

REF : 80460880 / 900010

Certificate of analysis /
Compliance

Manufacturing site

ROQUETTE ITALIA SPA, VIA SERRAVALLE 26, 15063, CASSANO SPINOLA, AL, ITALIA

References

Product name	ROQUETTE DEXTROSE MONOHYDRATE F
GTIN/EAN	03604740079387
Material Code	5100002560
Batch Number	448907
Manufacturing Date	2022/09/05
Expiry Date	2027/09/04
Sales Order / Item	10310290 / 10
Delivery / Item	80460880 / 900010
Your Reference	3223500011

Product description

Aspect	Crystalline powder
Color	White or almost white

Results of Analysis / Compliance

Parameter	Specification range	Result	Unit	Status
IDENTIFICATION TEST A (EP)	Conform	Conform		Guaranteed
IDENTIFICATION TEST A (USP/NF)	Conform	Conform		Guaranteed
IDENTIFICATION TEST B (EP)	Conform	Conform		Guaranteed
IDENTIFICATION TEST B (USP/NF)	Conform	Conform		Guaranteed
IDENTIFICATION TEST C (USP/NF)	Conform	Conform		Guaranteed
IDENTIFICATION TEST E (EP)	Conform	Conform		Guaranteed
APPEARANCE IN SOLUTION (CONFORMITY)	Conform	Conform		Guaranteed

REF : 80460880 / 900010

Certificate of analysis /
Compliance

Parameter	Specification range	Result	Unit	Status
CONDUCTIVITY AT 20% (W/W)	<= 20	2	µS/cm	Inspected
DEXTRIN TEST CONFORMITY	Conform	Conform		Inspected
GLUCOSE (ON DS)	97,5 - 102,0	99,8	%	Inspected
WATER CONTENT	7,5 - 9,5	8,1	%	Inspected
MALTOSE + ISOMALTOSE (AS IS)	<= 0,4	0,2	%	Inspected
FRUCTOSE (ON DS)	<= 0,15	0,00	%	Inspected
MALTOTRIOSE (AS IS)	<= 0,2	0,0	%	Inspected
ANY UNSPECIFIED IMPURITY (ON DS)	<= 0,10	< 0,10	%	Inspected
TOTAL OF IMPURITIES	<= 0,5	< 0,5	%	Inspected
SOLUBLE STARCH (CONFORMITY)	Conform	Conform		Guaranteed
SIEVE >315 MIC	<= 7,0	3,0	%.	Inspected
SIEVE >250 MIC/60 MESH	<= 25	7	%.	Inspected
SIEVE >100 MIC	>= 10	52	%.	Inspected
TOTAL COUNT	<= 1000	Conform	/g	Guaranteed
YEASTS AND MOULDS	<= 100	Conform	/g	Guaranteed
ESCHERICHIA COLI IN 1g	Not detected	Conform		Guaranteed
SALMONELLAE IN 10g	Not detected	Conform		Guaranteed

REF : 80460880 / 900010

**Certificate of analysis /
Compliance**

Other batch compliance:

Meets the requirements of the current monograph of:

- European Pharmacopoeia : GLUCOSE MONOHYDRATE (0178)
- US Pharmacopeia : DEXTROSE

When tested accordingly, this product complies with relevant monograph requirements. The compliance to the general chapters depends on plant manufacturing standards. This product is not recommended to be used as active ingredient since it is not fully manufactured according to pharma cGMPs . Please contact us for further information.

*Notes: This document has been produced and signed automatically through a validated IT system.
All the dates are formatted like YYYY/MM/DD.*

2022/09/14

BOETTI Andrea
PLANT QUALITY MANAGER



REF : 80500298 / 900010

Certificate of analysis /
Compliance

Manufacturing site

ROQUETTE ITALIA SPA, VIA SERRAVALLE 26, 15063, CASSANO SPINOLA, AL, ITALIA

References

Product name	ROQUETTE DEXTROSE MONOHYDRATE F
GTIN/EAN	03604740079387
Material Code	5100002560
Batch Number	500108
Manufacturing Date	2022/11/08
Expiry Date	2027/11/07
Sales Order / Item	10436723 / 10
Delivery / Item	80500298 / 900010
Your Reference	3223500644

Product description

Aspect	Crystalline powder
Colour	White or almost white

Results of Analysis / Compliance

Parameter	Specification range	Result	Unit	Status
IDENTIFICATION TEST A (EP)	Conform	Conform		Guaranteed
IDENTIFICATION TEST A (USP/NF)	Conform	Conform		Guaranteed
IDENTIFICATION TEST B (EP)	Conform	Conform		Guaranteed
IDENTIFICATION TEST B (USP/NF)	Conform	Conform		Guaranteed
IDENTIFICATION TEST C (USP/NF)	Conform	Conform		Guaranteed
IDENTIFICATION TEST E (EP)	Conform	Conform		Guaranteed
APPEARANCE IN SOLUTION (CONFORMITY)	Conform	Conform		Guaranteed

