

Method suitability validation for determination of microbiological purity of Ibuprofen film coated tablets 400mg

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Introduction

A microbiological quality control method that will be used in routine for determination of product microbiological purity must be subject of validation. Microbiological quality control parameters for Ibuprofen film coated tablets 400mg as non-aqueous pharmaceutical preparation for oral use are: Total Aerobic Microbial Count (TAMC), Total Yeasts and Molds Count (TYMC) and Absence of *Escherichia coli* (Ph.Eur. 10.0, 2019).

Materials and methods

For determination of the antimicrobial activity (Figure 1) and validation of the test method, challenge test was conducted with: *Escherichia coli* ATCC 8739, *Pseudomonas aeruginosa* ATCC 9027, *Bacillus subtilis* ATCC 6633, *Staphylococcus aureus* ATCC 6538, *Candida albicans* ATCC 10231 and *Aspergillus brasiliensis* ATCC 16404, test microorganisms that are standard microorganisms specified by the current European Pharmacopoeia for method suitability test (Ph.Eur. 10.0, 2019).

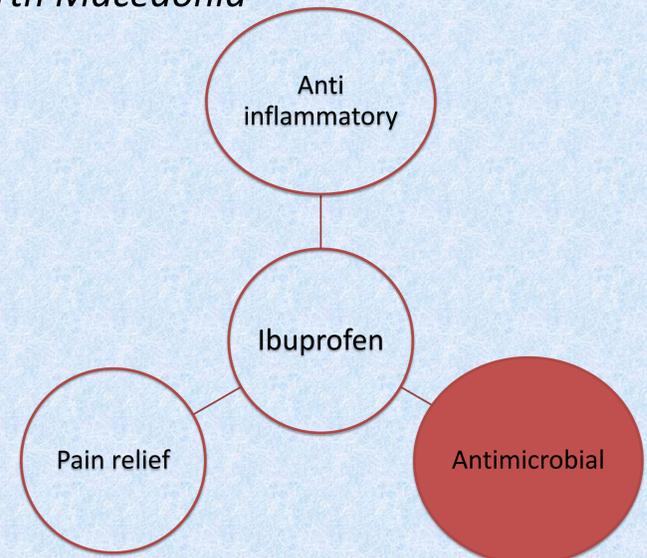


Figure 1: Determination of the antimicrobial activity

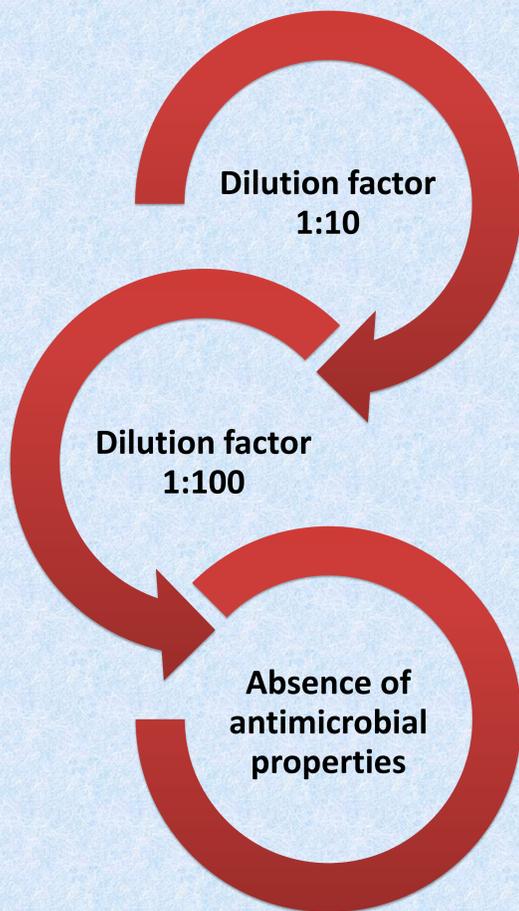


Figure 2: Validation of the test method

Results

The chosen test for determination of microbiological purity as suitable (Figure 2), must mimic the proposed microbial limit test - the sample preparation, types of media and buffers as well as incubation conditions must be reproduced during validation. In order to demonstrate that the proposed method is capable of recovering viable microbes that might be present in the product sample, the method suitability protocol requires the use of representative microorganisms to challenge the microbial recovery methods.

