

neoFroxx GmbH

Marie-Curie-Str. 3
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Specification

Product	di-Sodium hydrogen phosphate dihydrate pure EP, USP (pharma grade)
Brand	Labochem

Product number	LC-6772 (revised)
Synonym(s)	Sodium phosphate secondary, Sodium phosphate di-basic
Formula	$\text{HNa}_2\text{O}_4\text{P} \cdot 2\text{H}_2\text{O}$, $\text{Na}_2\text{HPO}_4 \cdot 2\text{H}_2\text{O}$
Molecular weight	177.99 g/mol
CAS number	10028-24-7
Melting point	95°C
Storage	below 25°C
Retest periode (months)	60

We herewith confirm that this product meets the requirements of the European Pharmacopoeia (EP) and the US Pharmacopoeia (USP).

TSE/BSE declaration: The product is from mineral origin and is not derived from specific risk materials as defined in Guideline EMEA/410/01 final Rev. 03/2004. (revised)

Parameter	Specification
Assay (calculated on dried substance acc. to EP)	98.0 - 101.0 %
Assay (calculated on dried substance acc. to USP)	98.0 - 100.5 %
Identity	passes test
Appearance of solution	passes test
In water insoluble matter	max. 0.3 %
pH (5 % in water)	8.9 - 9.2
Chloride (Cl)	max. 0.005 %
Sulfate (SO_4)	max. 0.02 %
As (Arsenic)	max. 0.0002 %
Fe (Iron)	max. 0.001 %
Sodium dihydrogen phosphate (NaH_2PO_4)	max. 1.7 %
Residual solvents (ICH Q3C)	excluded by manufacturing process
Substances reducing Potassium permanganate (as O)	passes test
Loss on drying (130°C)	19.5 - 21.0 %
Endotoxins	max. 2.5 I.U./g

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Specification

Parameter	Specification
Total aerobic microbial count	max. 1E+02 CFU/g
Total yeast and mould count	max. 1E+02 CFU/g
DNases (Exo- and endonucleases), RNases, Proteases (not detectable)	passes test

Einhausen, 15.09.2022 (revised)