



QUANZHOU LN BIOCHEMICAL CO.,LTD.

ADD: TAOXI VILLAGE, TAOCHENG TOWN, YONGCHUN COUNTY, QUANZHOU, CHINA

TEL: +86-595-23870659

FAX: +86-595-23870569

CELL: +86-13950178560

EMAIL: DECO007@126.COM

Stability Data Sheet

Products: Vitamin D3 100CWD Powder

Active Ingredient: Vitamin D3 100,000iu/g

Carrier: maltodextrin and sucrose, modified starch

1. Long term stability test

1.1 Samples

Sample name: Vitamin D3 100CWD Powder

Batch no: 71160809; 71160810; 71160711; 71160812; 71161113

1.2 Test methods: HPLC

1.3 Test items:

Appearance; assay; Loss On Drying

1.4 Test condition:

Temperature: 40±2°C, Humidity: 75%±2% RH

Packing: the inner package is Aluminum bags lined with PE bag(vacuum packed), the outside package is cartons.

Test time-points: 0th, 1st, 2nd, 3rd months

1.5 Test result

Imitate the standard QUANZHOU LN packages and stored for 3 months. The result shows that the products: Vitamin D3 100CWD Powder conforms to the corresponding specification. No significant change occurs at such conditions.

1.5.1 Stability Test Report

Sample name: Vitamin D3 100CWD Powder

Batch No: 71160809

Analysis Date	Storage (Months)	Appearance (white spherical-shaped powder)	Loss On Drying (standard:≤5.0%)	Content(standard: 95.0%-115.0%)
Aug.2016	0	Complies	3.4	106.3%
Sept.2016	1	Complies	3.3	106.1%
Oct.2016	2	Complies	3.4	105.1%
Nov.2016	3	Complies	3.6	104.9%



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1.5.2 Stability Test Report

Sample name: Vitamin D3 100CWD Powder

Batch No: 71160810

Analysis Date	Storage (Months)	Appearance (white spherical-shaped powder)	Loss On Drying (standard:≤5.0%)	Content(standard: 95.0%-115.0%)
Aug.2016	0	Complies	4.7	106.3%
Sept.2016	1	Complies	4.7	105.8%
Oct.2016	2	Complies	4.7	105.7%
Nov.2016	3	Complies	4.9	105.0%

1.5.3 Stability Test Report

Vitamin D3 100CWD Powder

Batch No: 71160711

Analysis Date	Storage (Months)	Appearance (white spherical-shaped powder)	Loss On Drying (standard:≤5.0%)	Content(standard: 95.0%-115.0%)
July.2016	0	Complies	3.6	106.2%
Aug.2016	1	Complies	3.8	105.8%
Sept.2016	2	Complies	3.8	105.8%
Oct.2016	3	Complies	4.1	105.7%

1.5.4 Stability Test Report

Vitamin D3 100CWD Powder

Batch No: 71160812

Analysis Date	Storage (Months)	Appearance (white spherical-shaped powder)	Loss On Drying (standard:≤5.0%)	Content(standard: 95.0%-115.0%)
Aug.2016	0	Complies	4.1	105.9%
Sept.2016	1	Complies	4.2	105.8%
Oct.2016	2	Complies	4.5	105.7%
Nov.2016	3	Complies	4.8	105.1%



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1.5.5 Stability Test Report

Vitamin D3 100CWD Powder

Batch No: 71161113

Analysis Date	Storage (Months)	Appearance (white spherical-shaped powder)	Loss On Drying (standard: ≤5.0%)	Content(standard: 95.0%-115.0%)
Nov.2016	0	Complies	4.1	105.1%
Dec.2016	1	Complies	4.2	104.8%
Jan.2017	2	Complies	4.4	104.7%
Feb.2017	3	Complies	4.8	104.7%

2. Long term stability test with natural conditions

2.1 Samples

Sample name: Vitamin D3 100CWD Powder

Batch no: 71160809; 71160810; 71160711; 71160812; 71161113

2.2 Test methods: HPLC

2.3 Test items:

Appearance; assay: Loss On Drying

2.4 Test condition:

Temperature: 30±1 °C, Humidity: 65%±5% RH

Packing: the inner package is Aluminum foil bag, the outside package is cartons.

Test time-points: 0th, 3rd, 6th, 9th, 12th, 18th, 24th, 30th, 36th months

2.5 Test result

Imitate the standard QUANZHOU LN packages and stored for 6-36 months. The result shows that the products: Vitamin D3 100CWD Powder conforms to the corresponding specification. No significant change occurs at such condition.



