

(USFDA FEI No.: 3017085815)

Extractable/Leachable Testing & Risk Assessment

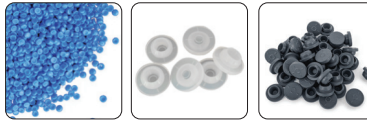
- 1 Estimation of Volatile Leachable by GC-MS/MS
- 2 Estimation of Non-Volatile Leachable by LC-MS/MS
- 3 Estimation of Elemental Leachable by ICM-OES/ICP-MS
- 4 Estimation of "Daily Allowable Limit (DAL)" of Leachable
- 5 Biological Risk Assessment

For Pharmaceutical Formulation



As per USP 1663 & USP 1664

For Plastic Packaging Material as per USP




As per USP 661 & USP 1661

For Medical Devices as per ISO



As per ISO 10993:17, ISO 10993:18, ISO 21726 & ISO 10993-1

For Other Formulation like Biopharm



As per PQRI and BPOG

For Intraocular Lens



As per ISO 11979-5

For Soft Contact Lens



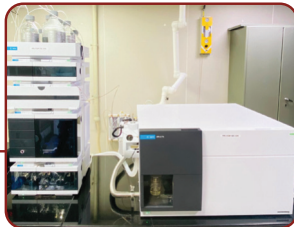
As per ISO 11981 & ISO 11986

For Blood Gas Pathway Devices



As per ISO 18562

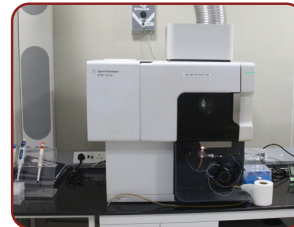
Facilities @ ACCUPREC



Agilent 6475 Triple Quadrupole LC/MS



Agilent 7010B GC/TQ GC-MS/MS System



Agilent 7850 ICP-MS System

With Best Compliments From

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