Art. 528.S100

FTM clear 100 mL

	Technical Data
Use in	• Pharmaceutical industry • For industrial, laboratory & research applications only
Use for	• Sterility test • Identification and growth of fastidious anaerobic micro-organisms as well as aerobic micro-organisms
Typical composition per liter	Basic medium according to Ph. Eur. 2.6.1 and USP <71> Casein peptone 15 g; Glucose-D(+) x H_2O 5.5 g Yeast extract 5 g; Na-thioglycolate 0.5 g NaCl 2.5 g; Resazurine 1 mg Agar/gel agent 0.35 g; L-Cysteine HCl 0.5 g This medium can be adjusted / or supplemented according to the performance criteria required.
Filling volume	• 100 mL
Bottle format	• 100 mL infusion bottle with flip cap • Opening acc. ISO 8536-1 (outside 32 mm / inside 20 mm) • Colour of flip cap: red • Colour of aluminium cap: red
Bottles per tray	• 20 bottles on a plastic tray wrapped with shrink foil
Shelf life	• 12 months from production date
Storage conditions	• Recommended storage temperature: 2 – 25 °C • Should be stored at temperatures as stable as possible • Store protected from light exposure
Label	• On the side • Contain autoclave indicator
Label information	• Product name: FTM clear 100 mL • Expiry date: YYYYMMMDD ➔ MMM in letters (e.g.: 2026Nov04) • Lot-number • Individual number • Barcode
Barcode	• 2-dimensional (data matrix), 20 digits: • Digits 1-3: Art.-No. • Digits 4-9: Lot-Number • Digits 10-14: Individual-Number • Digits 15-20: Date (YYMMDD)
Delivery	• Temperature controlled delivery on request • For shipments of larger amounts plastic pallets in Euro-size can be used

	Technical Data
Bottle information	• Label contains autoclaving indicator (brown ➔ green) • Bottles are incubated at 25 – 35 °C for at least 48 hours after autoclaving and then packed • Bottles are not touched any more by hand after autoclaving
Place of production	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany

	Quality control, Certificates
Certificates	Every batch of product can be obtained with a certificate of analysis (CoA):

Physico-chemical test parameters:				
Appearance	Clear, slightly yellowish, potentially with pink zone			
pH value	6.9 – 7.3			
Filling volume	98 – 104 mL			
Growth Promotion test: 10 – 100 CFU				
S. aureus	ATCC 6538	30-35 °C	≤ 3 days	Good growth
P. paraeruginosa	ATCC 9027	30-35 °C	≤ 3 days	Good growth
C. sporogenes	ATCC 11437	30-35 °C	≤ 3 days	Good growth
C. sporogenes	ATCC 19404	30-35 °C	≤ 3 days	Good growth
Sterility control				
≥ 14 days at 30-35 °C, no growth				

Certificate of origin	All media lots produced by PMM can be obtained with a Certificate of Origin (CoO). All animal derived raw materials are specified as follows: • Raw material • Tissue • Animal source • Country of origin • Infectivity category (acc. to TSE guideline: EMA/410/01 current version)
BSE policy	In compliance with the current note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy via human or veterinary medicinal products, we check the CoO of raw material in respect to the specified animal source, the country of origin and the infectivity category. We neither store or process ruminant raw materials obtained from high infectivity tissues (IA) nor ruminant raw materials whose animal source originates from countries or regions with an undetermined risk (cat C/GBR IV).

	Quality control, Certificates
Temperature stress	Art. 528.S100 has been exposed to temperature stress conditions (3 days at 2-8 °C as well as 3 days at 30-35 °C) and has passed shelf-life testing at least 30 days after the assigned expiry date. Shelf-life testing comprises all regular tests which are part of the normal release test of this article except for sterility control (see CoA).

	Recommendations for use
Release of negative pressure in media bottles	During the autoclaving process, chemical reactions inside the bottles may result in a slight vacuum. Please ensure that the vacuum is released without contaminating the bottle. Ideally, the vacuum is released by puncturing the septum with an aeration needle equipped with a sterile filter prior to opening a bottle.
Resazurin	Resazurin is an indicator for anaerobic conditions. The indicator is colourless under anaerobic condition and turns into pink colour under aerobic conditions. Due to the composition of the medium 2 relatively stable zones can be clearly separated: 1. an aerobic, pink zone on the top 2. an anaerobic, yellowish zone on the bottom. Acc. to Ph. Eur./USP not more than the upper third of the medium should be pink coloured. If a larger zone of the medium shows pink colour, the medium can be restored once, by heating for a period not longer than 20 minutes. To avoid excess pressure the bottle should be vented with an aeration cannula during heating as well as cooling down phase

	Safety Data
Toxic ingredients	• None
Basic composition	• See typical composition
Solvent content	• None
Safety data sheet required	• Not mandatorily required