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Analysezertifikat

Stoffname **Niacinamide USP**
Abkürzung **NSA USP**

Formel $C_6H_6N_2O$
Material 194749
Lieferschein 72059552
Probe 3307732
Batch OP12007006
Kundenbatch - - - - -
Kundenname A.C.E.F. Spa

CAS-Nummer [98-92-0]
Spezifikation G3-00612PN.8
Produktionsdatum 04-JUL-2020
Wiederholanalyse 04-JUL-2023
Analysendatum 05-JUL-2020
Kundenauftrag 2021/1828
Kundenartikel 001624-20

Produktionsstandort Lonza Guangzhou Nansha Ltd. 68, Huangge Dadaobei, Nansha District, Guangzhou, Guangdong Province, China (511455)
Tel +86 20 3497 3888, Fax +86 20 3497 1188, contact.cn@lonza.com

Kommentar Conforms to current requir. of EP,USP,FCC; Pb<2ppm, checked periodically; Residual solvents (USP<467>):conforms,solvents not used.

Bemerkung - - - - -

Prüfpunkt	Resultat	Einheit	Spezifikation
Aspekt G3000001TA.3/1/CNGZ-4092.1	Kristallines Pulver	- - - - -	Kristallines Pulver
Farbe G3000001TA.3/1/CNGZ-4092.1	Weiss	- - - - -	Weiss
Gehalt (HPLC) G3-00612QN.4/1/CNGZ-4244.3	100.2	Gew%	99.0 – 101.0
Nikotinsäure (HPLC) G3-00612QN.4/1/CNGZ-4244.3	<0.05	Gew%	<=0.10
NSN (HPLC) G3-00612QN.4/1/CNGZ-4244.3	<0.05	Gew%	<=0.10
Jede unspez. Verunreinigung (HPLC) G3-00612QN.4/1/CNGZ-4244.3	<0.05	Gew%	<=0.10
Summe Verunreinigungen (HPLC) G3-00612QN.4/1/CNGZ-4244.3	<0.1	Gew%	<=0.2
pH (5g / 100ml Wasser, EP) G3-00612PS.1/1/CNGZ-4235.1	6.6	- - - - -	6.0 – 7.5
Klarheit der Lösung (5g/100ml wasser,EP) G3-00612PU.1/1/CNGZ-4233.1	0.14	NTE	<=3.00
Farbwerte (CIELAB) L* G3-00612PX.4/1/CNGZ-4234.3	100.0	- - - - -	90.0 – 101.0
Farbwerte (CIELAB) a* G3-00612PX.4/1/CNGZ-4234.3	0.0	- - - - -	-10.0 – 10.0
Farbwerte (CIELAB) b* G3-00612PX.4/1/CNGZ-4234.3	0.2	- - - - -	-10.0 – 10.0
Farbe der Lsg. (5g/100ml Wasser,ber.) BY G3-00612PX.4/1/CNGZ-4234.3	<BG7	- - - - -	<=BG7
Trockenverlust (USP) G3-00612Q7.1/1/CNGZ-32636.1	0.0	Gew%	<=0.5

Fortsetzung Analysenzertifikat

Stoffname **Niacinamide USP**
Abkürzung **NSA USP**

Lieferschein 72059552
Probe 3307732
Batch OP12007006
Kundenbatch - - - - -

Produktionsdatum 04-JUL-2020
Wiederholanalyse 04-JUL-2023
Analysendatum 05-JUL-2020
Kundenauftrag 2021/1828

Prüfpunkt	Resultat	Einheit	Spezifikation
Schmelzbereich, Anfang (opt. Transm.) G3-00612PC.2/1/CNGZ-4096.1	129.2	°C	128.0 – 131.0
Schmelzbereich, Ende (opt. Transm.) G3-00612PC.2/1/CNGZ-4096.1	129.4	°C	128.0 – 131.0
Kornanteil >= 50µm G3-00612PO.1/1/CNGZ-4095.1	100	Gew%	>=90
Kornanteil >= 250 µm G3-00612PO.1/1/CNGZ-4095.1	1	Gew%	<=8
Sulfatasche (2h, 600°C, USP/EP) G3-00612QA.1/1/CNGZ-4098.1	<0.05	Gew%	<=0.10
Schwermetalle (USP, Methode II) G3-00612QB.1/1/CNGZ-4099.1	<20	mg/kg	<=20
Chlorid (Grenzwert-Test, JP) G3-00612PP.1/1/CNGZ-4236.1	<70	mg/kg	<=70
Sulfat (Grenzwert-Test, JP) G3-00612PZ.1/1/CNGZ-4237.1	<190	mg/kg	<=190
Leicht verkohlbare Substanzen (USP/JP) G3-00612PQ.1/1/CNGZ-4238.1	Matching Fluid A	- - - - -	Matching Fluid A
Identifikation (UV A245/A262 Verh., USP) G3-00612QU.1/1/CNGZ-4100.1	0.67	- - - - -	0.63 – 0.67
Identifikation (NaOH, JP) G3-00612Q8.1/1/CNGZ-4101.2	Corresponds	- - - - -	Corresponds
Identifizierung (IR, USP/EP/JP) G3-00612PW.2/1/CNGZ-4245.2	Corresponds	- - - - -	Corresponds
Trockenverlust (EP) G3-00612QQ.3/1/CNGZ-37728.1	0.0	Gew%	<=0.5
Laboranalytik: Kelly Chen 10-JUL-2020 QC Manager Batch freigegeben durch: Ou Cindy 17-JUL-2020 QA Manager			

Bemerkungen Marketing:
Your Product: 001624-20

Dieses Zertifikat ist die Ausgabe geschützter Daten und ist elektronisch unterzeichnet nach den geltenden Gesetzen.

