BIOVIAN

SAMPLE SUBMISSION AND ORDER FORM / CERTIFICATE OF ANALYSIS

D04581-T01

FILLED BY CUSTOMER / ASIAKAS TÄYTTÄÄ		FILLED BY BIOVIAN / BIOVIAN TÄYTTÄÄ	
Customer:	Shangyu Mingji Plastic Co.,Ltd	**Certificate no:**	D04581-T01
Requested analysis:	Bacterial endotoxin (Kin.), DNase, RNase	**Date of samples received:**	30.12.2015
Toimitusosoite / delivery:	Biovian Oy Tykistökatu 6 B FIN-20520 TURKU	**Analysis no:**	151180P (endotoxins) 151181P (DNase) 151182P (RNase)
Date of samples sent / Til. pvm:		**Date of analysis**	5-8.1.2016

	Item code / tuotekoodi	Volume / tilavuus µl	LOT numero	Date of sample taken / näytteenotto pvm	Bacterial endotoxin		DNase / RNase	DNase	RNase
					Extr. vol (ml)	Result (IU/ml)	Extr. vol (ml)	Result (U/µl)	Result (U/µl)
1	231580	Email Petri Heikkinen	1509243	29.12.2015	10	0.01	10	$< 6.25*10^{-5}$	$< 3.125*10^{-9}$
2	231584	Email Petri Heikkinen	1509232	29.12.2015	10	< 0.005	10	$< 6.25*10^{-5}$	$< 3.125*10^{-9}$

Add / Remove rows if needed:

☐ Do not discard sample after CoA.

Endotoxins

Analysis and test method used: Sample preparation is carried out according to FDA guidelines for medical devices by extracting the sample units for 1 hour at 37 °C with an optimized volume of pyrogen-free water. One test unit is 10 sample units. Endotoxins in the extractions are detected with chromogenic kinetic method according to Ph.Eur., 2.6.14, Method D, which is based on the cleavage of a substrate and release of a colorful product in the presence of bacterial endotoxins. The test has not been product-specifically validated. The detection limit is 0.005 IU/ml. The used method is modified from Biovian SOP 0571 v. 1.1.

DNase

Analysis and test method used: Sample preparation is carried out by vortexing the sample units with pure water for 5 minutes. One test unit is 10 sample units. DNase activity in the extraction is measured with fluorometric assay by detecting the degradation of a labeled DNase substrate. The detection limit for DNase is $6.25*10^{-5}$ U/µl using DNase I as a standard. The used method is modified from Biovian SOP 0119 v. 3.1.

RNase

Analysis and test method used: Same extraction samples used for DNase are used to measure RNase activity, which is measured with fluorometric assay by detecting the degradation of a labeled RNase substrate. The detection limit for RNase is $3.125*10^{-9}$ U/µl using RNase A as a standard. The used method is modified from Biovian SOP 0120 v. 3.1.

Biovian Ltd.

19.01.2016

Tero Virtanen
Head of Quality Control

Please send analysis results to:
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