

Generated Date:
Oct 9, 2019

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**zoetis**

Item: 10017093
 Title: CYTOPOINT 2X1ML (10MG/ML)
 Expiration Date: 06/2021
 Date Of Manufacture: 05/07/2019
 Market: Germany-Romania-Hungary
 Lot Number: 396584
 Associated Lots: 376889

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	%	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	285
Sterility	No growth	N/A	No Growth
Endotoxin content	≤ 6	IU / mL	0
Identity/Specific activity	≥ 0.80	N/A	1.14

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Diszpó: PN0807797359 Vevő: DR SZEKELY KFT Erd File név: PN00010263 Egyedi sorszám: PN0000092456 18 másolat
 Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 1 Anyaglap: PN0427/19
 Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2019.12.03
 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: Oct 9, 2019 7:52:48 AM UTC

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