

Protocol

Production of **TCX7D Feed** from 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.

ID-code: XELL-PR-238_Solubilization protocol

Version: V.02

1

Production of liquid feed solution with the TCX7D feed powder

Material:

- We recommend preparing the whole powder container in a single batch! For that, please adjust the amounts/volumes per L given in this protocol according to your container/batch size!
- TCX7D Powder (149.55 g/L; Cat.No. 1080-XXXXDPM)
- approx. 1 L H₂O per L feed solution (WFI or equivalent quality)
- 10.0 g/L NaOH pearls/Pellets Ph. Eur. (equivalent to 31.25 mL/L 8 M NaOH)
- 39.0 41.0 mL/L 6 M HCl Ph. Eur.
- We recommend wearing a dust mask during preparation!



Check:

Visual control:

A.	Container	Sealed and without any damage.		\bigcirc
Β.	Appearance	Free flowing powder (record color).	Color:	\bigcirc

Procedure:

1.	15 - 35 °C	 Fill 0.7 L per 1 L final feed solution 15-35°C water (WFI or equivalent quality) into the stirred tank/blending vessel. Note: Deviating temperature may alter dissolution rate. An adaption of time for solubilization might be necessary. 	\bigcirc		
2.		Start the stirrer of the system. Due to foam formation during feed production, the vortex should not reach the stirrer.	\bigcirc		
3.	NaOH 10 g/L	Add 10.0 g/L NaOH slowly to the stirred water. Note: Adjust amount according to batch size.	\bigcirc		

4.		Add 149.55 g/L of the TCX7D Powder Kit slowly to the solution to avoid clumping. Note: We recommend preparing the whole Powder Kit at once.	\bigcirc
5.	0.05 L	Rinse the weighing dish/container with 0.05 L water (WFI or equivalent quality) and pour liquid into the stirred tank.	\bigcirc
6.	15 min	Stir for 15 minutes (pH will be 9.4 - 9.9 at this point). Note: The powder will not be completely dissolved at this stage!	\bigcirc
7.	PH = 6.65	Titrate with 6 M HCl to pH 6.65 ± 0.25 (usually between 39.0 to 41.0 mL/L of 6M HCl is required) and adjust volume to batch size. Note: The powder should be completely dissolved and the solution should be clear.	\bigcirc
8.	60 min	Stir for 60 minutes (pH will be 6.4 - 6.9 at this point).	\bigcirc
9.		Add an appropriate volume of water (WFI or equivalent quality) into the stirred tank/blending vessel to reach the final volume. Note: Final volume depends on batch size!	\bigcirc
10.	15 min	Stir for 15 minutes . Note: If powder is not completely dissolved, stepwise increase mixing time by 10 min.	\bigcirc

11.	pH mOsmol	Check pH (pH 6.4 - pH 6.9) and osmolality (125 - 155 mOsmol/kg - for 1:10 dilution in water).	\bigcirc
12.		The feed solution can now be sterile filtered (0.45 µm + 0.1µm) and bottled .	\bigcirc

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