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2.5.1 Long term Stability Test Report

Sample name: Vitamin D3 100CWD Powder

Batch No: 71160809

Analysis Date	Storage (Months)	Appearance (white spherical-shaped powder)	Loss On Drying (standard: ≤5.0%)	Content(standard: 95.0%-115.0%)
Aug.2016	0	Complies	3.6	106.5%
Nov.2016	3	Complies	3.6	106.5%
Feb.2017	6	Complies	4.2	106.4%
May.2017	9	Complies	4.2	106.0%
Aug.2017	12	Complies	4.4	105.2%
Feb.2018	18	Complies	4.6	105.1%
Aug.2018	24	Complies	4.6	105.0%
Feb.2019	30	Complies	4.6	105.0%
Aug.2019	36	Complies	4.7	104.9%
Feb.2020	42	Complies	4.7	104.7%
Aug.2020	48	Complies	4.7	104.7%
Feb.2021	54	Complies	4.7	104.7%

2.5.2 Long term Stability Test Report

Sample name: Vitamin D3 100CWD Powder

Batch No: 71160810

Analysis Date	Storage (Months)	Appearance (white spherical-shaped powder)	Loss On Drying (standard: ≤5.0%)	Content(standard: 95.0%-115.0%)
Aug.2016	0	Complies	3.2	106.0%
Nov.2016	3	Complies	3.4	105.8%
Feb.2017	6	Complies	4.0	105.7%
May.2017	9	Complies	4.2	105.6%
Aug.2017	12	Complies	4.4	105.2%
Feb.2018	18	Complies	4.6	105.1%
Aug.2018	24	Complies	4.6	105.0%



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Feb.2019	30	Complies	4.6	105.0%
Aug.2019	36	Complies	4.7	104.9%
Feb.2020	42	Complies	4.7	104.9%
Aug.2020	48	Complies	4.7	104.9%
Feb.2021	54	Complies	4.7	104.9%

2.5.3 Long term Stability Test Report

Sample name: Vitamin D3 100CWD Powder

Batch No: 71160711

Analysis Date	Storage (Months)	Appearance (white spherical-shaped powder)	Loss On Drying (standard:≤5.0%)	Content(standard: 95.0%-115.0%)
Jul.2016	0	Complies	2.9	106.6%
Oct.2016	3	Complies	3.0	106.3%
Jan.2017	6	Complies	3.1	105.0%
Apr.2017	9	Complies	3.3	104.5%
Jul.2017	12	Complies	3.6	103.7 %
Jan.2018	18	Complies	3.8	103.1%
July.2018	24	Complies	4.2	103.0%
Jan.2019	30	Complies	4.6	103.0%
July.2019	36	Complies	4.7	103.0%
Jan.2020	42	Complies	4.7	103.0%
July.2020	48	Complies	4.7	103.0%
Jan.2021	54	Complies	4.7	103.0%



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2.5.4 Long term Stability Test Report

Sample name: Vitamin D3 100CWD Powder

Batch No: 71160812

Analysis Date	Storage (Months)	Appearance (white spherical-shaped powder)	Loss On Drying (standard: ≤5.0%)	Content(standard: 95.0%-115.0%)
Aug.2016	0	Complies	3.7	106.5%
Nov.2016	3	Complies	4.0	106.0%
Feb.2017	6	Complies	4.2	105.5%
May.2017	9	Complies	4.3	104.9%
Aug.2017	12	Complies	4.4	104.8%
Feb.2018	18	Complies	4.6	104.0%
Aug.2018	24	Complies	4.6	103.8%
Feb.2019	30	Complies	4.6	103.8%
Aug.2019	36	Complies	4.7	103.6%
Feb.2020	42	Complies	4.7	103.6%
Aug.2020	48	Complies	4.7	103.6%
Feb.2021	54	Complies	4.7	103.6%

2.5.5 Long term Stability Test Report

Sample name: Vitamin D3 100CWD Powder

Batch No: 71161113

Analysis Date	Storage (Months)	Appearance (light yellow spherical-shaped powder)	Loss On Drying (standard: ≤5.0%)	Content(standard: 95.0%-115.0%)
Nov.2016	0	Complies	3.0	105.8%
Feb.2017	3	Complies	3.1	105.5%
May.2017	6	Complies	3.4	104.5%
Aug.2017	9	Complies	3.7	104.0%
Nov.2017	12	Complies	3.9	104.0%



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May.2018	18	Complies	4.0	103.8%
Nov.2018	24	Complies	4.1	103.6%
May.2019	30	Complies	4.3	103.4%
Nov.2019	36	Complies	4.4	103.4%
May.2020	42	Complies	4.4	103.4%
Nov.2020	48	Complies	4.4	103.4%

General conclusion:

According to test results and past experience, the shelf life of Vitamin D3 100,000IU/G Powder can be guaranteed for 36 months stored in unopened original package under recommended conditions.

Note: the data of 12-18 months after 3 years are also listed in the table.

Quanzhou LN Biochemical CO., LTD.
泉州雷恩生化有限公司