incepbio®

Trusted for Compliance

COMPANY CASE STUDY

Restoring a Critical WFI Distribution Network Using Advanced Bioderouging

Executive Summary

- **The Client:** A major sterile injectables and biosimilar manufacturer in India.
- **The Challenge:** Severe Class I and Class II rouge contamination discovered during a routine preventive maintenance (PM) audit-ready inspection of a multi-point Water for Injection (WFI) and clean steam distribution network. Traditional aggressive acid cleanings risked metal pitting and posed severe environmental disposal hazards.
- **The Solution:** Incepbio partnered with HENKEL Epol to deploy an integrated, pH-neutral chemical remediation strategy using **Bioderouging Solution HC 4200** and **Biopassivation Solution HC 4000.**
- **The Outcome:** 100% rouge removal, full restoration of a homogenous chromium oxide passive layer, zero system downtime extensions, and eco-friendly waste disposal.

Technical Profile & Challenge

The client's clean utility infrastructure utilized standard AISI 316L (1.4404/1.4435) austenitic stainless steel. Due to continuous operation at temperatures exceeding 80°C, the inner passive film degraded over a 12-month cycle.
A standard white cloth wipe test and trace metal ICP-MS analysis revealed:

- Migratory red-brown iron oxide film lining the distillation storage tanks and loop networks.
- Risk of rouge shearing, which threatens to contaminate downstream compounding vessels and sterile filling lines.
- Traditional alternative restrictions: The client's internal EHS policy banned standard nitric or aggressive phosphoric acid treatments due to chemical handling hazards and costly wastewater neutralization requirements.

The Approach: Incepbio Lifecycle Execution

Incepbio structured a rapid, validation-first execution sequence to minimize facility downtime and maintain strict GMP compliance.

01

System Inspection & Mapping

Day 1

Incepbio engineers isolated the WFI loops, mapped the hydraulic circuits, and took baseline electrochemical measurements of the free iron surface concentrations.

02

Recirculated Bioderouging

Day 2

The network was flooded with a 5% wt solution of HENKEL HC 4200. This aqueous organic salt solution operates at a safe, neutral pH range of 6–8. The liquid was recirculated at 75°C for 6 hours, chemically binding and dissolving the heavy metal iron oxides without attacking the base 316L steel.

03

Wet-Chemical Biopassivation

Day 3 (AM)

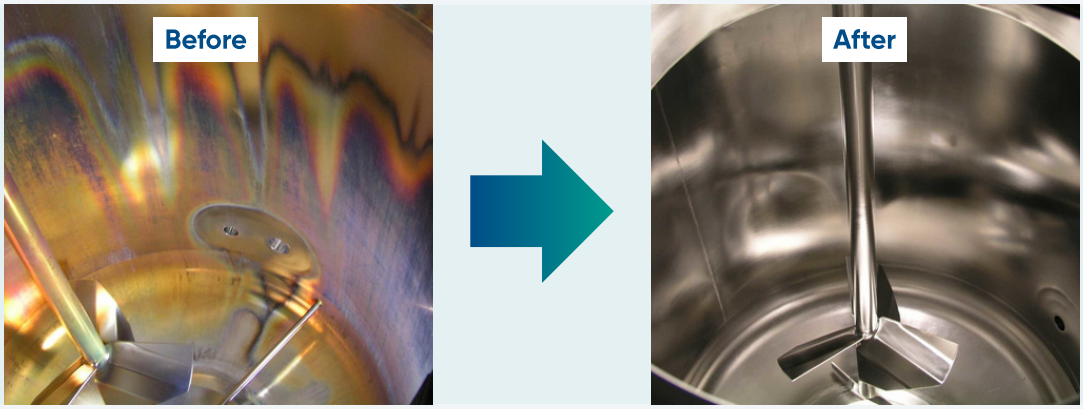
Following a high-purity water rinse, HENKEL Biopassivation Solution HC 4000 (a citric-based formula) was introduced. It forced a controlled, rapid, and highly uniform rebuild of the protective chromium oxide layer.

04

Validation & Document Handover

Day 3 (PM)

Conducted final passivation testing via electrochemical analysis and TOC/conductivity rinse water testing. Incepbio delivered an audit-ready, GMP-compliant validation folder detailing batch traceability and final parameters.



Performance & Operational Impact

Performance Metric	Traditional Acid Method	Incepbio Solution
pH Level	Highly Corrosive (pH less than 1)	Neutral (pH 6.0 – 8.0)
Base Material Risk	Micro-pitting, hydrogen embrittlement	Zero metal attack or etching
Effluent Treatment	Strict on-site neutralization & chemical hauling	Direct discharge to biological ETP
Passive Layer Quality	Variable depending on air-drying oxygen	Highly uniform, wet-chemical assurance

Key Project Achievements:

01

Asset Lifecycle Protection:

Unlike mineral acids that erode microns of pristine metal, HENKEL's neutral chelating chemistry specifically targeted only the oxidized iron.

02

Eco-Friendly Effluent Control:

Because the solutions are organic salt-based and neutral, the rinse water was routed directly to the plant's biological effluent treatment plant (ETP) with zero chemical pretreatment required, saving substantial disposal costs.

03

Regulatory Readiness:

Complete traceability of the chemical batches and continuous monitoring parameter prints ensured the facility easily cleared its subsequent regulatory inspection.

Conclusion

By pairing Incepbio's clinical qualification engineering with HENKEL Epol's specialized chemical formulas, the client successfully eliminated a major quality risk. The clean utility loop was returned to operation ahead of schedule, fully passive, clean, and safe for sterile biopharmaceutical manufacturing.