



PRODUCT CODE: Z41678

di-Sodium Hydrogen Phosphate 12-hydrate (USP, BP, Ph. Eur.) low endotoxin pure, pharma grade

$\text{HNa}_2\text{O}_4\text{P} \cdot 12\text{H}_2\text{O}$

$\text{Na}_2\text{HPO}_4 \cdot 12\text{H}_2\text{O}$

M.= 358,14

CAS [10039-32-4]

EINECS 231-448-7

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SYNONYMS: Disodium Phosphate dodecahydrate, Sodium Phosphate di-Basic dodecahydrate, Disodium Phosphate dodecahydrate

PHYSICAL DATA: crystals, White, Soluble in water 218 g/l at 20 °C D 1,52 • M.P.: 34 °C • pH(5% solution)9,0 - 9,4 •

BIBLIOGRAPHY: Merck Index **12**, 8.805 13, 8.733 Römp **8** , **2743** • ISO 6353/2-1983R - 33 , 47 • BP.**2021** • USP **42** • Ph. Eur. **9.0** (2017) **10.0** (2020) • BOE **243**(8-10-2009) • Regulation (EU) n° 231/2012 •

HAZARDOUS: LD50 ipr mus 430 mg/kg

OBSERVATIONS: Not recommended in areas with a very hot climate •

SPECIFICATIONS:

Assay (Acidim.) (calc. a.a.s)

98,5-100,5 %

Identity :

Identity according to Pharmacopoeias:

passes test

pH of 5% solution

8,7-9,4

Maximum limit of impurities

Appearance of solution

passes test

Insoluble matter in in H₂O

0,025%

Reducing substance to KMnO₄

passes test

Loss on drying at 130°C

57-61 %

Chloride (Cl)

0,003%

Nitrogen compounds (as N)	0,003%
Sulfate (SO ₄)	0,01%
Residual solvents (Ph.Eur/USP)	passes test
Microbial Limits	
Bacterial endotoxins	20 IU/g
Sodium di-Hydrogen Phosphate	2,5 %
Water (H ₂ O)	57,0-61,0 %
As	0,0001 %
Fe	0,001 %
Elemental impurities (ICH Q3D):	
Class 1	
Cd	0,5 ppm
Pb	0,5 ppm
As	1 ppm
Hg	1,5 ppm
Class 2A	
Co	5 ppm
V	10 ppm
Ni	20 ppm
Class 2B	
Tl	5 ppm
Au	10 ppm
Pd	10 ppm
Ir	10 ppm
Os	10 ppm
Rh	10 ppm
Ru	10 ppm
Se	15 ppm
Ag	15 ppm
Pt	10 ppm
Class 3	
Li	55 ppm
Sb	120 ppm
Ba	140 ppm
Mo	25 ppm
Cu	250 ppm
Sn	600 ppm
Cr	25 ppm