

## 수입식품등의 수입신고확인증

처리부서	부산청 신항수입식품검사소
연락처	051-831-2150

접 수 번 호	2023	접수일자	2023년 11월 14일
발 급 번 호	2BE2023	발급일자	2023년 11월 22일

수입 신고인 (수입 화주)	상 호	(주)세원통상	대표자	윤재식
	주 소	서울특별시 영등포구 당산로46길 3(당산동6가,4층)		

제 조 가 공 업 자	상 호		대표자	
	주 소			

수 입 신 고 대 행 업 자	성 명	
	주 소	

제품명	MICROCRYSTALLINE CELLULOSE CHEMICEL-102	한글명	결정셀룰로스 102
총수량		순중량	
과세가격		검사종류	
화물관리번호		B/L번호	
생산국(제조국)	인도	수출국	인도
해외제조업소(해외작업장)	CHEMFIELD CELLULOSE PVT.LTD.	수출업소	
HSK번호		품목	결정셀룰로스
용도	관매용	소비기한만료일	2028년 08월 01일
유전자변형식품표시	해당없음		
유기식품등 여부	아니오		
이력번호 (수입신고기만 해당함)			
수입신고확인증 발급조건			

### 제 품 내 역

No.	제품명	화물관리번호	수량 (단위:BAG)	순중량 (단위:kg)	과세가격 (단위:US\$)	소비기한만료일
1	MICROCRYSTALLINE CELLULOSE CHEMICEL-102					2028년 08월 01일
2	MICROCRYSTALLINE CELLULOSE CHEMICEL-102					2028년 08월 01일

「수입식품안전관리 특별법」 제20조 및 같은 법 시행규칙 제30조제1항에 따라 위와 같이 신고하였음을 확인합니다.

2023년 11월 22일

부산지방식품의약품안전청







# 수 입 신 고 필 증

(갑 제)

※ 처리기간 : 3일

① 신고번호 14750-23-100354M		② 신고일 2023/11/22		③ 세관.과 030-83		⑥ 입항일 2023/11/10		⑦ 전자인보이스 제출번호	
④ B/L(AWB)번호			⑤ 화물관리번호			⑧ 반입일 2023/11/11		⑨ 징수형태 11	
⑩ 신고인 ⑪ 수입자 (주)세원통상(세원통상-1-01-1-01-1 A) ⑫ 납세의무자 (세원통상-1-01-1-01-1 / 107-81-98575) (주소) 서울특별시 영등포구 당산로46길 3(당산동67) 4층 (07223) (상호) (주)세원통상 (성명) 윤재식 ⑬ 운송주선인 ⑭ 무역거래처				⑮ 통관계획 ⑯ 신고구분 ⑰ 거래구분 ⑱ 종류 21 일반수입(내수용) ⑳ MASTER B/L번호		② 원산지증명서 유무 ㉑ 가격신고서 유무 ㉒ 국내도착항 ㉓ 운송형태 ㉔ 적출국 IN INDIA ㉕ 선기명		㉖ 총중량 ㉗ 총포장갯수	
⑳ 검사(반입)장소									
● 품명·규격 (란번호/총란수 : 001/001 )									
㉑ 품 명 OTHER CELLULOSE						㉒ 상표 NO			
㉓ 거래품명 MICROCRYSTALLINE CELLULOSE									
㉔ 모델·규격		㉕ 성분		㉖ 수량		㉗ 단가(USD)		㉘ 금액(USD)	
(NO. 01) MICROCRYSTALLINE CELLULOSE CHEMICEL PH-102(FCC)									
(NO. 02) MICROCRYSTALLINE CELLULOSE CHEMICEL PH-102(FCC)									
㉙ 세번번호		㉚ 순중량		㉛ C/S검사 S 생략		㉜ 사후확인기관			
\$		㉝ 수 량		㉞ 검사변경					
₩		㉟ 환급물량		㊱ 원산지 IN-4-S-		㊲ 특수세액		0.00	
⑳ 수입요건확인 (발급서류명)		89-2BE2023 식품등의 수입신고확인증							
㉑ 세종 관 부		㉒ 세율(구분)		㉓ 감면율		㉔ 세액		㉕ 감면분납부호	
								감면액	
								*내국세종부호	
㉖ 결제금액(인도조건-통화종류-금액-결제방법)				㉗ 환 율					
㉘ 총과세가격 \$		㉙ 운 임		㉚ 가산금액		㉛ 납부번호			
₩		㉜ 보험료		㉝ 공제금액		㉞ 부가가치세과표			
㉟ 세 종		㊱ 세 액		※신고인기재란		㊲ 세관기재란 - 사후심사결과에 따라 적용세율 변경될 수 있음. '20.7.1일부터 중추기업의 컨테이너 수출입화물에 대해 세관검사비용을 지원하고 있으니, 지원 대상여부를 확 인하시어 신청하시기 바랍니다. (unipass.customs.go.kr) - 관세법 제157조의 2에 따라 화주 또는 반입자는 수입 신고 수리 후 15일 이내 수입화물을 반출하여야 함.(위 반시 과태료 부과) 			
관 세									
개별소비세									
교통에너지환경세									
주 세									
교 육 세									
농어촌특별세									
부가가치세									
신고기연가산세									
미신고가산세									
㊳ 총세액합계		㊴ 담당자 이선미		㊵ 접수일시 2023/11/22 13:59		㊶ 수리일자 2023/11/22			

