

F-18 Glutamine specifications as of August 2021 in the MSK IND

<b>PRE-RELEASE TEST</b>	<b>DESCRIPTION</b>	<b>REQUIREMENTS FOR PASS</b>
<b>Appearance (particulates)</b>	Visual inspection for color and particulates	<b>Clear and Colorless</b>
<b>pH</b>	USP <791> pH strips	<b>pH must be between 5.0 and 7.5</b>
<b>Radionuclidic Identity</b>	Half-life determination	<b>105 – 115 minutes</b>
<b>Radiochemical Identity</b>	HPLC - Compare retention time with reference standard	<b>Sample retention time conforms to the reference standard retention time</b>
<b>Chemical Purity</b>	HPLC	<b>1) L-Glutamine (2S,4R) mass of less than 100 micrograms per dose 2) Total UV impurities mass of less than 100 micrograms per dose.</b>
<b>Radiochemical Purity</b>	HPLC	<b>Radiochemical Purity &gt; 80%</b>
<b>Residual Solvent Levels</b>	Gas Chromatography	<b>Ethanol: &lt;5000 µg/mL Acetonitrile &lt; 410 µg/mL Methanol &lt;3000 µg/mL</b>
<b>Filter Integrity</b>	Test bubble point	<b>Meets pressure specified by manufacturer (&gt;50psi)</b>
<b>Bacterial Endotoxin Levels</b>	Limulus Amoebocyte Lysate (LAL) by PTS	<b>&lt; 5 EU/ml</b>
<b>Radioactive Concentration</b>	Calculation	<b>Radioactive concentration of NLT 1.2mCi at Tol for a maximum injection volume of 10mL</b>
<b>POST-RELEASE TEST</b>	<b>DESCRIPTION</b>	<b>REQUIREMENTS FOR PASS</b>
<b>Sterility</b>	USP sterility test (USP <823>)	<b>No growth observed in 14 days</b>