

CERTIFICATE OF ANALYSIS

SWEDEN

Name: **OCTAGAM 5 %**
 Description: **Intravenous Immunoglobulin human 5 % SD**
 Filling size: **100 ml**
 Packaging batch no.: **L729A8442**
 Internal Code: **008928**
 Man. Date: **07/2017**
 Exp. Date: **06/2019**

TEST	SPECIFICATIONS ¹	RESULTS
<u>Characters</u>		
Clarity	Complies	Passed test
Coloration	The liquid preparation is colourless or not more intensely coloured than reference solution Y5.	Passed test
<u>Identification</u>		
Immunoelectrophoresis	Immunoglobulin precipitation bands	Passed test
<u>Tests</u>		
pH value	5.1 - 6.0	5.2
Osmolality	≥ 240 mosmol/kg	330 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	< 0.5 %
Monomers and Dimers:	≥ 90.0% of the total chromatogram area	99.8 %
Anticomplementary activity	≤ 1.00 CH ₅₀ /mg Immunoglobulin	0.40 CH₅₀/mg Ig
Prekallikrein activator:		
PKA:	≤ 35.0 IU/ml	< 2.0 IU/ml
PKA-blank:	≤ 10.0 IU/ml	< 2.0 IU/ml
Hemagglutinins (Determination of the highest dilution of the preparation where there is still an agglutination of A1- and B- erythrocytes)	Anti A ≤ 64 Anti B ≤ 64	8 8

Octapharma
 72, rue du Maréchal Foch
 67380 Lingolsheim / France

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 Fax (+33) (0)3 88 77 62 01



F. BAL
 25 AOUT 2017

¹ Spec. no.: 013FPS840/15/SE

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TEST	SPECIFICATIONS ¹	RESULTS
Anti D	Pass test	Passed test
Sterility	Sterile	Passed test
Endotoxin	< 0.5 IU/ml	< 0.1 IU/ml
HBsAb	≥ 1 IU/g Immunoglobulin	62 IU/g Ig
IgA content	≤ 0.2 mg/ml	0.1 mg/ml
<u>Additional Tests</u>		
IgG content	42.8 - 55.0 mg/ml	50.7 mg/ml
IgM content	≤ 0.10 mg/ml	< 0.01 mg/ml
Chloride	≤ 15 mmol/l	9 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	5.8 IU/ml
Factor XIa-like activity (referring to a 5% Total Protein solution)	≤ 2 mIU/ml	< 1 mIU/ml

It is certified that the above lot was manufactured according to GMP regulations and fulfils 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, HIV-1/HIV-2 Ab by EIA and HCV-RNA by Polymerase Chain Reaction method (PCR).

Qualified Person



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CERTIFICATION

I herewith certify that,

Name of product: **OCTAGAM 5 g, 100 mL**
Batch N°: **L729A8442**

was manufactured and tested according to Sweden process (mop_840_SE_13) and that blood banks for the plasmapool used for the manufacturing of this batch are in the current PMF (EMA/H/PMF/000008/05; 15.09.2016).

Qualified Person


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25 AOUT 2017

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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-proprietary 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:	L729A844
Type of container:	vial
Total number of containers in this batch:	6200
Nominal dose per container:	5 g/ 100 ml
Date of start of period of validity:	17.07.2017
Date of expiry:	30.06.2019
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 S.A. 72 rue du Marechal Foch FR-67380 Lingolsheim
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.






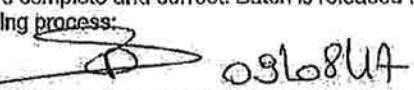
This examination is based on the relevant EU OCABR guideline for this product.
All constituent plasma pools have been tested by an OMCL for virological markers.

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:	Dipl.Ing. (FH) Christoph Kefeder, Assessor
Date of Issue:	24.08.2017
AGES Release Certificate Number:	ZAT-172693

17089577

octapharma Dessau GmbH	OCTAGAM 5% 100ML SWEDEN	Herstellungsprotokoll Standard 2 Original 09.08.2017
	Ch.-B.: L729A8442	

Auftragskopf		Packaging (Internal release)	
Prozessauftrags-Nr.: 17026633		Comments: It is confirmed that all batch related activities which took place at Octapharma Dessau GmbH were performed according to the procedure approved by the authorities, according to GMP regulations and according to the packaging order (gSCM/ CS/production site). The packed batch complies with the quality requirements. Deviations occurred during all batch related activities have been approved, all release relevant CAPAs have been completed. Quantity: 35 W. Bauer 16. AUG. 2017  Date/Signature QP Dessau GmbH	
Mat.-Nr.: 5600101			
Ausstellungsdatum: 09.08.2017			
Aussteller: OPHBATCH			
Ausführungstermin: 21.08.2017			
Auftragsmenge [Stk.] /Quantity: 36	Incl. 1 RHM		
Ch.-B. / Batch: L729A8442			
Herst.datum / Man. Date: -			
Verw. bis / Exp. Date: 06/2019			
Inkjet.-Nr.: 008928			
Land / Country: Sweden			
Lagertemp./ storage temp.: T = 2°C bis 25 °C			
Ww: 8401SE101 Zusatzdruck/- etikett/special requirements:		Batch release Confirmation and release for shipment It is herewith confirmed that no deviations occurred during manufacturing of the above mentioned product which negatively influence the quality, safety or efficacy of finished product. I hereby certify that the above information is authentic and accurate. This batch has been manufactured and tested in full compliance with the GMP regulations and Method of Preparation. The batch manufacturing and analysis record were reviewed and found to be in compliance with the GMP and with the country-specific requirements. <input checked="" type="checkbox"/> OMCL pending F. BAL 17 AOUT 2017  Date/Signature QP Production Site Certification/ the batch is released to the market F. BAL 17 AOUT 2017  Date/Signature QP Releasing Site	
Wellere Angaben (z. Bsp. Code auf FS)/ Comments (Code/-typ):			
Transportrichtung durchführen: Nein			
PZA geprüft und ergänzt: S. Heenemann 09. AUG. 2017 			
Datum/Unterschrift (A&R Dessau)			
Auftragsdaten geprüft: Dr. A. Bilzer 09. AUG. 2017 			
Datum/Unterschrift (A&R Dessau)			
Verpackungsfreigabe/Authorisation for packaging Data are complete and correct. Batch is released for packaging process:  036844 Date/Signature (A&R site of production)			Technical release in SAP Comments: Datum/Unterschrift (A&R Dessau)

Dokumentation lt. AA2711

Prozessauftrag Nr.: 17026633

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AA2711 Anhang2 Dokument: Herstellungs- und Prüfprotokoll Standard 2 vom 09.01.2017