octapharma

CERTIFICATE OF ANALYSIS
SWEDEN

Product: **OCTAGAM Intravenous Immunoglobulin human 5 % SD**
Manufacturing batch no.: **M205A8447**
Filling size **200 mL**
Internal Code: **87695**
Man. Date: **02/2022**
Exp. Date: **01/2024**
Date of start of period of validity: 2022-02-01

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	APPROVED
Tests		
pH value	5.1 – 6.0	5.3
Osmolality, mosmol/kg	≥ 240	335
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
Anticomplcmcntary activity, CH_{50}/mg Immunoglobulin	≤ 1.00	0.69
Prekallikrein activator, IU/mL		
PKA:	≤ 35.0	<2.0
PKA-Blank:	≤ 10.0	<2.0

Octapharma AB
SE-112 75 Stockholm
Sweden
Visiting address:
Lars Forssells gata 23

Tel +46 8 566 430 00
Fax +46 8 566 430 10

[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	48
IgA content, mg/mL	≤ 0.2	0.1
ADDITIONAL TESTS		
IgG content, mg/mL	42.8 – 55.0	48.9
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	<30
Maltose, mg/mL	90 – 110	98
Tri(n-butyl)phosphate, µg/mL	≤ 1.0	<0.3
Octoxynol, µg/mL	≤ 5.0	<0.5

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TEST	SPECIFICATION[1]	RESULT
HAV Ab, IU/mL	≥ 2.5	12.0
Parvo B19 Ab, IU/mL	≥ 60	171
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 fulfills 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 and found negative for HBsAg, HIV-1/HIV-2 Ab by CLIA As well for HIV-1, HBV AND HCV-RNA by PCR .

Not For Human Use.

Stockholm,
Octapharma AB

2022 -03- 09

Qualified Person Göran Jonsäll

Octapharma AB
SE-112 75 Stockholm
Sweden
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REPÚBLICA PORTUGUESA
SAÚDE

SNS
SERVIÇO NACIONAL DE SAÚDE

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

EC OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE FOR MEDICINAL PRODUCTS DERIVED FROM HUMAN BLOOD OR PLASMA

Certificado Oficial Europeu de Libertação de Lote para Medicamentos Derivados do Plasma ou do Sangue Humano

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

Certificado CE/EEE de Libertação de Lote por Autoridade Oficial de Controlo – Produto Acabado

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

Examinado nos termos do Artigo 114 da Directiva 2001/83/CE, alterada pela Directiva 2004/27/CE, que estabelece um código comunitário relativo aos medicamentos para uso humano e de acordo com o Procedimento Administrativo de Libertação de Lote pela Autoridade Oficial de Controlo

Trade name: *Nome comercial:*	Octagam
INN / Ph. Eur. name / common name: *Denominação comum:*	Human Normal Immunoglobulin for Intravenous Administration / Imunoglobulina Humana Normal para Via Intravenosa
Batch numbers: *Número(s) de lote:*	M205A844
Type of container: *Tipo de recipiente:*	Vial / Frasco
Total number of containers in this batch: *Número de unidades do lote:*	3745
Nominal dose per container: *Dose nominal:*	50 mg/mL
Date of start of period of validity: *Data de início do período de validade:*	01-02-2022
Expiry date: *Prazo de validade:*	31-01-2024
Marketing authorisation number: *Autorização de Introdução no Mercado (AIM):*	5761614
Name and address of manufacturer: *Nome e morada do fabricante:*	Octapharma AB SE-112 75 Stockholm Sweden
Name and address of marketing authorisation holder if different: *Nome e morada do detentor de AIM:*	Octapharma Produtos Farmacêuticos, Lda. Rua dos Lagares d'El Rei 21-C r/c Dtº 1700-268 Lisboa

This batch has been examined by INFARMED I.P., using documented procedures which form part of a quality system which is in accordance with the ISO/IEC 17025 standard. This examination is based on the relevant Note for Guidance for this product. Accredited test methods are indicated on the Annex for Accreditation - IPAC.

Este lote foi analisado pelo INFARMED I.P., com base em procedimentos que fazem parte do sistema de Gestão da Qualidade acreditado, de acordo com a NP EN ISO/IEC 17025:2018, e a análise baseia-se nas Guidelines relevantes para o produto, aprovadas na rede de Laboratórios Oficiais Europeus. Os métodos acreditados fazem parte do Anexo do IPAC.

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

As pools de plasma foram testadas por um Laboratório Oficial, para marcadores virais.

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.

Este lote cumpre as especificações das monografias relevantes da Farmacopeia Europeia e da AIM acima, sendo libertado.

Signature and date of issue: *Assinatura e data do certificado:*	MARIA JOÃO ANTUNES GASPAR PORTELA Assinado de forma digital por MARIA JOÃO ANTUNES GASPAR PORTELA Dados: 2022.03.04 17:04:49 Z
Function of signatory: *Função:*	**Head of the Official Medicines Control Laboratory** *Diretora da Direção de Comprovação da Qualidade*
Certificate Number: *Número de Certificado:*	**06122-COELL**

INFARMED – Autoridade Nacional do Medicamentos e Produtos de Saúde, I.P./ *INFARMED – National Authority of Medicines and Health Products, I.P.*
Endereço / *Address:* Parque de Saúde de Lisboa - Av. do Brasil, 53
1749-004 LISBOA • PORTUGAL
Tel.: +351 21 798 7350 **Fax.:** +351 21 798 7369 **Website:** www.infarmed.pt **E-mail:**coell.dcq@infarmed.pt