

Protocol

Production of **TCX6D** Medium from powder

Production of liquid medium with the TCX6D Powder Kit

Material:

- We recommend preparing the whole Powder Kit in a single batch! For that, please adjust the amounts/volumes per L given in this protocol according to your container/batch size!
- TCX6D Powder (26.88 g/L)
- ESK-Supplement (2.0 mL/L)
- approx. 1 L H₂O per L medium (WFI or equivalent quality)
- 0.5 mL/L 6 M HCl Ph. Eur.
- 9.75 mL/L 1 M NaOH Ph. Eur.
- 2.1 g/L NaHCO₃ Ph. Eur.
- We recommend wearing a dust mask during preparation!



Visual control:

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

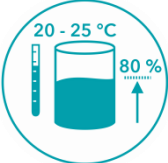


Check:






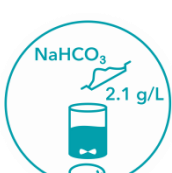








Color: _____

Procedure:

Check:

1.		Fill 0.8 L per 1 L final medium 20-25°C pre-warmed water (WFI or equivalent quality) into the stirred tank/blending vessel.	<input type="checkbox"/>
2.		Start the stirrer of the system. Due to foam formation during medium production, the vortex should not reach the stirrer.	<input type="checkbox"/>
3.		Add 0.5 mL/L of 6 M HCl to the stirred tank. <i>Adjust volume according to batch size.</i>	<input type="checkbox"/>

4.		<p>Add 26.88 g/L of TCX6D powder slowly to the stirred water. Avoid clumping.</p> <p>Note: <i>We recommend preparing the whole powder kit at once.</i></p>	<input type="radio"/>
5.		<p>Rinse the empty medium container with a suitable amount of water (WFI or equivalent quality) and pour liquid into the stirred tank.</p>	<input type="radio"/>
6.		<p>Stir for 30 minutes.</p> <p>Note: <i>The powder will not be completely dissolved at this stage.</i></p>	<input type="radio"/>
7.		<p>Add 9.75 mL/L of 1 M NaOH to the stirred tank.</p> <p><i>Adjust volume according to batch size.</i></p>	<input type="radio"/>
8.		<p>Stir for 20 minutes.</p> <p>Note: <i>The powder should be completely dissolved and the solution should be clear.</i></p>	<input type="radio"/>
9.		<p>Add 2.1 g/L NaHCO₃ to the stirred tank.</p> <p><i>Adjust volume according to batch size.</i></p>	<input type="radio"/>
10.		<p>Add an appropriate volume of water (WFI or equivalent quality) to reach the final volume.</p> <p><i>Final volume depends on batch/container size!</i></p>	<input type="radio"/>

11.		Stir for 10 minutes .	<input type="radio"/>
12.		Add 2.0 mL/L ESK Supplement to the stirred tank. <i>Adjust volume according to batch size.</i>	<input type="radio"/>
13.		Stir for 10 minutes .	<input type="radio"/>
14.		Check pH (pH 7.1 - pH 7.6) and osmolality (283 - 343 mOsmol/kg).	<input type="radio"/> <input type="radio"/>
15.		The Medium can now be sterile filtered (0.45 µm + 0.1µm) and bottled .	<input type="radio"/>

For further information or assistance contact us.

www.xell.de
info@xell.de

Xell AG
Alte Verler Str. 1
33689 Bielefeld
Germany

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



