

Generated Date:
May 18, 2020

CERTIFICATE OF ANALYSIS

ZOETIS BELGIUM SA, a wholly-owned subsidiary of Zoetis Inc.
RUE LAID BURNIAT, 1
B-1348 LOUVAIN-LA-NEUVE
BELGIUM
AUTHORIZATION NUMBER 419V

Item: 10022551
 Title: CYTOPOINT 1X1ML (30MG/ML)
 Expiration Date: 02/2022
 Date Of Manufacture: 11/03/2020
 Market: Germany-Romania-Hungary
 Lot Number: 435906
 Associated Lots: 423472

TEST NAME	SPECIFICATION	UNIT	RESULT
Description/Opalescence	The product should be not more opalescent than standard III (18 NTU).	N/A	Conform
Description/Coloration	The product should be not more coloured than B5	N/A	Conform
Description/Visible particles	The product should be free from plainly visible particulate matter.	N/A	Conform
pH	$4.7 \leq x \leq 5.3$	N/A	5.0
Purity	$\geq 95\%$ Monomer	%	96
Free Methionine content	$0.09 \leq x \leq 0.11$	mg/mL	0.10
Protein content by absorbance	$27 \leq x \leq 33$	mg/mL	30
Product-related impurities (LMMS)	≤ 5	%	4
Product-related impurities (HMMS)	≤ 1	%	NMT 0.5%
Osmolality	≥ 240	mOsm/kg	288
Sterility	No growth	N/A	No Growth
Endotoxin content	≤ 6	IU / mL	0
Identity/Specific activity	≥ 0.80	N/A	1.04

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Diszpó: PN0810286587 Vevő: DR SZEKELY KFT Erd File név: PN00010538 Egyedi sorszám: PN0000095870 29 másolat
 Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 1 Anyaglap: PN0243/20
 Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2020.09.21
 Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

CertEx v3.10

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After reviewing all manufacturing and testing data, I hereby certify that the above information is authentic and accurate. The batch has been tested and manufactured including packaging and quality control in full compliance with Good Manufacturing Practices and in compliance with methods and standards, as described in the applicable quality agreements, the local regulatory requirements and those requirements stipulated in the marketing authorization.

Batch Release Authorized by Electronic Signature: Philippe Perz
 Position/Title: Qualified Person
 Lot Release System Timestamp: May 18, 2020 9:20:33 AM UTC

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