DEVELOPMENT AND VALIDATION OF ANALYTICAL METHOD FOR MICROBIOLOGICAL QUALITY CONTROL OF CANNABIS OIL SOLUTION

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INTRODUCTION



As of January 22, 2021, the US FDA has approved Cannabidiol (CBD) and Tetrahydrocannabinol (THC) containing medications for therapeutic use. Exogenous cannabinoids, such as THC and CBD, and their effect on the endocannabinoid system are frequently discussed regarding their role in oncology related diseases (Bodine and Kemp, 2022).

MATERIALS AND METHODS



- TOTAL AEROBIC MICROBIAL COUNT
- TOTAL COMBINED YEAST AND MOLD COUNT
- TOTAL BILE-TOLERANT GN BACTERIA
- ABSENCE OF STAPHYLOCOCCUS AUREUS
- ABSENCE OF ESCHERICHIA COLI
- ABSENCE OF SALMONELLA

European Pharmacopeia specifies reference criteria for microbiological quality control as “Special Ph. Eur. provisions for oral dosage forms containing raw materials of natural origin”. with specified quality control parameters: Total Aerobic Microbial Count (TAMC), Total Combined Yeasts and Molds Count (TYMC), Total Bile-tolerant GN bacteria (TBTGN), as well as Absence of Staphylococcus aureus, Absence of Escherichia coli and Absence of Salmonella.

