PHENOTYPIC STERILITY TESTING FOR ATMPS WITH DETECTION <3 DAYS WITH CALSCREENER+

SYMCEL

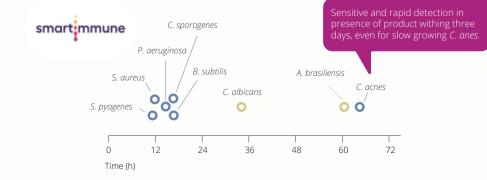
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CALSCREENER+ STREAMLINED WORKFLOW CALSCREENER+ STREAMLINED WORKFLOW The need for rapid sterility testing in Advanced Therapy Medicinal Products (ATMPs) is critical to ensure patient safety and product efficacy. PLATE PREPARATION 1 We present a novel instrument on isothermal microcalorimetry, enabling continuous monitoring of metabolic activity from a broad range of microorganisms in a non-destructive and product matrix independent manner. jer. With minimal sample input and maximum sensitivity (LOD <5 CFU), our method detects a wide range of organisms even in presence of high cell backgrounds. Sample Vial Add medium Place vials on plate Ο Ο Disposable glas vial (500 µl total volume). Most organisms tested in product are detected within 24 hours, while molds and r each sample fill I with sterile TSB or slow-grower *C. acnes* are detected within 72 hours. Seal with cripm cap with 2 DIRECT INOCULATION **High sensitivity** Results < 72 h **Direct Inoculation** LOD <5 CFU Insert Plate Sample Loading 0 Real-Time Results sample to TSB and Continuous reading fo immediate signal Continuous Non-destructive monitoring CALSCREENER + FOR **RAPID STERILITY TESTING RAPID AND SENSITIVE DETECTION < 72 H REDUCED RISK OF FALSE POSITIVES Clear distinction** between background signal from Growth promotion assay shows fast detection А of compendial organisms (USP) with low inoculum cells and product components and microbial signal. (CFU <5). xponential signal Signal (heat flow) processing in product shown here in power time 30 µW curve of a high cell density Jurkat B. subtilis (10⁶ cells) sample (yello compared to lurkat sample spiked C. albicans with S.aureus (blue). C. sporogenes 20 A. brasiliensis P. aeruginosa C. acnes S. aureus + Ο S. aureus lurkat cells Ο Ο O Ο 10 O. FTM 35°C 72 0 12 24 36 48 60 0 12 18 24 30 36 0 h 6 Time (h)

Case study using a T-cell progenitor therapy product. Product SMART101-DP from SmartImmune was spiked with CFU < 5 in a 1:1 product to media ratio.



SYSTEM HIGHLIGHTS

The calScreener+ system provides a biocalorimetry based phenotypic sterility assay as describe in USP1071 and EP 5.1.6).

O Detection of microbial activity within **three days** in presence of cell based products with a low risk for false positive signal.

Real-time result through continuous and automated reading for **yes/no** result

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