

Fosun Phosphate Buffered Saline Instruction for Use

PRODUCT NAME

Fosun Phosphate Buffered Saline

SIZE

3 mL×100 tubes

INTENDED USE

Fosun Phosphate Buffered Saline is for transport of clinical material and serves as a culture media, non-selective and non-differential.

DESCRIPTION AND PRINCIPLE

The product includes a pH buffer and an osmotic pressure maintainer to preserve the integrity of cells without cell lysis and cell swelling. The product is supplied sterile in a screw-cap test tube. Please refer to Table 1 below for details.

Table 1. Product Description

Name	Part No.	Amount	Tube	Ingredient
Fosun Phosphate Buffered Saline	PCSYWE-a	100 tubes per carton	3 mL of Fosun Phosphate Buffered Saline in 18 x 101 mm screw-cap tube	Na ₂ HPO ₄ ·12H ₂ O, KH ₂ PO ₄ , NaCl and Water

STORAGE & SHELF LIFE

Store and transport upright at 2°C to 30°C (36°F to 86°F). Fosun Phosphate Buffered Saline is stable for 12 months while stored at 2°C to 30°C (36°F to 86°F). Please see carton and tube label for expiration date.

SAMPLING & HANDING

1. Confirm that the product is within expiration date;
2. Collect the sample with swabs (not provided) following relevant clinical protocols;
3. Aseptically remove the screw top of the collection tube, break the shaft of the swab, gently put sampling tip into Fosun Phosphate Buffered Saline, and tighten and seal the tube cap to prevent drying.
4. Complete vial label with patient information in accordance with relevant laboratory requirements
5. Store the collection tube at 2-8°C in upright position. Viral particles are expected to remain in a non-replicating viable status for up to 48 hours at 2-8°C.

LIMITATIONS

For In Vitro Diagnostic Use.

For transport of specimens only. Not to be taken internally.









APPEARANCE AND PHYSICAL PERFORMANCE






Clear and transparent solution, pH=7.2±0.05.

WARNING AND PRECAUTIONS

- **Single-Use Device.**
- **Do not use beyond the expiration date printed on carton and tube label.**
- **Do not use Fosun Phosphate Buffered Saline if (1) there is evidence of damage or contamination to the product, (2) there is evidence of leakage, (3) there are other signs of contamination and deterioration.**
- **Do not use the Fosun Phosphate Buffered Saline for premoistening or prewetting the applicator swab prior to collecting the sample or for rinsing or irrigating the sampling sites.**
- **Handle all specimens as if infectious using safe laboratory procedures. Refer to CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with SARS-CoV-2 <https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html>**
- **Wear appropriate protective eyewear, mask, clothing and gloves as appropriate.**
- **Discard all materials in a safe and acceptable manner, in compliance with all legal requirements.**

SYMBOLS GLOSSARY

SYMBOL	REFERENCE No.	SYMBOL TITLE	EXPLANATORY TEXT
Symbols from <i>ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements</i>			
	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	5.5.5	Contains sufficient for <n> tests	Indicates the total number of IVD tests that can be performed with the IVD.
	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured.
	5.1.4	Use-by-date	Indicates the date after which the medical device is not to be used.
	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directive 90/385/EEC, 93/42/EEC and 98/79/EC.
	5.5.1	In vitro diagnostic medical	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.
	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.

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Symbols from <i>ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements</i>			
	5.2.1	Sterile	Indicates a medical device that has been subjected to a sterilization process
	5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	5.4.2	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 7000 Reference no. 0623	This way up	Indicates correct upright position of the transport package.
	5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.

TECHNICAL SUPPORT

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Made in China.

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The Fosun Phosphate Buffered Saline Instruction for Use can be downloaded from the following link:
www.fosunpharmausa.com/covid19/pcr/