

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/EudraCT No 2023-507441-29-00 Roche Protocol ID: MV45225	Name of the IMP(s) BALOXAVIR MARBOXIL, XOFLUZA
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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_2020_0096/DE_BW_01_Roche Pharma

Part A

Name of the IMP(s)	Manufacturing site(s)	Activity performed at this site
719-1686/F04-01 BALOXAVIR MARBOXIL, XOFLUZA	<i>ALMAC CLINICAL SERVICES LLC, 25 FRETZ ROAD, SOUDERTON, PA 18964, UNITED STATES</i>	- secondary packaging
719-1686/F04-01 BALOXAVIR MARBOXIL, XOFLUZA	<i>ALMAC CLINICAL SERVICES LTD, SEAGOE INDUSTRIAL ESTATE, 9 CHARLESTOWN ROAD, CRAIGAVON BT63 5PW, UNITED KINGDOM</i>	- secondary packaging
719-1686/F04-01 BALOXAVIR MARBOXIL, XOFLUZA	<i>F. HOFFMANN-LA ROCHE AG, WURMISWEG, 4303 KAISERAUGST, SWITZERLAND</i>	- primary packaging - secondary packaging
719-1686/F04-01 BALOXAVIR MARBOXIL, XOFLUZA	<i>FISHER CLINICAL SERVICES GMBH, STEINBUEHLWEG 69, 4123 ALLSCHWIL, SWITZERLAND</i>	- primary packaging - secondary packaging
719-1686/F04-01 BALOXAVIR MARBOXIL, XOFLUZA	<i>FISHER CLINICAL SERVICES INC., 7554 SCHANTZ ROAD, ALLENTOWN, PA 18106, UNITED STATES</i>	- secondary packaging

719-1686/F04-01 BALOXAVIR MARBOXIL, XOFLUZA	<i>GENENTECH, INC., 1 DNA WAY, SOUTH SAN FRANCISCO, CA 94080, UNITED STATES</i>	- secondary packaging
719-1686/F04-01 BALOXAVIR MARBOXIL, XOFLUZA	<i>SHIONOGI PHARMA CO. LTD., SETTSU PLANT, 2-5-1, MISHIMA, SETTSU, OSAKA 566-0022, JAPAN</i>	- 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>02 Sep 2020</u>
<i>F. HOFFMANN-LA ROCHE AG, WURMISWEG, 4303KAISERAUGST, 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>15 Jun 2021</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>15 Sep 2021</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>18 Aug 2022</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>18 Mar 2022</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