

# Certificate of Compliance for Investigational Medicinal Products

## Certificate of Release

<b>Study No:</b>	<b>MV45225</b>
EU CT / EudraCT No.:	2023-507441-29-00 / 2020-001113-21
Delivery No.:	9618144704
SAP Batch No.:	1185830
Process Order No.:	1061621
Material No.:	39029609
Quantity of packages:	500. BOX WITH 1 BLISTER WITH 2 TABLETS
MEDNO:	N/A
Use by / Exp. date:	28.02.2027
Storage conditions:	Store at 15°-30°C/59°-86°F.
Use Restrictions:	Material for: United Kingdom
Issue Date:	19.12.2024
Inspection Lot:	890000212706

Manufacturing Site of Primary Packaging:	F. HOFFMANN-LA ROCHE AG WURMISWEG 4303 KAISERAUGST SWITZERLAND License No: 511265 GMP-Certificate: GMP-CH-1000098
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Manufacturing Site of Secondary Packaging:	F. HOFFMANN-LA ROCHE AG WURMISWEG 4303 KAISERAUGST SWITZERLAND License No: 511265 GMP-Certificate: GMP-CH-1000098
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### Certified Components:

Roformis-No.:	719-1686/F04-00	Batch No.:	S22009
Product Name:	BALOXAVIR MARBOXIL	Manufacturing Date:	21-FEB-2022
Dosage Form / content:	tablets		
Strength / Potency:	20MG		
Analysis No.:	PA-22023S OF 23-MAR-2022		
Manufacturer Name or Marketing Authorization Holder:	Shionogi & Co., Osaka, Japan		

I hereby certify that the above information is authentic and accurate. All the manufacturing stages of this batch of finished product have been carried out in full compliance with GMP requirements at least equivalent to those of the EU and with the requirements of the regulatory filings in the destination country.

I hereby certify that this batch complies with the requirements of Article 62(1) of Regulation (EU) No 536/2014 and article 4 of Delegated Regulation 1569/2017.

This batch is released by the Qualified Person of Roche Pharma AG, Grenzach, Germany (Manufacturing License No.: DE\_BW\_01\_MIA\_2024\_0094).

Additional comments:

N/A

Date of approval:

19-DEC-2024 , 12:06:13 CET

Approved by:

Deborah Roidl

(Qualified person, Roche Pharma AG,  
Emil Barell Straße 1,  
79639 Grenzach-Wyhlen, Germany)

This certificate has been signed  
electronically by an authorized  
person in an IT-system compliant  
to CFR Part11 and EudraLex Volume  
4 Annex 11