발 행 번 호 : 2023155438850(2023.11.22)

세관.과 : 030-83 신고번호 : 14750-23-100354M

Page : 1/1

- \* 본 신고필증은 발행 후 세관심사 등에 따라 정정·수정될 수 있으므로 정확한 내용은 발행번호 등을 이용하여 관세청 인터넷통관포털 (<http://unipass.customs.go.kr>)에서 확인하시기 바랍니다.
- \* 본 수입신고필증은 세관에서 형식적 요건만을 심사한 것이므로 신고내용이 사실과 다른 때에는 신고인 또는 수입화주가 책임을 져야 합니다.
- \* 본 신고필증은 전자문서(PDF파일)로 발급된 신고필증입니다.
- \* 출력된 신고필증의 진본여부 확인은 전자문서의 '시점확인필' 스탬프로 클릭하여 확인할 수 있습니다.



### CERTIFICATE OF ANALYSIS

<b>Product:</b>	<b>Chemical® Microcrystalline Cellulose, E-460 (I)/FCC/USP-NF/BP/Ph. Eur./JP/IP</b>		
<b>Grade:</b>	PH-102	<b>Batch Size:</b>	
<b>Batch Number:</b>	CB23I2253	<b>A.R. Number:</b>	QCFG/2309010
<b>Manufacturing Date:</b>	Sep 2023	<b>Retest Date:</b>	Aug 2028
<b>Specification Number:</b>	FPSC.04.06	<b>Sample Quantity:</b>	
<b>Date of Analysis:</b>	10/10/2023	<b>Date of Release:</b>	10/10/2023

#	TEST	RESULT	SPECIFICATION
1	Description	Complies	White or almost white, fine or granular powder.
2	Solubility	Complies	Practically insoluble in water, in acetone, in anhydrous ethanol, in toluene in dilute acids and in 50g/L solution of sodium hydroxide.
3	Identification test A (USP-NF/Ph. Eur.)	Complies	Infrared Scan Complies with spectrum of reference substance.
4	Identification test B (USP-NF/Ph. Eur.), Method 1 (JP), Method A (BP)	Complies	Substance takes violet-blue colour
5	Identification Method 2 (JP) Method C (IP)	Complies	A white, opaque, bubble free dispersion is obtained that does not produce a supernatant liquid.
6	Identification test C (USP/Ph. Eur.) Method 3 (JP), Method B (BP)	212	Degree of Polymerization: NMT 350
7	Identification test A (IP)	Complies	A red colour is produced
8	Identification test B (IP)	Complies	A blue-purple colour is produced
9	Solubility in Ammoniacal solution of Copper Tetramine	Complies	Soluble
10	pH	6.4	Between 5.0 to 7.5
11	Conductivity, $\mu\text{S}/\text{cm}$	29	Not more than 75 $\mu\text{S}/\text{cm}$
12	Ether soluble substances, %	0.04	Not more than 0.05%
13	Water soluble substances, %	0.14	Not more than 0.20%
14	Arsenic	BDL	Not more than 2 ppm
15	Carboxyl group	0.10	Not more than 1%
16	Lead	0.107	Not more than 2 ppm
17	Mercury	BDL	Not more than 1 ppm
18	Cadmium	BDL	Not more than 0.5 ppm
19	Heavy metals, ppm	< 10	Not more than 10 ppm
20	Assay (on dried basis) %	98.9	97.0% - 102.0%
21	Starch and Dextrins	Complies	No blue or brownish red colour is produced
22	Organic Impurities	Complies	No red colour is produced
23	Loss on drying, %	3.7	Not more than 5.0%
24	Residue on Ignition/Sulfated Ash, %	0.04	Not more than 0.05%

