

ISO 13019:2018 (E)

Tissue-engineered medical products — Quantification of sulfated glycosaminoglycans (sGAG) for evaluation of chondrogenesis

Contents

| | |
|---------|--|
| | Foreword |
| 1 | Scope |
| 2 | Normative references |
| 3 | Terms and definitions |
| 4 | General and principle |
| 5 | Apparatus |
| 6 | Preparation of parallel test samples from test samples |
| 6.1 | General |
| 6.2 | Preparation of parallel test samples |
| 7 | Procedure |
| 7.1 | General |
| 7.2 | Procedure for pre-treatment of parallel test samples |
| 7.2.1 | Procedure for dissection |
| 7.3 | Procedure for extraction of sGAG from pre-treated parallel test samples |
| 7.3.1 | General |
| 7.3.2 | Procedure for papain digestion |
| 7.4 | Procedure for measurement of sGAG content of parallel test samples by DMMB assay |
| 7.4.1 | Principle |
| 7.4.2 | Procedure for preparation of 1,9-dimethylmethylene blue (DMMB) solution |
| 7.4.3 | Procedure for DMMB assay |
| 7.5 | Normalization of sGAG contents |
| 8 | Test report |
| 9 | Evaluation |
| Annex A | (informative) Flowchart of the overall procedure steps |
| Annex B | (informative) Reagents |
| Annex C | (informative) Alternative procedure for pre-treatment |
| C.1 | Procedure for pulverization |
| C.2 | Procedure for lyophilization |
| Annex D | (informative) Alternative procedure for extraction of sGAG |
| D.1 | Procedure for collagenase digestion |
| D.2 | Procedure for guanidine salt extraction |
| D.3 | Procedure for guanidine extraction/pepsin digestion/elastase digestion |
| D.3.1 | Adjustment of volumes of the reagents |
| D.3.2 | Procedure for guanidine extraction |
| D.3.3 | Procedure for pepsin digestion |
| D.3.4 | Procedure for elastase digestion |
| Annex E | (informative) Example of test report format for sGAG measurement |