RESULTS AND DISCUSSION



Fig 1. Recovery percent of Staphylococcus aureus on TSA

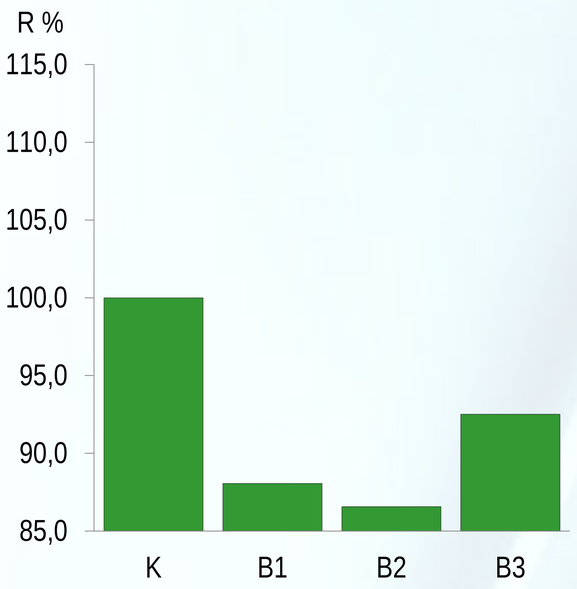


Fig 2. Recovery percent of Pseudomonas aeruginosa on TSA

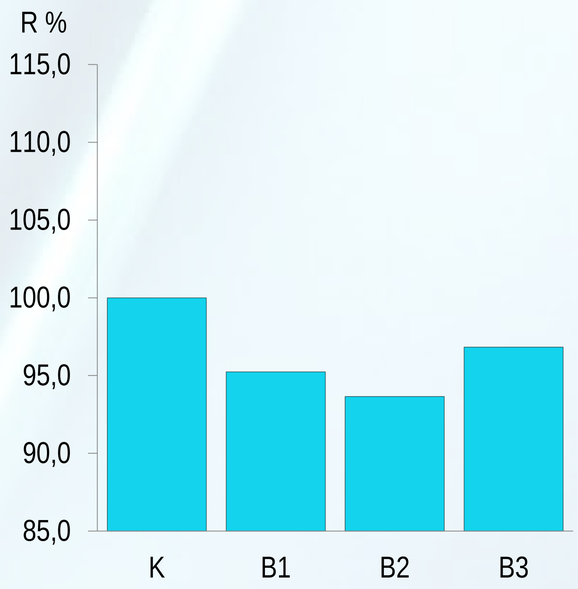


Fig 3. Recovery percent of Bacillus subtilis on TSA

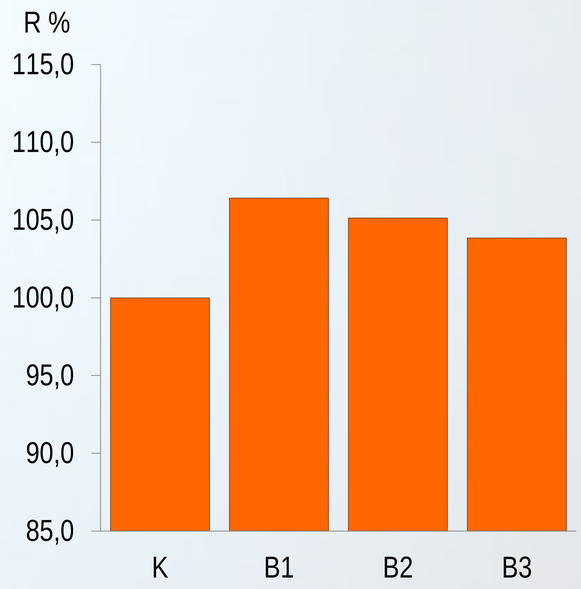


Fig 4. Recovery percent of Candida albicans on TSA

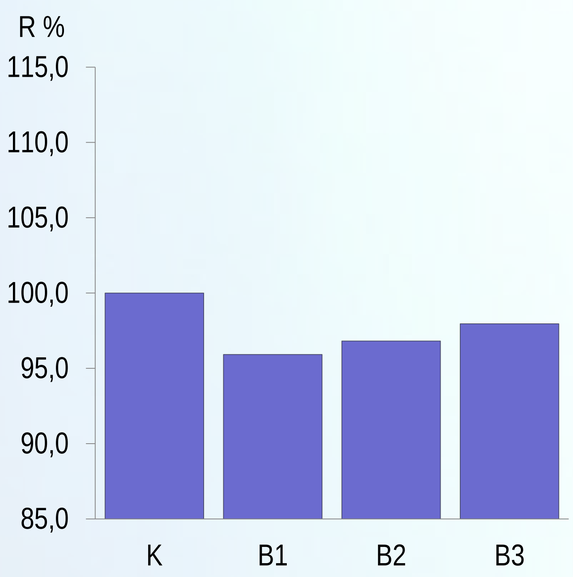


Fig 5. Recovery percent of Aspergillus brasiliensis on TSA



Fig 6. Recovery percent of Candida albicans on SDA

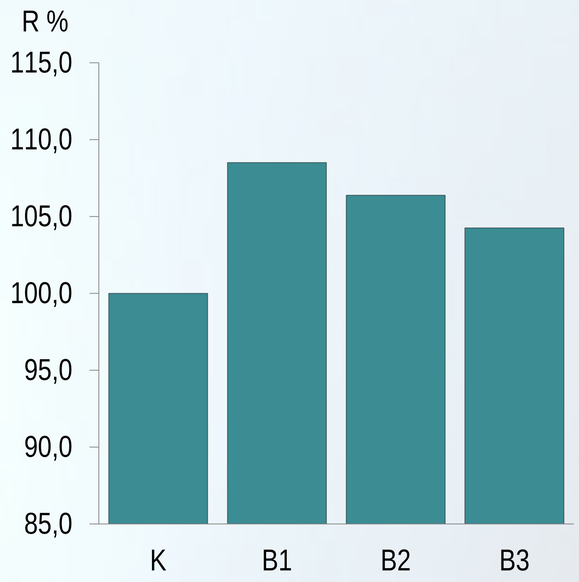


Fig 7. Recovery percent of Aspergillus brasiliensis on SDA

Table 1. Relative recovery of specified microorganisms

Parameter	K	B1	B2	B3
Absence of S. aureus	+	+	+	+
Absence of E. coli	+	+	+	+
Absence of S. typhimurium	+	+	+	+
Total Bile Tolerant GN E. coli	+	+	+	+
Total Bile Tolerant GN P. aeruginosa	+	+	+	+

The Recovery Percent results obtained from all quantitative challenge tests show that the tested Cannabis oil solution product doesn’t demonstrate significant product matrix interference or antimicrobial properties against any reference microorganisms while using primary suspension of the product (1:10 dilution in TSB), thus resulting with readable plate count and Recovery factor values ≤2 for all testing microogranisms (Figure 1-7).
The results obtained from qualitative challenge tests for Absence of Staphylococcus aureus/ml, Escherichia coli/ml and Salmonella/10ml, demonstrated positive recovery on all three testing iterations, with relative Recovery rate of 100% for all specified microoranisms while using primary suspension (1:10 dilution in TSB) of the product (Table 1).

CONCLUSION

The Cannabis oil solution: THC 40 mg + CBD 40 mg/1 ml doesn’t demonstrate product matrix or antimicrobial interference by 1:10 dilution in Tryptic Soy Broth, without the necessity for addition of any surface active agent, such as isopropyl myristate or polysorbate 80. The stabilization of the primary suspension of the product is achieved by temperature controlled dispersion.

REFERENCES

MacGillivray, N., 2015. Sir William Brooke O’Shaughnessy (1808–1889), MD, FRS, LRCS Ed: Chemical pathologist, pharmacologist and pioneer in electric telegraphy. J. Med Biogr. 25(3):186-196. doi: 10.1177/0967772015596276.

Bodine M, Kemp AK. Medical Cannabis Use In Oncology. 2022 May 15. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan–. PMID: 34283433.

European Pharmacopoeia - 10th edition, Volume 1, 2019. Council of Europe, 67075 Strasbourg, France, pp, 185-194.