1.0 General Information

Medistri Address	Route de l'industrie 96 CH – 1564 Domdidier	Tel : 0041 26 676 90 80 Fax : 0041 26 676 90 85
Medistri Laboratory Labo Batch #	**27473**	
Customer name	**C-CIT**	
Customer's address	**Einsiedlerstrasse 29** **CH – 8820 Wädenswil**	
Date of reception of the product	**25th September 2020**	
Product identification (name and reference)	**BIO / MeMo Flowcell**	
Manufacturing batch	**GoD / LoD 200824** **GoD / LoD 200810** **GoD / LoD 200903**	
Packaging conditions	☐ Under vaccum packaging	☒ Standard packaging
Sterilisation conditions	☒ Sterile : ☐ *EtO* ☐ *Steam* ☒ *Gamma* ☐ *Medistri SA : Ste lot # **n.a.*** ☒ *Other: Data available at customer*	
Quantity of samples	**3 samples**	
Quantity of analysis	**1 validation**	
Date of analysis	29th September 2020	

2.0 Method

According to European Pharmacopoeia chapter 2.6.14 and 5.1.10, harmonized with USP 85 and JP The method is chromogenic kinetic. The conditions of tests comply with the recommendations of AAMI st72.

Acceptance limit	**< 20 EU/sample**
Sensibility	**0.05 EU/ml**
Soaking volume	**100 ml**

3.0 Results

3.1. Endotoxin concentration in the solution to be examined

ID of product: **BIO / MeMo Flowcell**

Working conditions: **1** sample is soaked in **100** ml of LAL reagent water. The analyses are performed on the undiluted soaking water (dilution 1/1).

Product tested	Product batch no.	Endotoxin concentration	Endotoxin limit	Units	Conform/non -conform**
BIO / MeMo Flowcell	**GoD / LoD 200824**	**<6.4**	**20**	**EU/ml**	**Conform**
BIO / MeMo Flowcell	**GoD / LoD 200810**	**<5.9**	**20**	**EU/ml**	**Conform**
BIO / MeMo Flowcell	**GoD / LoD 200903**	**<5**	**20**	**EU/ml**	**Conform**

** The result is considered as conform when the value obtained (endotoxin concentration) ranges below the respective endotoxin limit.

3.2. Calculation of the Maximum Valid Dilution (MVD)

Prior to routine testing, it is required to characterize the sample with regard to factors of interference. To do so, it has to be proven that the sample to be analyzed neither displays an inhibitory effect nor is an activator at routine dosing concentration. The test is done on one batch (pre-characterization) or on three batches (characterization) of the product.

For a product the limit of endotoxins or maximum human posology is known for, the last dilution of the product must not exceed the Maximum Valid Dilution (MVD).

$$MVD = \frac{\text{Limit of endotoxins x Concentration of product}}{\text{Sensibility of method}}$$

With the following parameters:

Limit of endotoxins: **20** EU/samples

Concentration: **1** sample soaked in a volume of **100** ml, corresponding to **0.01** samples/ml

λ = sensibility of method: **0.05** EU/ml

$$\mathbf{MVD} = \frac{\text{EU/pool x pool/ml}}{\text{EU/ml}} = \mathbf{4}$$

3.3. Factors of interference

ID of product: **BIO / MeMo Flowcell, lot GoD / LoD 200824**

Working conditions: Dilution in LAL reagent water

Dilution	Recovery of surcharge**	Interference
1:100	121%	without
1:200	142%	without
1:400	165%	without
Conclusion→ The extract can be analyzed without dilution		

** the recovery of surcharge must range between 50% and 200%.

ID of product: **BIO / MeMo Flowcell, lot GoD / LoD 200810**

Working conditions: Dilution in LAL reagent water

Dilution	Recovery of surcharge**	Interference
1:100	176%	without
1:200	129%	without
1:400	146%	without
Conclusion→ The extract can be analyzed without dilution		

** the recovery of surcharge must range between 50% and 200%.

ID of product: **BIO / MeMo Flowcell, lot GoD / LoD 200903**

Working conditions: Dilution in LAL reagent water

Dilution	Recovery of surcharge**	Interference
1:100	133%	without
1:200	129%	without
1:400	121%	without
Conclusion→ The extract can be analyzed without dilution		

** the recovery of surcharge must range between 50% and 200%.

See validation report

The results are applicable to the samples as they were delivered to Medistri or as they were sampled by Medistri according to Customer's sampling plan.

5.0 Attachments

5.4. Picture of sample tested

6.0 Routine card

- ☒Entire product ☐cut product ☐representative portions (**n.a**)
- ☒single product ☐pool of n.a. products
- Lot number, product identification
- Should be sterile, kind of sterilization.
- Volume of WFI at 37°C
- Mention of depyrogenated vessel
- Incubation time and temperature of incubation
  ☒ 1hour at 20-24°C
  ☐ 15 minutes at 33-37°C
- Sensitivity of the cartridge (EU)
  ☐0.01 ☒0.05 ☐0.005
- Results expressed in
  ☐ EU/ml ☒EU/sample ☐EU/pool of n.a. products
- Equipment ID
- Acceptance limit is < **20** EU/**sample**.

7.0 Approvals

Date: 30th September 2020
Laboratory Department:

Date: 01st October 2020
Quality Department: