EU Official Control Authority Batch Release

Human Vaccines

Guideline for Pandemic COVID-19 Vaccine (mRNA)

New Guideline
In force from 12/11/2020

European Commission

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Document title	Official Control Authority Batch Release Of Pandemic COVID-19 Vaccine (mRNA)
Legislative basis	Council Directive 2001/83/EC formerly 89/342/EEC, amended by Directive 2004/27/EC
Date of entry into force of present version	12 November 2020
Adoption of present version	November 2020
Revision status	New guideline
Custodian organisation	The present document was elaborated by the EDQM in the OMCL network and finalised under PA/PH/OMCL (20) 127 DEF

OFFICIAL CONTROL AUTHORITY BATCH RELEASE OF PANDEMIC COVID-19 VACCINE (mRNA)

1. Introduction

Control Authority Batch Release of immunological medicinal products is performed within the framework of Article 114 paragraph 1 of Directive 2001/83/EC and Article 1 paragraph 78 of the amending Directive 2004/27/EC and following the current guideline on EC administrative procedure for Official Control Authority Batch Release.

All general and specific Ph Eur monographs pertaining to this product apply.

2. Sampling and tests to be performed by the Control Laboratory

The following samples should be supplied to the Official Medicines Control Laboratory performing batch release:

At least 30 single/multi dose containers of each final lot

The Control Laboratory should perform the following tests:

On the final lot:

- Appearance
- Identity
- Potency
- Integrity