Dissolvine®
master the elements

Technical Leaflet 244

Summary of specifications for Dissolvine® Na2-P

An overview of the valid specifications for Dissolvine® Na2-P according to the following monographs:

- European Pharmacopoeia (Ph.Eur.), 2017 edition
- United States Pharmacopoeia (USP), 40, NF26
- Japanese Pharmacopoeia (JP), 14th edition
- Food Chemicals Codex (FCC), 10th edition
- American Chemical Society (ACS), 9th edition

In the last column the overall specification of the product, based on the most stringent legislations, is given.

Spec item	Ph.Eur.	USP	JP	FCC	ACS	Overall spec
Assay as dihydrate	98.5-101.0 %		99.0-101.0 %	99.0-101.0 %	99.0-101.0 %	99.0-101.0 %
Assay on anhydrous basis		99.0-101.0 %				99.0-101.0 %
Identification	-IR -test on Ca -test on EDTA -test on Na	-IR -test on EDTA -test on Na	-test on EDTA -test on EDTA -test on Na	-IR -test on Na -test on EDTA		passes tests
pH (5%)	4.0-5.5	4.0-6.0			4.0-6.0 (25°C)	4.0-5.5
pH (1%)			4.3 – 4.7	4.3 - 4.7		4.3 – 4.7
Heavy metals (as Pb)	20 ppm max		10 ppm max		0.005 % max	10 ppm max
NTA-acid	0.1 % max	0.1 % max		0.1 % max		0.1 % max
Residue on ignition			37.0-39.0 %			37.0-39.0 %
Appearance of 5% solution	clear & colorless		clear & colorless			clear & colorless
Loss on drying		8.7-11.4 %				8.7-11.4 %
Calcium		passes test		passes test		passes test
Cyanide			passes test			passes test
Iron	80 ppm max				0.01 % max	80 ppm max
Arsenic			2 ppm max			1 ppm max *)
Lead				10 ppm max		2 ppm max *)
Insolubles					0.005 % max	0.005 % max

*) The specifications are stricter then then could be expected based on the above mentioned monographs. The reason is that these more strict specifications are from the Thai FDA regulations.