

Pharmatherm the Clean Steam Quality Specialists!

Clean Steam Specification Explained.

Determinand	Value	Recommended test compliance
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Based on Sterilized Water for Injections BP:

Acidity or alkalinity substitute.	NQ	BP test. Tests pH not acceptable
Ammonium	0.2 mg litre ⁻¹	BP test or other suitable method
Oxidisable substances	NQ	BP test.
Calcium and magnesium substitute.	NQ	BP test. Hardness not acceptable
Heavy metals acceptable	0.1 mg litre ⁻¹	BP test. Individual elements not
Chloride	0.5 mg litre ⁻¹	BP test or other suitable method.
Nitrate	0.2 mg litre ⁻¹	BP test or other suitable method.
Sulphate	NQ	BP test.
Residue on evaporation acceptable	30 mg litre ⁻¹	BP test. Conductivity not
Pyrogens	0.25 EU ml ⁻¹	BP test.

Based on EN 285:

Phosphate	0.1 mg litre ⁻¹	Any suitable method.
Silicate	0.1 mg litre ⁻¹	Any suitable method.

Routine monitoring only:

Electrical conductivity at 25°C 35 µS cm⁻¹

NQ = not quantified; BP = British Pharmacopoeia; EU = endotoxin unit

Contact Pharmatherm for a clean steam condensate quality test quotation however large or small the project maybe. We aim to provide a competitive validation service. Please 'don't delay and contact PharmaTherm today' email: info@pharmatherm.ie

See the Pharmatherm website please log onto www.pharmatherm.ie



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