

CERTIFICATE OF ANALYSIS



Generated Date:
Jul 10, 2019

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

Item: 10017093
Title: CYTOPOINT 2X1 ML (10MG/ML)
Expiration Date: 04/2021
Date Of Manufacture: 23/05/2019
Market: Germany-Romania-Hungary
Lot Number: 377924 Associated Lots: 371481

<u>TEST NAME</u>	<u>SPECIFICATION</u>	<u>UNIT</u>	<u>RESULT</u>
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	%	97
Free Methionine content	$0.09 \leq x \leq 0.11$	mg/mL	0.10
Protein content by absorbance	$9 \leq x \leq 11$	mg/mL	10
Product-related impurities (LMMS)	≤ 5	%	3
Product-related impurities (HMMS)	≤ 1	%	NMT 0.5%
Osmolality	≥ 240	mOsm/kg	283
Sterility	No growth	N/A	No Growth
Endotoxin content	≤ 6	IU / mL	1
Identity/Specific activity	≥ 0.80	N/A	1.01

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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.

Lot Release Electronic Signature: Philippe Perz
Lot Release System Timestamp: Jul 9, 2019 12:27:21 PM

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Diszpó: PN0806902774 Vevő: DR SZEKELY KFT Erd File név: PN00010151 Egyedi sorszám: PN0000091315 14 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 2 Anyaglap: PN0286/19
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2019.08.14 **CertEx v 3.10**
Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!