

Bagian : QC

ANALISA PERMINTAAN BARANG

Due date : 12-Aug-26

Tanggal : 9-Jul-26

No	Kode Barang	Nama Barang	Satuan	Stok Saat Ini	Rencana	Kekurangan	Pending	Jumlah	Realisasi	Realisasi
				Saat Ini (A)	Kebutuhan (B)	(A -B + C)	Penerimaan (C)		Pembelian	Penggunaan
1	IMO10028	Jasa analisa residual solvent Methanol bahan baku Citicollin Sodium	Js	0	4	-4	0	4	0	0
1	IMO10028	Jasa analisa residual solvent Ethanol bahan baku Citicollin Sodium	Js	0	4	-4	0	4	0	0
1	IMO10028	Jasa analisa residual solvent Acetone bahan baku Citicollin Sodium	Js	0	4	-4	0	4	0	0

Catatan :

- Analisa parameter residual solvent (methanol, ethanol dan acetone) pada bahan baku Citicoline Sodium ex. Kaiping Genuine dengan nomor batch :

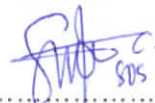
1. 241103 Ex. Kaiping Genuine
2. 240508 Ex. Kaiping Genuine
3. 240208 Ex. Kaiping Genuine
4. 250308 Ex. Kaiping Genuine

- Estimasi total biaya pengujian ~~Rp. 840.000~~ Rp. 4.200.000 fSDS 09/26/07

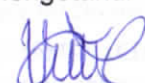
Latar belakang permintaan:

- Parameter tersebut belum dapat dilakukan analisa secara internal dikarenakan metode menggunakan instrumen GC-FID dan belum tersedia kolom GC polyetilenglycol
- Sebagai pemenuhan data untuk perilsan bahan baku
- Pengujian dilakukan di PT Equilab International
- Terlampir penawaran harga, dan CoA

Dibuat

 C. 09/26/07
SDS

Mengetahui

 09/26/07

LIST PARAMETER BAHAN BAKU BELUM BISA DIKERJAKAN OLEH QC

No.	Parameter	Nama Bahan	Kendala di QC	Keterangan (Bisa/Tidak oleh R&D)
1	Kadar	Aspartame	Masih proses pengadaan RS, belum pengembangan metode (HPLC)	Bisa dikerjakan oleh R&D
2	Batas Asam 5 Benzyl	Aspartame	Masih proses pengadaan RS, belum pengembangan metode (HPLC)	Bisa dikerjakan oleh R&D
3	Kemurnian Kromatografi	Aspartame	Masih proses pengadaan RS, belum pengembangan metode (HPLC)	Bisa dikerjakan oleh R&D
4	2-Propanol	Betahistine Mesilate	Belum pengembangan metode dan belum tersedia kolom GC	Belum pengembangan (menggunakan metode residual solvent BP) dibutuhkan kolom GC G43 30m 0,32 mm atau 0,53 mm 1,8um atau 3,0um
5	Sisa Pelarut	Citicoline Natrium	GC-FID (Belum tersedia kolom)	Belum tersedia kolom GC polyetilenglycol (20PEG-20m)
6	Batas Sodium Chloride & Glikolat	Crosscarmellose Sodium	Sudah dilakukan trial oleh QC namun belum berhasil, butuh pendampingan R&D untuk trial ulang	Bisa, tetapi perlu verifikasi
7	Eter Ekstrak	Eurolake Sunset Yellow	Prosedur tidak ada di kompendial, butuh pendampingan R&D untuk proses trial karena ada beberapa step di prosedur yang butuh penjelasan lebih rinci.	Bisa, tetapi perlu verifikasi
8	Kadar	Glycerin	Sudah dilakukan trial oleh QC namun belum berhasil, butuh pendampingan R&D untuk trial ulang	Bisa dikerjakan oleh R&D
9	EG DEG	Glycerin	Belum pengembangan metode dan sedang pengadaan RS	Bisa, tetapi belum validasi
10	Cemaran Organik	Glycerin	Belum pengembangan metode dan belum tersedia kolom GC	Bisa, tetapi belum validasi