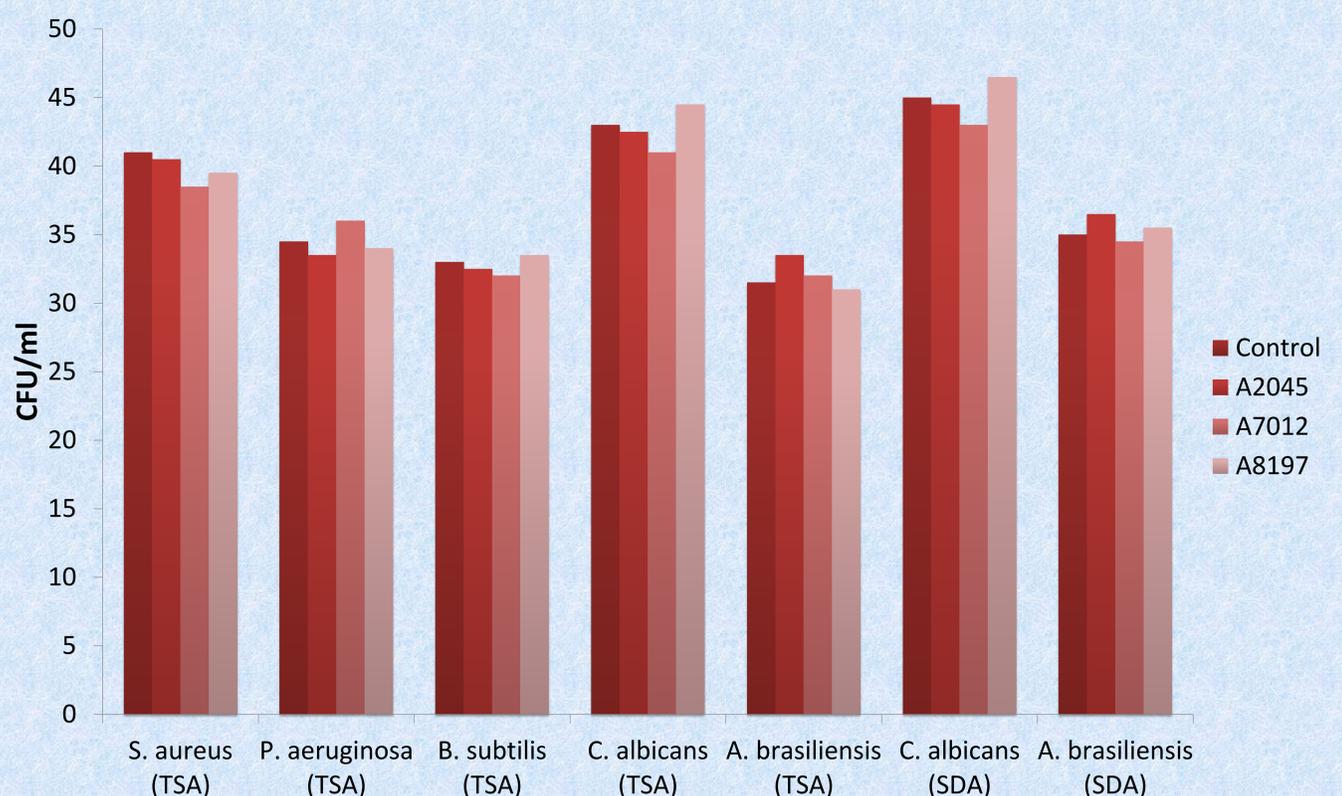


Figure 3: Microbial recovery using 1:100 product dilution

Conclusion

The product, Ibuprofen film coated tablets 400mg, demonstrates significant antimicrobial properties against test microorganism: *S. aureus*, *B. subtilis*, *C. albicans* and *A. brasiliensis* while using Pharmacopoeia diluent pH 7.0 for the preparation of Primary suspension (1:10 dilution). **Secondary suspension (1:100 dilution) demonstrates absence of product microbial interference and compliant Recovery Factor values ≤ 2 on all tested microorganisms (Figure 3).** Test for specified microorganisms using primary suspension of the product to be examined (1:10 dilution) is determined to be validated as suitable for the conduction of the qualitative tests for determination of Absence of *Escherichia coli*, as defined in Ph. Eur. 2.6.13., 4-2.

References

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