Austrian
Federal Office for
Safety in Health Care
BASG

BASG / AGES MEA
Institute Surveillance
Traiseng. 5, 1200 Vienna, Austria

Octapharma Pharmazeutika Produktionsgesellschaft m.b.H.
Denisia Wurstbauer
Oberlaaer Straße 235
1100 Wien
Österreich

Date: see official signature
Contact: Mag. Dr. Sandra Rieger
T: +43 50 555 36125, **Fax:** -36409
E-Mail: inspections@basg.gv.at
Our reference: INS-482518-101102957-17905394

INSPECTION OF THIRD COUNTRY SOURCE PLASMA / RECOVERED PLASMA SITES FOR Octapharma Pharmazeutika ProduktionsgesmbH

We refer to the inspection performed for your company at

National Genetics Institute (NGI), 2440 S. Sepulveda Boulevard, Suite 235, Los Angeles, CA, 90064, USA

premises on **06 – 07 October 2022** by the Federal Office for Safety in Healthcare (BASG).

On the basis of the inspection and subsequent correspondence, we can confirm that operations relating to the safety and quality of plasma are in general compliance with the requirements of Commission Directives 2004/33/EC and 2005/62/EC implementing Directive 2002/98/EC of the European Parliament and of the Council, the relevant European Pharmacopoeia Monograph(s) and Directive 2003/94/EC.

This letter reflects the status of the plasma collection site at the time of the inspection noted above. The Issuing Authority has established appropriate inspection and control measures for the above named site(s) to deem it compliant until **January 2025**. This letter should not be relied upon to reflect the compliance status if the above mentioned date has been exceeded, after which the issuing authority should be consulted.

Any matters arising from this inspection will be reviewed at the next inspection.

On behalf of the Austrian Federal Office for Safety in Health Care

Kraßnigg Andreas
am 17.2.2023