Autum 09/07/20
08



Kaiping Genuine

Biochemical Pharmaceutical Co., Ltd

GENUINE

CAS	:33818-15-4
Batch No.	:241103
Quantity	:750Kg
Date of Manufacture	:2024-11-10
Expiry Date	:2027-11-09
Sampling Date	:2024-11-15
Report Date	:2024-11-20

Certificate of Analysis No.	: CDP-C 20241116
Product name	: Citicoline Sodium
Grade	: Pharmaceutical grade
Storage	: Airtight and Room temperature
Labeling	: As stated
Analysis Standard	: ChP 2020 Part II



ANALYTICAL CONTROL TESTS APPLIED

Item	Result	Conclusion
Appearance	White crystals or crystalline powder, odorless. ✓	Complied
Solubility	Freely soluble in water, insoluble in ethanol and in acetone. ✓	Complied
Identification	1) In the assay, the retention time of the principal peak in the chromatogram obtained with the test solution is identical with that of the principal peak in the chromatogram obtained with the reference solution. ✓ 2) The infrared absorption spectrum is concordant with the reference spectrum (IR Album No.1096). ✓ 3) The aqueous solution yields the reaction characteristic of sodium salts. ✓	1) Complied 2) Complied 3) Complied
pH	6.0 ~ 7.5 ✓	6.7
Clarity and colour of solution	Should be clear and colorless ✓	Complied
Chlorides	N.M.T. 0.05% ✓	Complied
Ammonium	N.M.T. 0.05% ✓	Complied
Iron	N.M.T. 0.01% ✓	Complied
Phosphate	N.M.T. 0.1% ✓	Complied
Heavy metals	N.M.T. 5ppm ✓	Complied
Arsenic	N.M.T. 0.0001% ✓	Complied
Related substance		
5'-CMP	N.M.T. 0.3% ✓	0.007%
Other single impurity	N.M.T. 0.2% ✓	0.002%
Other total impurities	N.M.T. 0.7% ✓	0.002%
Residual solvents		
Methanol	N.M.T. 0.3% ✓	Not detected
Ethanol	N.M.T. 0.5% ✓	Not detected
Acetone	N.M.T. 0.5% ✓	Not detected
Loss on drying	N.M.T. 6.0% ✓	1.4%
Bacterial endotoxins	L.T. 0.30EU/mg ✓	Complied
Assay ($C_{14}H_{25}N_4NaO_{11}P_2$)	N.L.T. 98.0%, calculated on the dried basis. ✓	100.4%
Conclusion: Complies with the Standard of the ChP 2020 Part II.		
Analyst: <i>[Signature]</i>	Checked by: <i>[Signature]</i>	Manager of Quality Department: <i>[Signature]</i>

2024/11/20

2024/11/20





Kaiping Genuine

Biochemical Pharmaceutical Co., Ltd

GENUINE

ADD : NO. 1, XINKE RD, SHATANG TOWN, KAIPING,
GUANGDONG PROVINCE.

CAS	:33818-15-4
Batch No.	:240508
Quantity	:750Kg
Date of Manufacture	:2024-05-15
Expiry Date	:2027-05-14
Sampling Date	:2024-05-31
Report Date	:2024-06-06

Certificate of Analysis No.	: CDP-C 20240604
Product name	: Citicoline Sodium
Grade	: Pharmaceutical grade
Storage	: Airtight and Room temperature
Labeling	: As stated
Analysis Standard	: ChP2020 Part II and client's requirements

