

Protocol

Production of **HEK FS_2 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 latest release of this protocol is applied. Valid versions are made available via Xell's webshop.

Production of liquid feed solution with the HEK FS_2 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!
- HEK FS_2 Powder (92.76 g/L; Cat.No. 880-XXXXDPM)
- approx. 1 L H₂O per L feed solution (WFI or equivalent quality)
- 4.0 g/L NaOH pearls/Pellets Ph. Eur. (equivalent to 12.5 mL/L 8 M NaOH)
- 11.0 12.0 mL/L 6 M HCl 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).



Procedure: Check:

1.	15 - 35 °C	Fill 0.8 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.	
3.	NaOH 4 g/L	Add 4.0 g/L NaOH slowly to the stirred water. Note: Adjust amount according to batch size.	\bigcirc

Version: V.03

4.		Add 92.76 g/L of the HEK FS_2 Powder Kit slowly to the solution to avoid clumping. Note: We recommend preparing the whole Powder Kit at once.	
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.	
6.	30 min	Stir for 30 minutes (pH will be 9.4 – 9.9 at this point). Note: The powder will dissolve at this stage at pH 8.8 -9.3!	
7.	pH = 6.70	Titrate with 6 M HCl to pH 6.7 ± 0.1 (usually between 11.0 to 12.0 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.	
8.	30 min	Stir for 60 minutes (pH will be 6.4 – 6.9 at this point).	\bigcirc
9.	100 %	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!	0
10.	10 min	Stir for 5 – 10 minutes . Note: If powder is not completely dissolved, stepwise increase mixing time by 10 min.	

Version: V.03

11.	PH mOsmol	Check pH (pH 6.6 - pH 6.8) and osmolality (360 - 400 mOsmol/kg - for 1:2 dilution in water).	$\bigcirc\bigcirc$
12.		The feed solution can now be sterile filtered (0.45 μm + 0.1μm) and bottled .	

Version: V.03

Change History:

Revision	Date	Author	Comment/Description
01	21.09.2022	AWU	Initial version
02	25.10.2022	CBA	Adjustment of Product Name
03	04.10.2024		Change of contact details & company name

www.sartorius.com

Sartorius Xell GmbH Waldweg 21 33758 Schloss Holte-Stukenbrock, Germany

Version: V.03

For further information or assistance contact us.

Phone: +49 5207 9597 200

