octapharma

CERTIFICATE OF ANALYSIS
Sweden

Product: **OCTAGAM Intravenous Immunoglobulin human 5 % SD**
Manufacturing batch no.: **M335C8444**
Filling size **200 mL**
Internal Code: **89323**
Article number: **5601027**
Man. Date: **08/2023**
Exp. Date: **07/2025**
Date of start of period of validity: 2023-08-29

TEST	SPECIFICATION[1]	RESULT
CHARACTERS		
Clarity	The liquid preparation is clear or not more opalescent than the reference suspension II (6 NTU)	APPROVED
Coloration	The liquid preparation is colourless or not more intensely coloured than reference solution Y5.	APPROVED
IDENTIFICATION		
Immunoelectrophoresis	Immunoglobulin precipitation bands	POSITIVE
Tests		
pH value	5.1 – 6.0	5.2
Osmolality, mosmol/kg	≥ 240	327
Total protein, % (w/v)	4.5 – 5.5	5.0
Protein composition, % Immunoglobulin	≥ 95	98
Molecular size distribution, % of the total chromatogram area		
Polymers	≤ 3.0	<0.3
Monomers and Dimers	≥ 90.0	99.8
Anticomplementary activity, CH_{50}/mg Immunoglobulin	≤ 1.00	0.49
Prekallikrein activator, IU/mL		
PKA:	≤ 35.0	<2.0
PKA-Blank:	≤ 10.0	<2.0

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Visiting address:
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[1]) spec. nr: CORP-FPS-00329_2.0

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Haemagglutinins (Determination of the highest dilution of the preparation where there is still an agglutination of A_1- and B- erythrocytes)		
Anti A	≤ 64	8
Anti B	≤ 64	4
Anti D	Pass test	APPROVED
Sterility	Sterile	APPROVED
Endotoxin, IU/mL	< 0.5	<0.1
HBsAb, IU/g Immunoglobulin	≥ 1	85
IgA content, mg/mL	≤ 0.2	0.1
ADDITIONAL TESTS		
IgG content, mg/mL	42.8 – 55.0	49.7
IgM content, mg/mL	≤ 0.10	<0.01
Chloride, mmol/L	≤ 15	8
Sodium, mmol/L	≤ 15	0
Potassium, mmol/L	≤ 1.0	<0.1
Aluminium, µg/L	≤ 200	<5
Maltose, mg/mL	90 – 110	97
Tri(n-butyl)phosphate, µg/mL	≤ 1.0	<0.3
Octoxynol, µg/mL	≤ 5.0	<0.5
HAV Ab, IU/mL	≥ 2.5	6.8

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Parvo B19 Ab, IU/mL	≥ 60	173
Factor XIa-like activity: (referring to a 5% Total Protein solution), mIU/mL	≤ 2	0

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

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

Not for human use.

Stockholm,
Octapharma AB

2023 -11- 13

Qualified Person Göran Jonsäll

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Austrian
Federal Office for
Safety in Health Care
BASG

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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
International non-propriety name / Ph. Eur. name / common name:	Human normal immunoglobulin
Batch numbers appearing on package and other identification numbers associated with this batch:	M335C844
Type of container:	Glass bottle
Total number of containers in this batch:	3975
Nominal dose per container:	10 g / 200ml
Date of start of period of validity:	29.08.2023
Date of expiry:	31.07.2025
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 AB SE-112 75 Stockholm, Sweden
Name and address of marketing authorisation holder:	Octapharma Pharmazeutika Produktionsgesellschaft m.b.H. Oberlaaer Straße 235 AT-1100 Wien

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:	Ing. Stephanie Eichmeir
Date of Issue:	27.10.2023
Release Certificate Number:	ZAT-235122

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