BACKGROUND
Comparison of 2 recommended European Pharmacopeia 9th Ed methods of sterility assay (membrane filtration versus Direct Seeding (DS)) allows to highlight an important difference of sensitivity threshold. This threshold by membrane filtration method is at least lower or equal to 0.14UFC/mL.

PURPOSE
The aim of the study is to determine the sensitivity threshold of DS method. This one is currently used in our Hospital Pharmacy Unit (HPU) for binary Parenteral Nutrition (PN) bags.

MATERIAL AND METHODS
6 PN bags of 30mL : 4 PN bags “test” and 2 PN bags “negative control”

4 calibrated strains Bioball® 30 UFC

5 levels of concentration : 1UFC/mL - 0,8UFC/mL - 0,6UFC/mL - 0,4UFC/mL - 0,2UFC/mL

2 cultures media : Sabouraud dextrose agar slope (Biomérieux) or Brain-Heart Infusion Broth (BHIB - comic)

14 Incubated days

RESULTS
- No concentration made it possible to obtain 100% of positivity
- Sensitivity’s threshold is thus higher than 1UFC/mL
- Compared to membrane filtration, the detection’s threshold by DS is at least 7 times superior

CONCLUSION
Even if this study did not allow to estimate with precisely a sensitivity threshold for DS method, it highlighted limits for sterility assay of binary parenteral nutrition bags. Therefore, it possible to confirm the superiority of membrane filtration method. Following tests with higher micro-organisms concentrations in binary PN bags are planned to establish with precision the minimal detection threshold.