Prepared by: *[Signature]*  
10/10/2023

Executive - Quality Control

Reviewed by: *[Signature]*  
10/10/2023

Manager - Quality Control

Approved by: *[Signature]*  
10/10/2023

Quality Assurance

Factory: B-40/68/7, MIDC Industrial Area, Kalmeshwar, Nagpur - 441501, Maharashtra, India. Phone: +91-7118-272-172



## CERTIFICATE OF ANALYSIS

<b>Product:</b>	Chemical® Microcrystalline Cellulose, E-460 (i)/FCC/USP-NF/ BP/ Ph. Eur./JP/IP		
<b>Grade:</b>	PH-102	<b>Batch Size:</b>	
<b>Batch Number:</b>	CB23I2253	<b>A.R. Number:</b>	QCFG/2309010
<b>Manufacturing Date:</b>	Sep 2023	<b>Retest Date:</b>	Aug 2028
<b>Specification Number:</b>	FPSC.04.06	<b>Sample Quantity:</b>	
<b>Date of Analysis:</b>	10/10/2023	<b>Date of Release:</b>	10/10/2023


#	TEST	RESULT	SPECIFICATION
25	Bulk Density (g/mL)	0.28	0.26 - 0.33 g/mL
26	Particle Size Distribution by Sieve Analysis: % Retention on 60 mesh	1	Not more than 8%
27	Particle Size Distribution by Sieve Analysis: % Retention on 200 mesh	53	Not less than 45%
28	Total Aerobic Microbial Count (TAMC), CFU/g	20	Not more than 1000 CFU/g
29	Total Yeast and Mould Count (TYMC), CFU/g	<10	Not more than 100 CFU/g
30	Escherichia Coli	Absent	Absent in 10g
31	Staphylococcus Aureus	Absent	Absent in 10g
32	Pseudomonas Aeruginosa	Absent	Absent in 10g
33	Salmonella Species	Absent	Absent in 10g
34	Enterobacteriaceae	Absent	Absent in 10g
35	Shigella	Absent	Absent in 10g

\*BDL - Below Detection Limit.

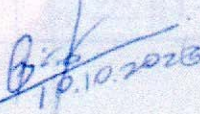
**Conclusion:** The above manufactured batch complies with the latest E-460(i) /FCC/USP/BP/Ph.Eur./JP/IP specifications and meets the requirement for residual solvents and elemental impurities as per USP43 <467>, BP 2020, Ph. Eur. 10 (5.4) and ICH Q3C and Q3D Guidelines.

The batch is manufactured in accordance to Indian FDA - GMP conditions and as per the latest ICH and IPEC guidelines for excipients, in an ISO 9001:2015, EXCIPACT Certified Quality System.

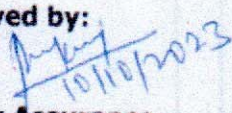
**Storage Conditions:** Store at ambient condition, keep containers sealed.

Prepared by:   
10.10.2023

Executive - Quality Control

Reviewed by:   
10.10.2023

Manager - Quality Control

Approved by:   
10/10/2023

Quality Assurance

Factory: B-40/6&7, MIDC Industrial Area, Kalmeshwar, Nagpur - 441501, Maharashtra, India. Phone: +91-7118-272-172





## CERTIFICATE OF ANALYSIS

<b>Product:</b>	<b>Chemical® Microcrystalline Cellulose, E-460 (i)/FCC/USP-NF/BP/Ph. Eur./JP/IP</b>		
<b>Grade:</b>	PH-102	<b>Batch Size:</b>	
<b>Batch Number:</b>	CB23I2254	<b>A.R. Number:</b>	QCFG/2309011
<b>Manufacturing Date:</b>	Sep 2023	<b>Retest Date:</b>	Aug 2028
<b>Specification Number:</b>	FPSC.04.06	<b>Sample Quantity:</b>	
<b>Date of Analysis:</b>	10/10/2023	<b>Date of Release:</b>	10/10/2023

