



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 MONOHYDRATE	PO Number	XXXXXXXX
Customer Product Code		Contract Number	XXXXXXXX
		CN Code	1702 30 50
Batch	0016430049	Truck/Rail/Container ID	XX-XXX-XX
Date of Manufacture	22.09.2021	Best Before Date:	09.2023

New:
batch number format

Characteristic	Result	Unit Of Measure	Min	Max	Method
Appearance Ph.Eur	PASS TEST				Ph.Eur.
Solubility Ph.Eur.	PASS TEST				Ph.Eur.
Identification B Ph.Eur. HPLC	PASS TEST				Ph.Eur.
Identification E Ph.Eur. water	PASS TEST				Ph.Eur.
Appearance of solution Ph.Eur.	PASS TEST				Ph.Eur.
Related substances Ph.Eur. on d.b.	PASS TEST				Ph.Eur.
Rel. Subst.,disregard limit Ph.Eur.on db	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 Ph.Eur./g	TYPICAL			50	Ph.Eur.
Tot.combined yeasts/moulds	TYPICAL			50	

New:
methods will be added



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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., Malt.-Isomalt. 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
Identification 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