REF : 80500298 / 900010

Certificate of analysis /
Compliance

Parameter	Specification range	Result	Unit	Status
CONDUCTIVITY AT 20% (W/W)	<= 20	2	µS/cm	Inspected
DEXTRIN TEST CONFORMITY	Conform	Conform		Inspected
GLUCOSE (ON DS)	97,5 - 102,0	99,7	%	Inspected
WATER CONTENT	7,5 - 9,5	8,4	%	Inspected
MALTOSE + ISOMALTOSE (AS IS)	<= 0,4	0,3	%	Inspected
FRUCTOSE (ON DS)	<= 0,15	0,00	%	Inspected
MALTOTRIOSE (AS IS)	<= 0,2	0,0	%	Inspected
ANY UNSPECIFIED IMPURITY (ON DS)	<= 0,10	< 0,10	%	Inspected
TOTAL OF IMPURITIES	<= 0,5	< 0,5	%	Inspected
SOLUBLE STARCH (CONFORMITY)	Conform	Conform		Guaranteed
SIEVE >315 MIC	<= 7,0	3,0	%.	Inspected
SIEVE >250 MIC/60 MESH	<= 25	7	%.	Inspected
SIEVE >100 MIC	>= 10	53	%.	Inspected
TOTAL COUNT	<= 1000	Conform	/g	Guaranteed
YEASTS AND MOULDS	<= 100	Conform	/g	Guaranteed
ESCHERICHIA COLI IN 1g	Not detected	Conform		Guaranteed
SALMONELLAE IN 10g	Not detected	Conform		Guaranteed

REF : 80500298 / 900010

**Certificate of analysis /
Compliance**

Other batch compliance:

Meets the requirements of the current monograph of:

- European Pharmacopoeia : GLUCOSE MONOHYDRATE (0178)
- USP-NF Pharmacopoeia : DEXTROSE
- Japanese Pharmacopoeia : GLUCOSE HYDRATE

When tested accordingly, this product complies with relevant monograph requirements. The compliance to the general chapters depends on plant manufacturing standards. This product is not recommended to be used as active ingredient since it is not fully manufactured according to pharma cGMPs . Please contact us for further information.

*Notes: This document has been produced and signed automatically through a validated IT system.
All the dates are formatted like YYYY/MM/DD.*

2022/11/15

BOETTI Andrea
PLANT QUALITY MANAGER



REF : 80500296 / 900010

Certificate of analysis /
Compliance

Manufacturing site

ROQUETTE ITALIA SPA, VIA SERRAVALLE 26, 15063, CASSANO SPINOLA, AL, ITALIA

References

Product name	ROQUETTE DEXTROSE MONOHYDRATE F
GTIN/EAN	03604740010052
Material Code	5100000666
Batch Number	500419
Manufacturing Date	2022/11/04
Expiry Date	2027/11/03
Sales Order / Item	10310318 / 10
Delivery / Item	80500296 / 900010
Your Reference	3223500012

Product description

Aspect	Crystalline powder
Colour	White or almost white

Results of Analysis / Compliance

Parameter	Specification range	Result	Unit	Status
IDENTIFICATION TEST A (EP)	Conform	Conform		Guaranteed
IDENTIFICATION TEST A (USP/NF)	Conform	Conform		Guaranteed
IDENTIFICATION TEST B (EP)	Conform	Conform		Guaranteed
IDENTIFICATION TEST B (USP/NF)	Conform	Conform		Guaranteed
IDENTIFICATION TEST C (USP/NF)	Conform	Conform		Guaranteed
IDENTIFICATION TEST E (EP)	Conform	Conform		Guaranteed
APPEARANCE IN SOLUTION (CONFORMITY)	Conform	Conform		Guaranteed

REF : 80500296 / 900010

Certificate of analysis /
Compliance

Parameter	Specification range	Result	Unit	Status
CONDUCTIVITY AT 20% (W/W)	<= 20	2	µS/cm	Inspected
DEXTRIN TEST CONFORMITY	Conform	Conform		Inspected
GLUCOSE (ON DS)	97,5 - 102,0	99,7	%	Inspected
WATER CONTENT	7,5 - 9,5	8,6	%	Inspected
MALTOSE + ISOMALTOSE (AS IS)	<= 0,4	0,2	%	Inspected
FRUCTOSE (ON DS)	<= 0,15	0,00	%	Inspected
MALTOTRIOSE (AS IS)	<= 0,2	0,1	%	Inspected
ANY UNSPECIFIED IMPURITY (ON DS)	<= 0,10	< 0,10	%	Inspected
TOTAL OF IMPURITIES	<= 0,5	< 0,5	%	Inspected
SOLUBLE STARCH (CONFORMITY)	Conform	Conform		Guaranteed
SIEVE >315 MIC	<= 7,0	4,0	%.	Inspected
SIEVE >250 MIC/60 MESH	<= 25	10	%.	Inspected
SIEVE >100 MIC	>= 10	58	%.	Inspected
TOTAL COUNT	<= 1000	Conform	/g	Guaranteed
YEASTS AND MOULDS	<= 100	Conform	/g	Guaranteed
ESCHERICHIA COLI IN 1g	Not detected	Conform		Guaranteed
SALMONELLAE IN 10g	Not detected	Conform		Guaranteed

REF : 80500296 / 900010

**Certificate of analysis /
Compliance**

Other batch compliance:

Meets the requirements of the current monograph of:

- European Pharmacopoeia : GLUCOSE MONOHYDRATE (0178)
- USP-NF Pharmacopoeia : DEXTROSE
- Japanese Pharmacopoeia : GLUCOSE HYDRATE

When tested accordingly, this product complies with relevant monograph requirements. The compliance to the general chapters depends on plant manufacturing standards. This product is not recommended to be used as active ingredient since it is not fully manufactured according to pharma cGMPs . Please contact us for further information.

*Notes: This document has been produced and signed automatically through a validated IT system.
All the dates are formatted like YYYY/MM/DD.*

2022/11/14

BOETTI Andrea
PLANT QUALITY MANAGER

