Annex 2. [↑](#footnote-ref-5)
6. WHO Technical Report Series, No. 999, Annex 2. [↑](#footnote-ref-6)
7. WHO Technical Report Series, No. 978, Annex 2. [↑](#footnote-ref-7)
8. Evaluation of the product-specific summary protocol, independent laboratory testing and/or specific procedures laid down in a defined document, and so on as appropriate. [↑](#footnote-ref-8)