

QUALIFIED PERSON'S DECLARATION EQUIVALENCE TO EU GMP FOR IMP
MANUFACTURED IN THIRD COUNTRIES (ARTICLE 63 AND ANNEX I (F) (33) (b)
OF REGULATION (EC) 536/2014)

EU CT Number / EudraCT Number 2023-507441-29-00 / 2020-001113-21 Roche Protocol ID: MV45225	Name of the IMP(s) BALOXAVIR MARBOXIL
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719-1686/F04-01 Roformis No	20 mg per 1 piece Strength/Concentration
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Manufacturing and Import Authorisation Number under which this declaration is made:
DE_BW_01_MIA_2024_0094

Part A

Name of the IMP(s)	Manufacturing site(s)	Activity performed at this site
719-1686/F04-01 BALOXAVIR MARBOXIL	ALMAC CLINICAL SERVICES LLC, 25 FRETZ ROAD, SOUDERTON, PA 18964, UNITED STATES	- secondary packaging
719-1686/F04-01 BALOXAVIR MARBOXIL	ALMAC CLINICAL SERVICES LTD, SEAGOE INDUSTRIAL ESTATE, 9 CHARLESTOWN ROAD, CRAIGAVON BT63 5PW, UNITED KINGDOM	- secondary packaging
719-1686/F04-01 BALOXAVIR MARBOXIL	F. HOFFMANN-LA ROCHE AG, WURMISWEG, 4303KAISERAUGST, SWITZERLAND	- primary packaging - secondary packaging
719-1686/F04-01 BALOXAVIR MARBOXIL	FISHER CLINICAL SERVICES GMBH, STEINBUEHLWEG 69, 4123 ALLSCHWIL, SWITZERLAND	- primary packaging - secondary packaging
719-1686/F04-01 BALOXAVIR MARBOXIL	FISHER CLINICAL SERVICES INC., 7554 SCHANTZ ROAD, ALLENTOWN, PA 18106, UNITED STATES	- secondary packaging
719-1686/F04-01 BALOXAVIR MARBOXIL	GENENTECH, INC., 1 DNA WAY, SOUTH SAN FRANCISCO, CA 94080, UNITED STATES	- secondary packaging
719-1686/F04-01 BALOXAVIR MARBOXIL	SHIONOGI PHARMA CO. LTD., SETTSU PLANT, 2-5-1, MISHIMA, SETTSU, OSAKA 566-0022, JAPAN	- manufacturing of drug product - analytical testing

Part B

I confirm that I am a QP and am authorised to make this declaration.

I declare that compliance with GMP at least equivalent to EU GMP has been verified on the basis of:

(i) Audit

Manufacturing site(s)	Auditing party	Date of Last Audit(s)(completion)
<i>ALMAC CLINICAL SERVICES LLC, 25 FRETZ ROAD, SOUDERTON, PA 18964, UNITED STATES</i>	I declare that compliance with GMP at least equivalent to EU GMP has been verified based on the audit(s) mentioned above carried out by Roche Global GMP Compliance Audit Group in close collaboration with the Qualified Person (Roche Pharma AG).	<u>31 Mar 2022</u>
<i>ALMAC CLINICAL SERVICES LTD, SEAGOE INDUSTRIAL ESTATE, 9 CHARLESTOWN ROAD, CRAIGAVON BT63 5PW, UNITED KINGDOM</i>	I declare that compliance with GMP at least equivalent to EU GMP has been verified based on the audit(s) mentioned above carried out by Roche Global GMP Compliance Audit Group in close collaboration with the Qualified Person (Roche Pharma AG).	<u>27 Mar 2024</u>
<i>F. HOFFMANN-LA ROCHE AG, WURMISWEG, 4303 KAISERAUGST, SWITZERLAND</i>	I declare that compliance with GMP at least equivalent to EU GMP has been verified based on the audit(s) mentioned above carried out by Roche Global GMP Compliance Audit Group in close collaboration with the Qualified Person (Roche Pharma AG).	<u>02 Sep 2022</u>
<i>FISHER CLINICAL SERVICES GMBH, STEINBUEHLWEG 69, 4123 ALLSCHWIL, SWITZERLAND</i>	I declare that compliance with GMP at least equivalent to EU GMP has been verified based on the audit(s) mentioned above carried out by Roche Global GMP Compliance Audit Group in close collaboration with the Qualified Person (Roche Pharma AG).	<u>17 Oct 2024</u>
<i>FISHER CLINICAL SERVICES INC., 7554 SCHANTZ ROAD, ALLENTOWN, PA 18106, UNITED STATES</i>	I declare that compliance with GMP at least equivalent to EU GMP has been verified based on the audit(s) mentioned above carried out by Roche Global GMP Compliance Audit Group in close collaboration with the Qualified Person (Roche Pharma AG).	<u>29 Oct 2024</u>
<i>GENENTECH, INC., 1 DNA WAY, SOUTH SAN FRANCISCO, CA 94080, UNITED STATES</i>	I declare that compliance with GMP at least equivalent to EU GMP has been verified based on the audit(s) mentioned above carried out by Roche Global GMP Compliance Audit Group in close collaboration with the Qualified Person (Roche Pharma AG).	<u>17 May 2024</u>
<i>SHIONOGI PHARMA CO. LTD., SETTSU PLANT, 2-5-1, MISHIMA, SETTSU, OSAKA 566-0022, JAPAN</i>	I declare that compliance with GMP at least equivalent to EU GMP has been verified based on the audit(s) mentioned above carried out by Roche Global GMP Compliance Audit Group in close collaboration with the Qualified Person (Roche Pharma AG).	<u>07 Mar 2024</u>

(ii) If an audit of the site has not been performed, please provide a brief justification and explanation on how the QP knows that standards at least equivalent to EU GMP are being followed at the site.

Manufacturing site(s)	Justification
n/a	n/a

Annotations: n/a

This declaration is submitted by:

Name, Signature, Date