



Chemische Fabrik Budenheim KG-Rheinstr. 27 • 55257 Budenheim-Germany

PT. Narda Tita
RUKAN PURI NIAGA III Blok M8 No. 3 B,C,D,
Kel. KEMBANGAN SELATAN
11610 JAKARTA BARAT
INDONESIA

Certificate of Analysis

Date

03.01.2024

Purchase order/date

NTI.105.07.23. / 04.07.2023

Delivery item/date

7243027 000020 / 03.01.2024

Order item/date

3454935 000050 / 04.07.2023

Contact:

CSC: Ms. Campanello, Tel. + , Mail: customerservice@budenheim.com

PharSQ Base DS 42
Disodium phosphate 2-hydrate
Ph.Eur., USP
cryst.
For excipient use

Material-No.	Batch-No.:	Production date:	Best before:	Delivered quantity:
0000623420	D35101A	(D.M.Y) 04.05.2023	(D.M.Y) 03.05.2026	4.200,00 KG

Characteristic	Unit	Value	Lower Limit	Upper Limit	Method
Assay (USP, on dried basis)	%	100,4	98,0	100,5	P11
Assay (Ph.Eur., on dried basis)	%	100,1	98,0	101,0	P11
Loss on Drying (130°C, 4h)	%	20,3	19,5	21,0	TV1
Arsenic	ppm			1	ICP-MS
Lead	ppm			0,5	ICP-MS
Cadmium	ppm			0,5	ICP-MS
Iron	ppm			20	OES
Mercury	ppm			1	ICP-MS
Cobalt	ppm			5	OES
Vanadium	ppm			3	ICP-MS
Nickel	ppm			6	OES
Chloride	ppm			400	CL10
Sulfate	%			0,1	SO10
H2O-insoluble substances	%	< 0,4		0,4	UR10
Identification (Tests)				passes Test	ID10
Reducing substances				passes Test	RS10
Solution appearance				passes Test	VIS10
Monosodium Phosphate	%	0,2		2,5	PHEUR

Country of Origin: Germany

The results of analysis were obtained using the methods listed above. If results are not listed, the conformity to specification is assured by periodical testing.

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Gesellschaftssitz (registered office): Budenheim - Handelsregister (commercial register): Amtsgericht Mainz (local court) HR A 0850 - VAT-ident-no. DE 149 024 126 - Tax no. 08 202 7004 0

Page

1 / 2

We confirm that none of the solvents listed in the supplement 467 "Residual solvents" of the United States Pharmacopeia and chapter 5.4. of the European Pharmacopeia are used in the manufacture of above mentioned product. We confirm that above mentioned product complies with the ICH Q3C guideline for residual solvents.

Following ICH Q3D guideline on elemental impurities and the risk assessment for oral route of administration we confirm, that class 2B or class 3 elements are not intentionally added during the manufacture of above mentioned product.

Any information contained herein is made to the best of our ability on the basis of current industrial practice and our own knowledge and experience. Any responsibility for damages resulting from the use of or reliance upon such information or products such information refers to is limited pursuant to our Conditions of Sale and Supply. The information contained herein shall not cause the purchaser or any other person or entity using or intending to use our products to refrain from testing our products and/or reviewing (and, if relevant, respecting) any conflicting patent and other proprietary rights; and we expressly request and invite the customer or such other user of our products to perform such tests, have such tests performed prior to any commercial use or other application of our products for the specific use and application intended and to review (and, if relevant, to respect) any conflicting patent and other proprietary rights relevant for the specific product and/or use.

The data shown in this document are provided for information only, and does not relieve receiver from performing any mandatory inspections or testing upon delivery.

This certificate of analysis is computer generated, thus no signature is required.

Budenheim, 03.01.2024

Manager Quality Control Dr. André Lemke