

Specification

690090 Naphazoline hydrochloride USP, Ph.Eur.

CAS	Formula	Molweight
550-99-2	C ₁₄ H ₁₄ N ₂ *HCl	246,74

Parameter	Specification
Aspect	white or almost white crystalline powder
Identity (IR)	passes test
Identity (HPLC)	compare Rt
Identity for Chloride	passes test
Assay (HPLC, against St., dried Subst.)	98.0 - 102.0 %
Assay (ac. titr.) calc. on dried Subst.	99.0 - 101.0 %
Melting Range (Decomposition) (begin)	256 - 262 °C
Melting Range (Decomposition) (end)	256 - 262 °C
Sulphated ash	max. 0.10 %
Loss on Drying	max. 0.50 %
Solubility (2% in Water)	clear and colourless
pH-Value (1% in Water)	5.0 - 6.6
pH-Value (2% in Water)	5.0 - 6.5
Acidity/Alkalinity	passes test
Limit of Nitrate	passes test
Acetone (GC)	max. 1,000 ppm
Benzene (GC)	max. 2,000 ppm
Diisopropyl ether (GC)	max. 500 ppm
Isopropyl alcohol (GC)	max. 5,000 ppm
Impurity A (HPLC)	max. 0.1%
1-Naphthylacetic acid (HPLC)	max. 0.10%
Unspecified impurities (HPLC)	max. 0.10%
Total impurities (HPLC)	max. 0.5%
Sum TAMC + TYMC	max. 100 CFU/g
Enterobacteria	absence in 1 g
Pseudomonas aeruginosa	absence in 1 g

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LOBA Feinchemie GmbH
Quality Control

Dr. Sonja Leder

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Parameter	Specification
Staphylococcus aureus	absence in 1 g
Escherichia coli	absence in 1g
Salmonella	absence in 10 g
Requirement	Ph.Eur., USP [current edition]

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