

# **Protocol**

# Production of **liquid medium** from TCX10D powder

Please note, this document may be periodically updated in order to ensure the most current practices are in place. It is the user's responsibility to ensure the lastest release of this protocol is applied. Valid versions are made available via Xell's webshop.

Version: V.03

## Production of liquid medium from TCX10D powder

#### Guideline:

We recommend preparing the whole powder container in a single batch. For that, please adjust the amounts/volumes per liter given in this protocol according to your batch size.

#### Material:

- TCX10D powder (23.76 g/L; Cat.No. 1150-XXXXDPM)
- H<sub>2</sub>O (WFI or equivalent quality)
- 2.40 g/L NaHCO₃ Ph. Eur.

We recommend wearing a dust mask during preparation.



Visual control: Check:

- A. Container **Sealed** and **without any damage**.
- B. Appearance Free flowing powder (record color).



Procedure: Check:

1.	15 - 35 °C	Fill <b>0.8</b> L per 1 L final medium solution <b>15-35°C water (WFI or equivalent quality)</b> into the stirred tank/blending vessel. <b>Note:</b> Deviating temperature may alter dissolution rate. An adaption of time for solubilization might be necessary.	
2.		Start the stirrer of the system. Due to foam formation during medium production, the vortex should not reach the stirrer.	
3.	Add 23.76 g/L of TCX10D powder slowly to the stirred water. Avoid clumping.  Note: We recommend preparing the whole powder container at once.		$\bigcirc$

Version: V.03

4.	H <sub>2</sub> O	Rinse the emptied powder container with a suitable amount of water (WFI or equivalent quality) and pour liquid into the stirred tank.	
5.	30 min	Stir for 30 minutes with lid closed.  Note: The powder should be completely dissolved and the solution should be clear.	
6.	NaHCO <sub>3</sub>	Add <b>2.4 g/L NaHCO</b> <sub>3</sub> Ph. Eur. to the stirred tank.	
7.	100 %	Add an appropriate volume of water (WFI or equivalent quality) to reach the final volume.  Note: Final volume depends on batch/container size.	
8.	10 min	Stir for 10 minutes with lid closed.  Note: The solution should be clear, without precipitates. If not, stepwise increase mixing time by 10 min.	
9.	Measure pH (7.1 - 7.6) and osmolality (300 ± 15 mOsmol/kg) of the medium.		
10.		The medium can now be sterile filtered (0.45 µm + 0.2 µm or 0.45 µm + 0.1 µm) and bottled.	

### **Change History:**

Revision	Date	Author	Comment/Description
01-02	n/a	n/a	Initial version
03	03.12.2021	SST	Addition of change history, adjustment of document steering acc. to amendment 13.04.2021
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www.xell.de info@xell.de

Xell AG Alte Verler Str. 1 33689 Bielefeld Germany

For further information or assistance contact us.

Fon: +49 (0)521 96989-200 Fax: +49 (0)521 96989-201

Version: V.03

