octapharma
For the safe and optimal use of human proteins

CERTIFICATE OF ANALYSIS

Preparation:	**OCTAGAM 5 %** **Intravenous Immunoglobulin Human 5 % SD**
Filling size:	**200 mL infusion bottle**
Packaging batch no.:	**K210E8446**
Internal Code:	**0920**
Man. Date:	**03/2022**
Exp. Date:	**02/2024**

TEST	SPECIFICATION[1]	RESULT
Characters		
Clarity	The liquid preparation is clear or not more opalescent than the reference suspension II (6 NTU).	**passed test**
Coloration	The liquid preparation is colourless or not more intensely coloured than reference solution Y5.	**passed test**
Identification		
Immunoelectrophoresis	Immunoglobulin precipitation bands	**passed test**
Tests		
pH value	5.1 - 6.0	**5.4**
Osmolality	≥ 240 mosmol/kg	**337 mosmol/kg**
Total protein	4.5 - 5.5 % (w/v)	**5.0 %**
Protein composition	≥ 95 % Immunoglobulin	**98 %**
Molecular size distribution	Polymers: ≤ 3.0 % of the total chromatogram area Monomers and dimers: ≥ 90.0 % of the total chromatogram area	**< 0.3 %** **99.8 %**
Anticomplementary activity	≤ 1.00 CH_{50}/mg Immunoglobulin	**0.77 CH_{50}/mg**
Prekallikrein activator	PKA: ≤ 35.0 IU/mL PKA-blank: ≤ 10.0 IU/mL	**< 2.0 IU/mL** **< 2.0 IU/mL**
Haemagglutinins	Anti A ≤ 64 Anti B ≤ 64	**8** **4**
Anti D	Pass test	**passed test**
Sterility	Sterile	**passed test**

1) spec.no.: CORP-FPS-00329_2.0

Quality Unit
Octapharma Pharmazeutika
Produktionsges.m.b.H.
Oberlaaer Straße 235
A-1100 Wien
Rufnummer: (+43-1) 610 32-0
Fax-DW 9350 und 9121
Firmenbuchgericht: HG Wien

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Endotoxin	< 0.5 IU/mL	**< 0.1 IU/mL**
HBsAb	≥ 1 IU/g Immunoglobulin	**50 IU/g**
IgA content	≤ 0.2 mg/mL	**0.1 mg/mL**
Additional Tests		
IgG content	42.8 - 55.0 mg/mL	**51.1 mg/mL**
IgM content	≤ 0.10 mg/mL	**0.01 mg/mL**
Chloride	≤ 15 mmol/L	**8 mmol/L**
Sodium	≤ 15 mmol/L	**< 3 mmol/L**
Potassium	≤ 1.0 mmol/L	**< 0.1 mmol/L**
Aluminium	≤ 200 µg/L	**< 5 µg/L**
Maltose	90 - 110 mg/mL	**96 mg/mL**
Tri(n-butyl)phosphate	≤ 1.0 µg/mL	**< 0.3 µg/mL**
Octoxynol	≤ 5.0 µg/mL	**< 0.5 µg/mL**
HAV Ab	≥ 2.5 IU/mL	**10.3 IU/mL**
Parvo B19 Ab	≥ 60 IU/mL	**190 IU/mL**
Factor XIa-like activity	≤ 2 mIU/mL	**1 mIU/mL**

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It is certified that the above lot was manufactured according to GMP regulations and fulfils the criteria of current European Pharmacopoeia.

It is certified that all donations of plasma were individually tested and found non-reactive to HBsAg, HIV-1/HIV-2 Ab and HCV Ab.

Each plasma pool was tested negative for HBsAg and HIV-1/HIV-2 Ab by EIA, as well as by PCR with negative outcome for HAV, HBV, HCV and HIV and with less than 10^5 IU/ml for Parvo B 19.

For excipient only.

E. TOMAZ 05. APR. 2022

Assessment & Release /AZ

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Austrian
Federal Office for
Safety in Health Care
BASG

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Dipl.Ing. (FH) Christoph Kefeder; e-mail: christoph.kefeder@ages.at
Phone: +43(0)5 0555 36331; Fax: +43(0)5 0555 36309
To: Octapharma Pharmazeutika Produktionsgese, AT

EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE - Finished Product

Examined under Article 114 of Directives 2001/83/EC as amended by Directive 2004/27/EC (Medicinal Products derived from Human Blood or Plasma) and in accordance with the Administrative Procedure for Official Control Authority Batch Release.

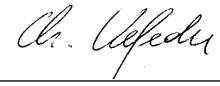
Trade name:	Octagam 50 mg/ml Infusionslösung
International non-propriety name / Ph. Eur. name / common name:	Human Normal Immunoglobulin for Intravenous Administration
Batch numbers appearing on package and other identification numbers associated with this batch:	K210E844
Type of container:	Glass bottle
Total number of containers in this batch:	3395
Nominal dose per container:	10 g / 200 ml
Date of start of period of validity:	10.03.2022
Date of expiry:	29.02.2024
Marketing authorisation number (member state / EU) issued by:	238569 (Austria)
Name and address of manufacturer (site of Qualified Person signing summary protocol unless otherwise indicated):	Octapharma Pharmazeutika Produktionsgesellschaft m.b.H. Oberlaaer Straße 235 AT-1100 Wien
Name and address of marketing authorisation holder:	(as above)

This batch has been examined using documented procedures which form part of a quality system which is in accordance with the EN/ISO 17025 standard.

This examination is based on the relevant EU OCABR guideline for this product.

All constituent plasma pools have been tested by an OMCL for virological markers.

This batch is in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monographs and the above marketing authorisation and is released.

Signed:	
Name and Function of Signatory:	Dipl.Ing. (FH) Christoph Kefeder
Date of Issue:	13.04.2022
Release Certificate Number:	ZAT-221853

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