

Repligen manufactures OPUS pre-packed chromatography columns in the United States of America using plastics sourced from qualified suppliers. The following statements are inclusive of all OPUS products 5cm GMP Run Ready columns and ≥ 10 cm internal diameter in size. All information included in the memo can also be found in the Regulatory Support File (RSF) for the OPUS products on the Repligen.com website.

Quality Standard

Manufactured in the United States of America under an ISO 9001:2015 Quality Management System

Material Compatibility

All materials in direct fluid contact path meet USP class VI <88> requirements for In Vivo B Biological Reactivity

Environment

Columns are packed in a controlled, classified clean room that meets ISO Class 7 standards.

Animal Free

Materials of construction comply to EMA/410/01.

Chromatography Resin Control

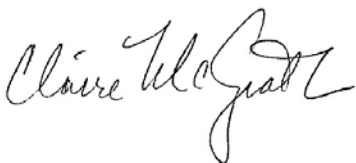
All resins are subject to incoming material controls including lot number identification. Traceability is achieved using controlled documents and records according to good documentation practices.

Shelf Life Statement:

OPUS columns do not have an expiration date. Repligen recommends adhering to the expiration date of the resin pre-packed into the column.

OPUS columns do not have a specified shelf life. However, QC stability tests demonstrate that columns can be stored for a period of months without degradation in performance parameters. Please reference the OPUS RSF for more information.

Sincerely,



Claire McGrath
Sr. Director of Quality
Repligen Corporation