octapharma
For the safe and optimal use of human proteins

CERTIFICATE OF ANALYSIS

SWEDEN

Preparation:	**OCTAGAM 5 %** **Intravenous Immunoglobulin Human 5 % SD**
Filling size:	**100 ml infusion bottle**
Packaging batch no.:	**K718A844C**
Internal Code:	**6423**
Man. Date:	**05/2017**
Exp. Date:	**04/2019**

TEST	SPECIFICATION[1]	RESULT
Characters		
Clarity	complies	**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	**5.3**
Osmolality	≥ 240 mosmol/kg	**334 mosmol/kg**
Total protein	4.5 - 5.5 % (w/v)	**5.0 %**
Protein composition	≥ 95 % immunoglobulin	**96 %**
Molecular size distribution	Polymers: ≤ 3.0 % of the total chromatogram area Monomers and dimers: ≥ 90.0 % of the total chromatogram area	**< 0.5 %** **99.7 %**
Anticomplementary activity	≤ 1.00 CH_{50}/mg immunoglobulin	**0.50 CH_{50}/mg Ig**
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.: 013FPS840/15/SE

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	**0.0 IU/ml**
HBsAb	≥ 1 IU/g immunoglobulin	**29 IU/g Ig**
IgA content	≤ 0.2 mg/ml	**0.1 mg/ml**
Additional Tests		
IgG content	42.8 - 55.0 mg/ml	**50.1 mg/ml**
IgM content	≤ 0.10 mg/ml	**< 0.04 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**
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	**6.6 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 fulfills the criteria of 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 and found negative for HBsAg and HIV-1/HIV-2 Ab by EIA and HCV-RNA by Polymerase Chain Reaction method (PCR).

E. Tomaz 13. JUNI 2017

Assessment & Release /Rau

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Firmenbuchgericht: HG Wien

BASG / AGES, Institut BGA
Possingergasse 38, AT-1160 Wien
Dipl.Ing. (FH) Christoph Kefeder, Assessor ; e-mail: christoph.kefeder@ag
Phone: +43(0)5 0555 36331; Fax: +43(0)5 0555 36309
To: Octapharma Pharmazeutika Produktion

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:	K718A844
Type of container:	vial
Total number of containers in this batch:	7619
Nominal dose per container:	5 g / 100 ml
Date of start of period of validity:	04.05.2017
Date of expiry:	30.04.2019
Marketing authorisation number (member state / EU) issued by:	2-00169 (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:	Ch. Kefeder
Name and Function of Signatory:	Dipl.Ing. (FH) Christoph Kefeder, Assessor
Date of Issue:	07.06.2017
AGES Release Certificate Number:	ZAT-171684

F_VIE_LAB_00QM_L085_05 17057878

octapharma Pharmazeutika Prod.g.m.b.H	OCTAGAM 5% 100ML SWEDEN Charge: **K718A844C** Auftrags-Nr. **12078177**	**Verpackungsbericht** 1 . Ausdruck 13.06.2017

Verpackungskontrollblatt

Land: **Sweden**

Herstelldatum + Ablaufdatum: **MD-, ED 04/2019**

Zusatzinfo: **Tamro AB/PO 4500012498**

verpackte Menge: 30 Stück

davon Muster beurteilt: 1 Stück

InkjetNr	Einsatzchargenr.	Lieferantenchargennr.
6423	K718A844V1	

Mat.Bez.	PM-Code	Inkjet Nr.				Charge				Herstell-datum				Ablauf-datum				PM-Code / Lieferant.-charge			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Octagam 5 %100ml VI FP		X																			
ETK Octagam 100ml BG Schweden	E.840.015.SW					X								X				X			
FKT Octagam 100ml Schweden	F.840.014.SW					X								X				X			
BPT Octagam Schweden	B.840.003.SW																	X			
WPK 30 x 100ml, braun, unbedruckt																					
ETK 50 x 93mm, unbedruckt																					
Versandkarton 60x100ml 2°C-25°C																					
ETK "Time&TemperatureSensitive 2-25																					

Bemerkungen:

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Abweichung: ☒ nein ☐ ja .....

S. GUDZIC 19. JUNI 2017

Datum / Unterschrift

Die Verpackung entspricht dem Verpackungsauftrag und wird zum Versand freigegeben.

N. STAMENKOVIC 16. JUNI 2017

Datum / Unterschrift / Prüfer

E. Tomaz 20. JUNI 2017

Datum / Unterschrift / Qualified Person