

<b>LICKSON S.r.l.</b>	<b>QUALITY CONTROL</b> DUAL PLATE DERMATOFITI (DTM AGAR / SABOURAUD DEXTROSE AGAR)	<b>REF. 3400607/20</b>
-----------------------	--	------------------------

Code/REF: **3400607/20**

Manufact. Date: XX/YY/ZZZZ

Product: **SABOURAUD DEXTROSE AGAR**

Batch: **XXX**

Content: **20 dual plates**

Exp. XX/YY/ZZZZ

Stability: **6 Months**

Storage: **+10/+25°C**

### CHEMICAL-PHYSICAL CHARACTERISTICS

pH		Color		Transparency	
Expected	Observed	Expected	Observed	Expected	Observed
<b>5.6 ± 0.2</b>	5.6	<b>Light Amber</b>	Light Amber	<b>Transparent</b>	Transparent

**Result**

Compliant

Not Compliant

### MICROBIOLOGICAL CHECK

Days/Temperature	Growth	Growth	
	Expected	Observed	Observed
<b>5 days a 20°C ± 2</b>	<b>No microbial growth</b>	<input checked="" type="checkbox"/> No growth	<input type="checkbox"/> Growth
<b>5 days a 35°C ± 2</b>	<b>No microbial growth</b>	<input checked="" type="checkbox"/> No growth	<input type="checkbox"/> Growth

**Result**

Compliant

Not compliant

### TEST STRAIN AND INOCULATION METHOD

(Test microorganisms and performance criteria for culture media, according to ISO 11133:2020)

FUNCTION	INCUBATION According European Pharmacopoeia 7.0	CONTROL STRAINS	REFERENCE MEDIUM	METHOD OF CONTROL	CRITERIA	CHARACTERISTIC REACTIONS	Result of conformity
<b>Productivity</b> Working culture: <b>10-100 CFU</b>	<b>5 days</b> <b>25±1°C</b> <b>Aerobic</b>	<b>Aspergillus brasiliensis</b> ATCC 16404	<b>Media batch</b> <b>SDA</b> <b>already</b> <b>validated</b>	<b>Quantitative</b>	<b>PR ≥ 0,7</b>	<b>Characteristic colony/ propagules/ germs according to each species</b>	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
		<b>Saccharomyces cerevisiae</b> ATCC 9763					<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

**Result**

Compliant

Not compliant

<b>LICKSON S.r.l.</b>	<b>QUALITY CONTROL</b> <b>DUAL PLATE DERMATOFITI</b> (DTM AGAR / SABOURAUD DEXTROSE AGAR)	<b>REF. 3400607/20</b>
-----------------------	---	------------------------

Code/REF: **3400607/20**

Manufact. Date: XX/YY/ZZZZ

Product: **DTM AGAR**Batch: **XXX**Content: **20 dual plates**

Exp. XX/YY/ZZZZ

Stability: **6 Months**Storage: **+10/+25°C****CHEMICAL-PHYSICAL CHARACTERISTICS**

pH		Color		Transparency	
Expected	Observed	Expected	Observed	Expected	Observed
<b>5.5 ± 0.2</b>	5.5	<b>Yellowish/ orange</b>	Yellowish/ orange	<b>Transparent</b>	Transparent

**Result**  Compliant  Not Compliant**MICROBIOLOGICAL CHECK**

Days/Temperature	Growth Expected	Growth Observed	
<b>5 days a 20°C ± 2</b>	<b>No microbial growth</b>	<input checked="" type="checkbox"/> No growth	<input type="checkbox"/> Growth
<b>5 days a 35°C ± 2</b>	<b>No microbial growth</b>	<input checked="" type="checkbox"/> No growth	<input type="checkbox"/> Growth

**Result**  Compliant  Not compliant**TEST STRAIN AND INOCULATION METHOD**

(Test microorganisms and performance criteria for culture media, according to ISO 11133:2020)

FUNCTION	INCUBATION	CONTROL STRAINS	REFERENCE MEDIUM	METHOD OF CONTROL	CRITERIA	CHARACTERISTIC REACTIONS	Result of conformity	
<b>Productivity</b> Working culture: 10-100 CFU	<b>5 Days</b> <b>25±1°C</b> <b>Aerobic</b>	Trichophyton mentagrophytes ATCC 9533	Media batch DTM Agar already validated	Qualitative	Good Growth	Red medium	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	
		Candida albicans ATCC 10231				no color change in the medium	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	
		Staphylococcus aureus ATCC 25923			No growth	//		<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
		Aspergillus brasiliensis ATCC 16404						<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
		Escherichia coli ATCC 25922						<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

**Result**  Compliant  Not compliant**RESULTS** Compliant Not compliant

Control date XX/YY/ZZZ

Director Quality