octapharma

CERTIFICATE OF ANALYSIS
SWEDEN

Product: **OCTAGAM Intravenous Immunoglobulin human 5 % SD**
Manufacturing batch no.: **M849A8446**
Filling size **200 ml**
Internal Code: **84383**
Man. Date: **12/2018**
Exp. Date: **11/2020**
Date of start of period of validity: 2018-12-08

TEST	SPECIFICATION[1]	RESULT
Characters		
Clarity	The liquid preparation is clear or not more opalescent than the reference suspension II	APPROVED
Coloration	The liquid preparation is colourless or not more intensely coloured than reference solution Y5	>Y7
Identification		
Immunoelectrophoresis	Immunoglobulin precipitation bands	APPROVED
Tests		
pH value	5.1 – 6.0	5.4
Osmolality, mosmol/kg	≥ 240	337
Total protein, % (m/V)	4.5 – 5.5	5.0
Protein composition, %Ig	≥ 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 Ig	≤ 1.00	0.56
Prekallikrein activator, I.U./mL	≤ 35.0	< 2.0
PKA-blank, I.U./mL	≤ 10.0	< 2.0
Hemagglutinins, Anti-A	≤ 64	8
Hemagglutinins, Anti-B	≤ 64	4

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TEST	SPECIFICATION[1]	RESULT
Anti D	Pass test	APPROVED
Sterility	Sterile	APPROVED
Endotoxin, IU/mL	< 0.5	< 0.1
HBsAb, IU/g Ig	≥ 1	54
IgA content, mg/mL	≤ 0.2	0.1
Additional tests		
IgG content, mg/mL	42.8 – 55.0	50.3
IgM content, mg/mL	≤ 0.10	< 0.04
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	97
Tri(n-butyl)phosphate, µg/mL	≤ 1.0	< 0.3
Octoxynol, µg/mL	≤ 5.0	< 0.5
HAV Ab, IU/mL	≥ 2.5	8.4
Parvo B19 Ab, IU/mL	≥ 60	151

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TEST	SPECIFICATION[1]	RESULT
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 HB_SAg, HIV-1/HIV-2 Ab, HCV Ab.

Each plasma pool was tested and found negative for HB_SAg, HIV-1/HIV-2 Ab and HCV-RNA by Polymerase Chain Reaction method (PCR).

Released.

Stockholm, 2019-01-24
Octapharma AB

Göran Jonsäll

Qualified Person / QP Delegate

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