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Certificate of Analysis

Substance name	Niacinamide USP		
Abbreviation	NSA USP		
Formula	C ₆ H ₆ N ₂ O	CAS number	[98-92-0]
Material	194749	Specification	G3-00612PN.8
Delivery note	72059552	Production date	04-JUL-2020
Sample	3307732	Retest Date	04-JUL-2023
Batch	OP12007006	Analysis date	05-JUL-2020
Customer batch	-----	Customer order	2021/1828
Customer name	A.C.E.F. Spa	Customer article	001624-20
Manufacturing site	Lonza Guangzhou Nansha Ltd. 68, Huangge Dadaobei, Nansha District, Guangzhou, Guangdong Province, China (511455) Tel +86 20 3497 3888, Fax +86 20 3497 1188, contact.cn@lonza.com		
Comment	Conforms to current requir. of EP,USP,FCC; Pb<2ppm, checked periodically; Residual solvents (USP<467>):conforms,solvents not used.		
Remark	-----		

Test	Result	Unit	Specification
Appearance G3000001TA.3/1/CNGZ-4092.1	Crystalline powder	-----	Crystalline powder
Colour G3000001TA.3/1/CNGZ-4092.1	White	-----	White
Assay (HPLC) G3-00612QN.4/1/CNGZ-4244.3	100.2	%w/w	99.0 – 101.0
Nicotinic acid (HPLC) G3-00612QN.4/1/CNGZ-4244.3	<0.05	%w/w	<=0.10
3-Cyanopyridine (HPLC) G3-00612QN.4/1/CNGZ-4244.3	<0.05	%w/w	<=0.10
Any unspecified impurity (HPLC) G3-00612QN.4/1/CNGZ-4244.3	<0.05	%w/w	<=0.10
Total impurities (HPLC) G3-00612QN.4/1/CNGZ-4244.3	<0.1	%w/w	<=0.2
pH (5g / 100ml water, EP) G3-00612PS.1/1/CNGZ-4235.1	6.6	-----	6.0 – 7.5
Clarity of sol. (5g /100ml water, EP) G3-00612PU.1/1/CNGZ-4233.1	0.14	NTU	<=3.00
Colour values (CIELAB) L* G3-00612PX.4/1/CNGZ-4234.3	100.0	-----	90.0 – 101.0
Colour values (CIELAB) a* G3-00612PX.4/1/CNGZ-4234.3	0.0	-----	-10.0 – 10.0
Colour values (CIELAB) b* G3-00612PX.4/1/CNGZ-4234.3	0.2	-----	-10.0 – 10.0
Colour of sol. (5g/100ml water,calc.) BY G3-00612PX.4/1/CNGZ-4234.3	<BY7	-----	<=BY7
Loss on drying (USP) G3-00612Q7.1/1/CNGZ-32636.1	0.0	%w/w	<=0.5

Continued Certificate of Analysis

Substance name **Niacinamide USP**
Abbreviation **NSA USP**

Delivery note 72059552
Sample 3307732
Batch OP12007006
Customer batch - - - - -

Production date 04-JUL-2020
Retest Date 04-JUL-2023
Analysis date 05-JUL-2020
Customer order 2021/1828

Test	Result	Unit	Specification
Melt. range, start. point (opt. transm.) G3-00612PC.2/1/CNGZ-4096.1	129.2	°C	128.0 – 131.0
Melt. range, end. point (opt. transm.) G3-00612PC.2/1/CNGZ-4096.1	129.4	°C	128.0 – 131.0
Particle size fraction $\geq$ 50 μ m G3-00612PO.1/1/CNGZ-4095.1	100	%w/w	$\geq$ 90
Particle size fraction $\geq$ 250 μ m G3-00612PO.1/1/CNGZ-4095.1	1	%w/w	$\leq$ 8
Sulphated ash (2h, 600°C, USP/EP) G3-00612QA.1/1/CNGZ-4098.1	<0.05	%w/w	$\leq$ 0.10
Heavy metals (USP, method II) G3-00612QB.1/1/CNGZ-4099.1	<20	mg/kg	$\leq$ 20
Chloride (limit test, JP) G3-00612PP.1/1/CNGZ-4236.1	<70	mg/kg	$\leq$ 70
Sulfate (limit test, JP) G3-00612PZ.1/1/CNGZ-4237.1	<190	mg/kg	$\leq$ 190
Readily carbonizable substances (USP/JP) G3-00612PQ.1/1/CNGZ-4238.1	Matching Fluid A	- - - - -	Matching Fluid A
Identification (UV A245/A262 ratio, USP) G3-00612QU.1/1/CNGZ-4100.1	0.67	- - - - -	0.63 – 0.67
Identification (NaOH, JP) G3-00612Q8.1/1/CNGZ-4101.2	Corresponds	- - - - -	Corresponds
Identification (IR, USP/EP/JP) G3-00612PW.2/1/CNGZ-4245.2	Corresponds	- - - - -	Corresponds
Loss on drying (EP) G3-00612QQ.3/1/CNGZ-37728.1	0.0	%w/w	$\leq$ 0.5
For the lab: Kelly Chen 10-JUL-2020 QC Manager Batch released by: Ou Cindy 17-JUL-2020 QA Manager			

Remarks from Marketing:
Your Product: 001624-20

This certificate is the output of protected data and is signed electronically in compliance with the law.