ANALYTICAL CONTROL TESTS APPLIED

Test Items	Specification	Results
Appearance ✓	White crystals or crystalline powder, odorless.	Complied
Solubility ✓	Freely soluble in water, insoluble in ethanol and in acetone.	Complied
Identification ✓	1) The color of solution reaction was positive reaction. 2) In the assay, the retention time of the principal peak in the chromatogram obtained with the test solution is identical with that of the principal peak in the chromatogram obtained with the reference solution. 3) The infrared absorption spectrum is concordant with the reference spectrum (IR Album No.1096). 4) The aqueous solution yields the reaction characteristic of sodium salts.	1) Complied 2) Complied 3) Complied 4) Complied
pH ✓	6.0 ~ 7.5	6.6
Clarity and colour of solution ✓	Should be clear and colorless	Complied
Chlorides ✓	N.M.T. 0.05%	Complied
Ammonium ✓	N.M.T. 0.05%	Complied
Iron ✓	N.M.T. 0.01%	Complied
Phosphate ✓	N.M.T. 0.1%	Complied
Heavy metals ✓	N.M.T. 5ppm	Complied
Arsenic ✓	N.M.T. 0.0001%	Complied
Related substance		Complied
5'-CMP ✓	N.M.T. 0.3%	
Other single impurity ✓	N.M.T. 0.2%	0.007%
Other total impurities ✓	N.M.T. 0.5%	0.005%
Residual solvents		0.008%
Methanol	N.M.T. 0.3%	
Ethanol	N.M.T. 0.5%	Not detected
Acetone	N.M.T. 0.5%	Not detected
Loss on drying	N.M.T. 6.0%	Not detected
Bacterial endotoxins	L.T. 0.30EU/mg	1.4%
Assay (C ₁₄ H ₂₅ N ₄ NaO ₁₁ P ₂)	N.L.T. 98.0%, calculated on the dried basis.	Complied 99.4%

Conclusion: Complies with the Standard of the ChP2020 Part II and client's requirements.

Analyst:

Checked by:

Manager of Quality Department:



09/07/24



Kaiping Genuine

Biochemical Pharmaceutical Co., Ltd

GENUINE

ADD : NO. 1, XINKE RD, SHATANG TOWN, KAIPING,
GUANGDONG PROVINCE.

CAS	:33818-15-4
Batch No.	:240208
Quantity	:750Kg
Date of Manufacture	:2024-02-26
Expiry Date	:2027-02-25
Sampling Date	:2024-03-02
Report Date	:2024-03-07

Certificate of Analysis No.	: CDP-C 20240303
Product name	: Citicoline Sodium
Grade	: Pharmaceutical grade
Storage	: Airtight and Room temperature
Labeling	: As stated
Analysis Standard	: ChP2020 Part II and client's requirements



ANALYTICAL CONTROL TESTS APPLIED

Test Items	Specifications	Results
Appearance	White crystals or crystalline powder, odorless.	Complied
Solubility	Freely soluble in water, insoluble in ethanol and in acetone.	Complied
Identification	1) The color of solution reaction was positive reaction. 2) In the assay, the retention time of the principal peak in the chromatogram obtained with the test solution is identical with that of the principal peak in the chromatogram obtained with the reference solution. 3) The infrared absorption spectrum is concordant with the reference spectrum (IR Album No.1096). 4) The aqueous solution yields the reaction characteristic of sodium salts.	1) Complied 2) Complied 3) Complied 4) Complied
pH	6.0 ~ 7.5	6.6
Clarity and colour of solution	Should be clear and colorless	Complied
Chlorides	N.M.T. 0.05%	Complied
Ammonium	N.M.T. 0.05%	Complied
Iron	N.M.T. 0.01%	Complied
Phosphate	N.M.T. 0.1%	Complied
Heavy metals	N.M.T. 5ppm	Complied
Arsenic	N.M.T. 0.0001%	Complied
Related substance		
5'-CMP	N.M.T. 0.3%	0.023%
Other single impurity	N.M.T. 0.2%	0.009%
Other total impurities	N.M.T. 0.5%	0.031%
Residual solvents		
Methanol	N.M.T. 0.3%	Not detected
Ethanol	N.M.T. 0.5%	Not detected
Acetone	N.M.T. 0.5%	Not detected
Loss on drying	N.M.T. 6.0%	1.9%
Bacterial endotoxins	L.T. 0.30EU/mg	Complied
Assay ($C_{14}H_{25}N_4NaO_{11}P_2$)	N.L.T. 98.0%, calculated on the dried basis.	99.6%

Conclusion: Complies with the Standard of the ChP2020 Part II and client's requirements.

