



Lot status: **APPROVED**

MODEL: BioCapt single use manufactured by CPC Biotech srl	PRODUCT CODE: 79001409
MEDIA: Sabouraud Dextrose Agar + 0.07% Lecithin + 0.5% Tween80 + 0.1% L-Hystidine + 0.05% S-Thiosulphate	
BATCH: 20D2702	STORAGE CONDITIONS: at 2-25°C until expiry date
DATE OF MANUFACTURING: 27 Apr 2020	EXPIRY DATE: 27 Jan 2021

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	amber coloured, clear to slightly opalescent gel forms in BioCapt device plates	Conforms
pH specification	5.6±0.2	Conforms
Filling media volume	30ml±1ml	Conforms
Media composition	SDA+NEUTRALIZERS (Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer)	Conforms
Packaging	Triple Wrapped Sterile Irradiated (T.W.S.I.)	Conforms
Dose of irradiation	≥10 KGy	Conforms Irradiation certificate Nr: 3596/2020

MICROBIOLOGICAL TEST CONTROLS

- **Sterility control** (performed before gamma irradiation)

TESTS	SPECIFICATION	RESULT
32.5±2.5°C aerobic for 168 hours	No growth	Conforms
22.5±2.5°C aerobic for 168 hours		

- **Fertility – Growth Promotion Test** (performed after gamma irradiation)

Control strain	Medium inoculation level	Incubation Conditions	Recovery Specifications	Recovery Results	Cultural Response
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	92.9%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	93.9%	Conforms

GROWTH PROMOTION TEST IN ACCORDANCE TO HARMONISED EP – USP PHARMACOPOEIAS CHAPTER, BY QUANTITATIVE SURFACE PLATING METHOD.

RECOVERY: RESULTS AS CFU ENUMERATION ON TEST BATCH AGAR PLATES X 100/CFU ENUMERATION ON REFERENCE TESTS.

REFERENCE MEDIUM FOR RECOVERY TESTS: TRYPTONE SOYA AGAR FOR ALL BACTERIA AND SABOURAUD DEXTROSE AGAR FOR YEAST & MOLD SPECIES.

ATCC IS REGISTERED TRADE MARK OF AMERICAN TYPE CULTURE COLLECTION.

Date analysis start	27 Apr 2020	Date analysis end	11 Jun 2020
Quality Control	Stefania Nichele	<i>Nichele Stefania</i>	
Quality Assurance	Celeste Annovazzi	<i>Celeste Annovazzi</i>	