ETTERNITY DERMAL
– SKINTECH LABORATORY –

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Technical CDMO capabilities

Cleanroom, PW loop, filling and packaging for professional dermocosmetics

Executive answer

What cleanroom filling capabilities does Etternity Dermal offer?

Etternity Dermal operates with an ISO 7 cleanroom (Class C at rest), terminal HEPA H14 filtration and a pressure cascade. The site integrates a Purified Water (PW) loop and filling for 2-50 ml Type I glass vials. Nitrogen inerting is assessed for sensitive formulas. The 1-5 ml Luer-Lock syringe platform is in development and is not presented as commercially available until qualification and validation are complete.

CAPABILITY STATUS	**Current: cleanroom, PW loop, vials and processes subject to project assessment. In development: 1-5 ml Luer-Lock syringe platform with a target filling tolerance of +/-0.5%.**

Institutional capability data sheet. It does not replace a product specification, technical agreement, process validation or batch release. An aseptic or sterile claim may only be made where required by the specific scope and supported by validated evidence.

Reference technical parameters

Environment and air handling

Parameter	Declared reference	Application / control
Classification	ISO 7 / Class C at rest	Project-specific environmental qualification
Terminal filtration	HEPA H14; nominal 99.995% at 0.3 µm	Integrity and maintenance programme
Pressure	Staged positive differential	Monitored between airlocks and process zones
Environment	Temperature and relative humidity	Continuous monitoring within defined limits

Purified Water (PW)

Parameter	Declared reference	Application / control
Conductivity	<1.3 µS/cm at 25 °C	Defined sampling and trending
Total Organic Carbon	<500 ppb	Routine monitoring against specification
Endotoxins	<0.25 EU/ml	Confirmed when required by project scope
Distribution	Closed sanitary loop	Continuous recirculation and controlled points of use

Formats and packaging

Parameter	Declared reference	Application / control
Type I vials	2, 5, 10 and 50 ml	Closure selected by compatibility study
Nitrogen	Up to 99.999% purity	Used when justified and validated for sensitive formula
GAG blister	600 µm PETG/APET/PETG	Secondary protection and professional presentation
Luer-Lock syringes	1, 2.5, 3 and 5 ml	Future platform; target +/-0.5%, not yet available

From parameter to validated project

01 Technical brief and market	02 Product-container compatibility	03 Testing and scale-up	04 Qualification and validation	05 Specifications and release

Quality and documentation framework

ISO 9001	Certified quality management system (EC-12138/25).
ISO 22716	Certified cosmetic Good Manufacturing Practices (BPF-0024/25).
PIF / CPNP	Documentation support and coordination within the contracted scope.
STANPA	Sector membership declared by Etternity Dermal.

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