Analyst: 胡颖珊

Checked by: 胡颖珊 Manager of Quality Department: 2024/3/7

2024/3/7



Kaiping Genuine

Biochemical Pharmaceutical Co., Ltd

GENUINE

CAS	:33818-15-4
Batch No.	:250308
Quantity	:750Kg
Date of Manufacture	:2025-03-17
Expiry Date	:2028-03-16
Sampling Date	:2025-03-21
Report Date	:2025-03-27

Certificate of Analysis No. : CDP-C 20250316

Product name : Citicoline Sodium

Grade : Pharmaceutical grade

Storage : Airtight and Room temperature

Labeling : As stated

Analysis Standard : ChP 2020 Part II

ANALYTICAL CONTROL TESTS APPLIED

Test Items	Test Results	Result
Appearance	White crystals or crystalline powder, odorless.	Complied
Solubility	Freely soluble in water, insoluble in ethanol and in acetone.	Complied
Identification	1) In the assay, the retention time of the principal peak in the chromatogram obtained with the test solution is identical with that of the principal peak in the chromatogram obtained with the reference solution. 2) The infrared absorption spectrum is concordant with the reference spectrum (IR Album No.1096). 3) The aqueous solution yields the reaction characteristic of sodium salts.	1) Complied 2) Complied 3) Complied
pH	6.0 ~ 7.5	6.5
Clarity and colour of solution	Should be clear and colorless	Complied
Chlorides	N.M.T. 0.05%	Complied
Ammonium	N.M.T. 0.05%	Complied
Iron	N.M.T. 0.01%	Complied
Phosphate	N.M.T. 0.1%	Complied
Heavy metals	N.M.T. 5ppm	Complied
Arsenic	N.M.T. 0.0001%	Complied
Related substance		
5'-CMP	N.M.T. 0.3%	0.004%
Other single impurity	N.M.T. 0.2%	0.003%
Other total impurities	N.M.T. 0.7%	0.003%
Residual solvents		
Methanol	N.M.T. 0.3%	Not detected
Ethanol	N.M.T. 0.5%	Not detected
Acetone	N.M.T. 0.5%	Not detected
Loss on drying	N.M.T. 6.0%	2.0%
Bacterial endotoxins	L.T. 0.30EU/mg	Complied
Assay (C ₁₄ H ₂₅ N ₄ NaO ₁₁ P ₂)	N.L.T. 98.0%, calculated on the dried basis.	100.2%

Conclusion: Complies with the Standard of the ChP 2020 Part II.

Analyst: *[Signature]*

Checked by: *[Signature]*

Manager of Quality Department: *[Signature]*



[Handwritten signature] 09/07/26

PT Equilab International
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Jakarta, 12430, Indonesia

Nama Perusahaan
Mersifarma
ALAMAT
Sukabumi
Nama Penanggung Jawab
Ibu Julfriaeni

No. Quotation
Tanggal Pembuatan
Tanggal Berlaku

826-MKT-VII-2026
06-Jul-2026
04-Oct-2026

Kategori	ID Produk	Nama Sampel	Parameter Uji	Metode Analisa	Harga/ Sampel (Rp)	Discount	Jumlah Sampel	Harga Total/ Sampel (Rp)	Leadtime Pengujian
Residu Pelarut	355	Bahan Baku/Produk Jadi	Methanol	GC-FID	Rp 350,000	20.00%	1	Rp 280,000	7-10 HK
Residu Pelarut	356	Bahan Baku/Produk Jadi	Ethanol	GC-FID	Rp 350,000	20.00%	1	Rp 280,000	7-10 HK
Residu Pelarut	370	Bahan Baku/Produk Jadi	Acetone	GC-FID	Rp 350,000	20.00%	1	Rp 280,000	7-10 HK
							Total Harga	Rp 840,000	

Keterangan

1. Logistik yang harus disiapkan oleh pihak sponsor 50 gr/batch sampel
2. Dokumen PO/ Persetujuan Penawaran Harga dan Surat Pengantar Sampel
3. Biaya analisa di atas belum termasuk biaya Pajak Pertambahan Nilai (11% PPN).
4. Termin pembayaran untuk pemeriksaan sample <Rp10.000.000 dilakukan dalam 14 hari, sedangkan >Rp10.000.000 dilakukan dalam 30 hari sejak tanggal invoice.

Demikian penawaran ini kami sampaikan, atas perhatian serta kerjasama yang baik kami mengucapkan terima kasih.

Hormat Kami,
PT Equilab International



Ronal Simanjuntak
President Director

Menyetujui

(Nama dan Tanda Tangan)

Kontak Equilab :

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