



ROQUETTE

LC E AELP CERTIFICATE OF ANALYSIS / COMPLIANCE

PAGE 1

PT BRENNTAG

GRAHA PRATAMA BUILDING 17TH FLOOR

JL.MT.HARYONO KAV.15

ID-12810 JAKARTA SELATAN - INDONESIA

LYCADEX PF/DEXTROSE MONOHYDRAT EP-BP-USP CUSTOMER.... BTG/SG/ID/50/JAKARTA

361102 K

DELIVERY REF PTA74P1
TONNAGE..... 10.000 KG
ORDER..... 4500178441/10
BATCH..... E2CK1
MANUF&TESTED 13 MAY 2021

RETEST DATE

13 MAY 2024

EP / USP / JP

DESCRIPTION

WHITE OR ALMOST WHITE CRYSTALLINE
POWDER, ODOURLESS.

MEANING TESTED = ANALYZED
MONITORED = MONITORING PLAN
GUARANTEED = COMPLIANCE DATA

IDENTIFICATION TEST-A	EP	CONFORM	TESTED
IDENTIFICATION TEST-A	USP	CONFORM	GUARANTEED
IDENTIFICATION TEST-B	EP-USP	CONFORM	TESTED
IDENTIFICATION TEST-C	USP	CONFORM	TESTED
IDENTIFICATION TEST-E	EP	CONFORM	TESTED
IDENTIFICATION 1	JP	CONFORM	GUARANTEED
IDENTIFICATION 2	JP	CONFORM	TESTED
APPEARANCE IN SOLUTION		CONFORM	TESTED
CONDUCTIVITY	MICS/CM	1	TESTED
DEXTRIN		CONFORM	TESTED



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SOLUBLE STARCH, SULPHITES	MG/KG	< 15	MONITORED
WATER CONTENT	%	8,7	TESTED
HEAVY METALS	MG/KG	< 4,0	MONITORED
DEXTROSE	%	100,2	TESTED
MALTOSE + ISOMALTOSE	%	< 0,4	TESTED
MALTOTRIOSE	%	< 0,2	TESTED
FRUCTOSE	%	< 0,15	TESTED
ANY UNSPECIFIED IMPURITIES	%	< 0,10	TESTED
TOTAL OF IMPURITIES	%	< 0,5	TESTED



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PAGE 3

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TOTAL AEROBIC MICROBIAL COUNT	CFU/G	< 100	MONITORED
TOTAL YEASTS AND MOULDS COUNT	CFU/G	< 100	MONITORED
ESCHERICHIA COLI	ABS/G	CONFORM	MONITORED
SALMONELLAE	ABS/10G	CONFORM	MONITORED
PYROGEN TEST EP 3 RABBITS	.	< 1,15	MONITORED
PYROGEN TEST EP 6 RABBITS		CONFORM	MONITORED
ENDOTOXIN /LAL TEST IN EU/G	1,25MAX	CONFORM	TESTED


THIS BATCH MEETS THE REQUIREMENTS OF THE CURRENT
EP/USP/JP OFFICIAL MONOGRAPHS.

MANUFACTURING SITE

ROQUETTE FRERES, 1 RUE DE LA HAUTE LOGE, 62136 LESTREM, FRANCE

DERBOIS BENJAMIN, 22 JUNE 2021

QUALITY ASSURANCE MANAGER

Certificate has an electronic signature.