The ^{68}Ga-PSMA-11 radiopharmaceutical drug product is expected to be formulated in isotonic solution, typically 0.9% NaCl for Injection, containing ≤10% ethanol.

Product release criteria, and process validation standards, are outlined below.

Batch Release Criteria for 68Ga-PSMA (CTN Gallium Users Group)

Test	Suggested Acceptance Criteria
Appearance Visual Inspection	Clear, colorless solution; no visible foreign matter
pH	4 – 8
Endotoxins	<175 EU per dose or < 17.5 EU/mL whichever is lower
Radiochemical Identity and Purity	≥90% Ga-68 PSMA-11
Radioisotope Identity and purity	Target half-life of 68 min (accepted range: 64-72 minutes)
Mass Dose	≤ 10 micrograms
Filter Integrity Test	Meets or exceeds filter manufacturer's defined testing specifications
Retrospective USP Sterility Test	Pass

Testing performed during Process Qualification and Periodic Verification (3 consecutive lots) + annual or for each new batch of PSMA or Ge/Ga-Generator

Test	Suggested Qualification and Validation Criteria
Radiochemical Identity	HPLC: Retention matches reference standard (i.e., cold Ga-PSMA-11) and ITLC: >90% radiochemical purity based on ITLC analysis for initial qualification. Perform one test annually.
Residual solvents - Acetonitrile (if used in process)	Meets USP specifications for any class 2 solvents used (GC)
Residual solvents - Acetone (if used in labeling process)	≤ 5 mg/mL for any Class 3 solvents used (GC)
Upper limit for contamination by Ge-68 Breakthrough*	<0.01% of the total radioactivity is 68-Ge at the time of product expiration.

*It is recommended that sites check for Ge-68 breakthrough on a weekly basis.