

Certificate of Analysis

CARGILL S.L..U.
MARIE CURIE 06
E-08760 MARTORELL

New: Manufacturing location will be printed

Ship to:

Customer name & adress

Material 100145764 Delivery XXXXXXXX

C*PHARMDEX 02010 DEXTROSE PO Number XXXXXXXX

MONOHYDRATE

Customer Product Code Contract Number XXXXXXX

CN Code 1702 30 50

Batch 0016430049 New: Truck/Rail/Container ID XX-XXX-XX batch number format Best Before Date: 09.2023

Characteristic	Result	Unit Of Measure	Min	Max	Method	
Appearance Ph.Eur	PASS TEST				Ph.Eur.	
Solubility Ph.Eur.	PASS TEST				Ph.Eur.	New:
Identification B Ph.Eur. HPLC	PASS TEST				Ph.Eur.	methods will be added
Identification E Ph.Eur. water	PASS TEST				Ph.Eur.	
Appearance of solution Ph.Eur.	PASS TEST			1	Ph.Eur.	
Related substances Ph.Eur. on d.b.	PASS TEST				Ph.Eur.	
Rel. Subst.,disregard limit Ph.Eur.on di	0,05	%		0,05	Ph.Eur.	
Rel. Subst., total Ph.Eur. on d.b.	0,40	%		0,50	Ph.Eur.	
Rel. Subst., unspecified Ph.Eur. on d.b	. 0,09	%		0,10	Ph.Eur.	
Impurity D, fructose Ph.Eur. on d.b.	0,10	%		0,15	Ph.Eur.	
Impurity C, maltotriose Ph.Eur. on d.b.	0,02	%		0,20	Ph.Eur.	
Sum of impurities A and B Ph.Eur. d.b.	0,33	%		0,40	Ph.Eur.	
Conductivity Ph.Eur.	19,0	μS/cm		20,0	Ph.Eur.	
Dextrin Ph.Eur.	PASS TEST				Ph.Eur.	
Water Ph.Eur.	8,0	%	7,5	9,5	Ph.Eur.	
Soluble starch, sulfites Ph.Eur.	13,0	ppm		15,0	Ph.Eur.	
Bacterial endotoxins Ph.Eur.	1,00	IU/g		1,25	Ph.Eur.	
Tot. aerobic microbial count Ph.Eur. /g	TYPICAL			50	Ph.Eur.	
Tot. comb. yeasts/moulds count	TYPICAL			50	Ph.Eur.	
Ph.Eur./g						
Tot.combined yeasts/moulds	TYPICAL			50		



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E-08760 MARTORELL

Characteristic	Result	Unit Of Measure	Min	Max	Method
countUSP/NFg					
Identification A Ph.Eur. sp.opt.rot.	TYPICAL				Ph.Eur.
Tot. aerobic microbial count USP/NF /g	TYPICAL			50	
Rel. Subst., Fructose USP/NF on d.b.	TYPICAL	%		0,15	USP/NF
Identification C USP/NF water	TYPICAL	%	7,5	9,5	USP/NF
Rel. Subst., MaltIsomalt. USP/NF on db	TYPICAL	%		0,40	USP/NF
Rel. Subst., tot.impurities USP/NF on db	TYPICAL	%		0,50	USP/NF
E. coli Ph.Eur. Abs/g	TYPICAL				Ph.Eur.
Identification C Ph.Eur. TLC	TYPICAL				Ph.Eur.
Colour and clarity of solution USP/NF	TYPICAL				USP/NF
Soluble starch, sulfites USP/NF	TYPICAL	ppm		15,0	USP/NF
Conductivity USP/NF 25°C	TYPICAL	μS/cm		20	USP/NF
Related substances, unspecified Ph.Eur.	TYPICAL	%		0,10	USP/NF
ldentification D Ph.Eur. cupri tartari	TYPICAL				Ph.Eur.
Rel. Subst., Maltotriose USP/NF on d.b	. TYPICAL	%		0,20	USP/NF
Aluminium	TYPICAL	mg/kg		0,1	AAS
Identification B USP/NF HPLC	TYPICAL				USP/NF
Pyrogens Ph.Eur.	TYPICAL				Ph.Eur.
E. coli USP/NF Abs/g	TYPICAL				
Assay, content USP/NF on d.b.	TYPICAL	%	97,5	102,0	USP/NF
Dextrin USP/NF	TYPICAL				USP/NF
Identification A USP/NF IR	TYPICAL				USP/NF

Results listed on the COA as typical or identified with an asterisk (*) are not tested on each batch, have not been tested for the batch, and represent values or ranges normally found in this material.

SPECIFICA: N.26-02-10-02_0/04 DEL 12/2017

THE PRODUCT WAS DERIVED FROM NON-GM RAW MATERIALS.

HEREWITH WE CONFIRM THAT THIS BATCH IS IN COMPLIANCE WITH THE QUALITY REQUIREMENTS OF THE CURRENT VERSIONS OF PH.EUR. AND USP/ NF.

This COA was generated electronically. If you have any questions concerning this document, please feel free to contact Cargill at the number listed below.

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New:

Conformity values will be indicated as typical result on the CoA

No legal requirements will be printed on CoA (information will be available on product data sheet)

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