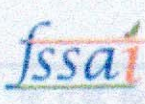
#	TEST	RESULT	SPECIFICATION
1	Description	Complies	White or almost white, fine or granular powder.
2	Solubility	Complies	Practically insoluble in water, in acetone, in anhydrous ethanol, in toluene in dilute acids and in 50g/L solution of sodium hydroxide.
3	Identification test A (USP-NF/Ph. Eur.)	Complies	Infrared Scan Complies with spectrum of reference substance.
4	Identification test B (USP-NF/Ph. Eur.), Method 1 (JP), Method A (BP)	Complies	Substance takes violet-blue colour
5	Identification Method 2 (JP) Method C (IP)	Complies	A white, opaque, bubble free dispersion is obtained that does not produce a supernatant liquid.
6	Identification test C (USP/Ph. Eur.) Method 3 (JP), Method B (BP)	213	Degree of Polymerization: NMT 350
7	Identification test A (IP)	Complies	A red colour is produced
8	Identification test B (IP)	Complies	A blue-purple colour is produced
9	Solubility in Ammoniacal solution of Copper Tetramine	Complies	Soluble
10	pH	6.6	Between 5.0 to 7.5
11	Conductivity, $\mu\text{S/cm}$	20	Not more than 75 $\mu\text{S/cm}$
12	Ether soluble substances, %	0.03	Not more than 0.05%
13	Water soluble substances, %	0.13	Not more than 0.20%
14	Arsenic	BDL	Not more than 2 ppm
15	Carboxyl group	0.10	Not more than 1%
16	Lead	0.109	Not more than 2 ppm
17	Mercury	BDL	Not more than 1 ppm
18	Cadmium	BDL	Not more than 0.5 ppm
19	Heavy metals, ppm	< 10	Not more than 10 ppm
20	Assay (on dried basis) %	99.1	97.0% - 102.0%
21	Starch and Dextrins	Complies	No blue or brownish red colour is produced
22	Organic Impurities	Complies	No red colour is produced
23	Loss on drying, %	3.5	Not more than 5.0%
24	Residue on Ignition/Sulfated Ash, %	0.04	Not more than 0.05%

Prepared by: *[Signature]*  
10/10/2023  
Executive - Quality Control

Reviewed by: *[Signature]*  
10/10/2023  
Manager - Quality Control

Approved by: *[Signature]*  
10/10/2023  
Quality Assurance

Factory: B-40/6&7, MIDC Industrial Area, Kalmeshwar, Nagpur - 441501, Maharashtra, India. Phone: +91-7118-272-172





## CERTIFICATE OF ANALYSIS

<b>Product:</b>	<b>Chemical® Microcrystalline Cellulose, E-460 (I)/FCC/USP-NF/BP/Ph. Eur./JP/IP</b>		
<b>Grade:</b>	PH-102	<b>Batch Size:</b>	
<b>Batch Number:</b>	CB23I2254	<b>A.R. Number:</b>	QCFG/2309011
<b>Manufacturing Date:</b>	Sep 2023	<b>Retest Date:</b>	Aug 2028
<b>Specification Number:</b>	FPSC.04.06	<b>Sample Quantity:</b>	
<b>Date of Analysis:</b>	10/10/2023	<b>Date of Release:</b>	10/10/2023

#	TEST	RESULT	SPECIFICATION
25	Bulk Density (g/mL)	0.29	0.26 – 0.33 g/mL
26	Particle Size Distribution by Sieve Analysis: % Retention on 60 mesh	2	Not more than 8%
27	Particle Size Distribution by Sieve Analysis: % Retention on 200 mesh	52	Not less than 45%
28	Total Aerobic Microbial Count (TAMC), CFU/g	10	Not more than 1000 CFU/g
29	Total Yeast and Mould Count (TYMC), CFU/g	<10	Not more than 100 CFU/g
30	Escherichia Coli	Absent	Absent in 10g
31	Staphylococcus Aureus	Absent	Absent in 10g
32	Pseudomonas Aeruginosa	Absent	Absent in 10g
33	Salmonella Species	Absent	Absent in 10g
34	Enterobacteriaceae	Absent	Absent in 10g
35	Shigella	Absent	Absent in 10g

\*BDL – Below Detection Limit.

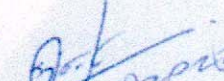
**Conclusion:** The above manufactured batch complies with the latest E-460(I) /FCC/USP/BP/Ph.Eur./JP/IP specifications and meets the requirement for residual solvents and elemental impurities as per USP43 <467>, BP 2020, Ph. Eur. 10 (5.4) and ICH Q3C and Q3D Guidelines.

The batch is manufactured in accordance to Indian FDA - GMP conditions and as per the latest ICH and IPEC guidelines for excipients, in an ISO 9001:2015, EXCIPACT Certified Quality System.

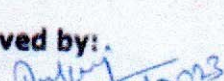
**Storage Conditions:** Store at ambient condition, keep containers sealed.

Prepared by:   
10.10.2023

Executive - Quality Control

Reviewed by:   
10.10.2023

Manager - Quality Control

Approved by:   
10/10/2023

Quality Assurance

Factory: B-40/6&7, MIDC Industrial Area, Kalmeshwar, Nagpur - 441501, Maharashtra, India. Phone: +91-7118-272-172

