

Dextran Products Standard Operating Procedures

S.O.P.# QC3450-02

Title: Specifications for Dextran Powder MW 3,000 Supersedes: SOP #QC3450-01

Effective Date: AUG 17 2021

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FINISHED PRODUCT SPECIFICATIONS

<u>TEST</u>	<u>SPECIFICATION</u>
Appearance:	White to slightly off-white powder
Colour of Solution at 375nm (10% Solution)	NMT 0.12 OD Units
Specific Rotation $[\alpha]^{20}_D$ (2% Solution)	NLT +140°
pH (10% solution)	4.5 to 7.0
Loss on Drying	NMT 7.0%
Ash Content	NMT 2.0%
Intrinsic Viscosity at 37°C (1% solution)	0.045 to 0.055
Cold Water Solubility (1% solution)	Soluble in cold water

Written By: <i>BB</i>	Title: Analytical Chemist	Date: July 22, 2021
Reviewed By: <i>2n</i>	Title: QC Manager	Date: July 22, 2021
Approved By: <i>Ctrul</i>	Title: QA Manager	Date: July 22, 2021

Dextran Products, Scarborough, Ontario, M1L 2H5, Canada

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S.O.P.# QC3451-02

Title: Specifications for Dextran Powder MW 6,000 Supersedes: SOP #QC3451-01

Effective Date: AUG 17 2021

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FINISHED PRODUCT SPECIFICATIONS

TEST

SPECIFICATION

Appearance:	White to slightly off-white powder
Colour of Solution at 375nm (10% Solution)	NMT 0.12 OD Units
Specific Rotation $[\alpha]^{20}_D$ (2% Solution)	NLT +148°
pH (10% solution)	4.5 to 7.0
Loss on Drying	NMT 7.0%
Ash Content	NMT 2.0%
Intrinsic Viscosity at 37°C (1% solution)	0.063 to 0.077
Cold Water Solubility (1% Solution)	Soluble in cold water

Written By: <i>BB</i>	Title: Analytical Chemist	Date: July 22, 2021
Reviewed By: <i>SM</i>	Title: QC Manager	Date: July 22, 2021
Approved By: <i>Chad</i>	Title: QA Manager	Date: July 22, 2021

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S.O.P.# QC3452-02

Title: Specifications for Dextran Powder MW 10,000 Supersedes: SOP #QC3452-01

Effective Date: AUG 17 2021

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FINISHED PRODUCT SPECIFICATIONS

TEST

SPECIFICATION

Appearance:	White to slightly off-white powder
Colour of Solution at 375nm (10% Solution)	NMT 0.20 OD Units
Specific Rotation $[\alpha]^{20}_D$ (2% Solution)	NLT + 148°
pH (10% solution)	4.5 to 7.0
Loss on Drying	NMT 7.0%
Ash Content	NMT 2.0%
Intrinsic Viscosity at 37°C (1% solution)	0.08 to 0.11
Cold Water Solubility (1% solution)	Soluble in cold water

Written By: <i>GG</i>	Title: Analytical Chemist	Date: July 22, 2021
Reviewed By: <i>rn</i>	Title: QC Manager	Date: July 22, 2021
Approved By: <i>Chul</i>	Title: QA Manager	Date: July 22, 2021

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S.O.P.# QC3453-02

Title: Specifications for Dextran Powder MW 20,000 Supersedes: SOP #QC3453-01

Effective Date: AUG 17 2021

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FINISHED PRODUCT SPECIFICATIONS

TEST

SPECIFICATION

Appearance:	White to slightly off-white powder
Colour of Solution at 375nm (10% Solution)	NMT 0.20 OD Units
Specific Rotation $[\alpha]^{20}_D$ (2% Solution)	NLT +148°
pH (10% Solution)	4.5 to 7.0
Loss on Drying	NMT 7.0%
Ash Content	NMT 2.0%
Intrinsic Viscosity, at 37°C (1% solution)	0.11 to 0.14
Cold Water Solubility (1% solution)	Soluble in cold water

Written By: <i>bb</i>	Title: Analytical Chemist	Date: July 22, 2021
Reviewed By: <i>m</i>	Title: QC Manager	Date: July 22, 2021
Approved By: <i>Clnd</i>	Title: QA Manager	Date: July 22, 2021

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S.O.P.# QC3454-02

Title: Specifications for Dextran Powder MW 40,000

Supersedes: QC #QC3454-1

Effective Date: AUG 17 2021




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FINISHED PRODUCT SPECIFICATIONS

TEST

SPECIFICATION

Appearance:	White to slightly off-white powder
Colour of Solution at 375nm (10% Solution)	NMT 0.20 OD Units
Specific Rotation $[\alpha]^{20}_D$ (2% Solution)	Between +195° and +203°
pH (10% Solution)	4.5 to 7.0
Loss on Drying	NMT 7.0%
Ash Content	NMT 2.0%
Intrinsic Viscosity at 37°C (1% Solution)	0.16 to 0.20
Cold Water Solubility (1% Solution)	Soluble in cold water

Written By: 	Title: Analytical Chemist	Date: July 22, 2021
Reviewed By: 	Title: QA Manager	Date: July 22, 2021
Approved By: 	Title: QA Manager	Date: July 22, 2021

Dextran Products, Scarborough, Ontario, M1L 2H5, Canada

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S.O.P.# QC3455-02

Title: Specifications for Dextran Powder MW 70,000 Supersedes: SOP #QC3455-01

Effective Date: AUG 17 2021




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FINISHED PRODUCT SPECIFICATIONS

TEST

SPECIFICATION




Appearance:	White to slightly off-white powder
Colour of Solution at 375nm (6% Solution)	NMT 0.15 OD Units
Specific Rotation $[\alpha]^{20}_D$ (2% Solution)	Between +195° and +203°
pH (6% Solution)	4.5 to 7.0
Loss on Drying	NMT 7.0%
Ash Content	NMT 2.0%
Intrinsic Viscosity at 37° C (1% Solution)	0.22 to 0.27
Cold Water Solubility (1% Solution)	Soluble in cold water

Written By: 	Title: Analytical Chemist	Date: July 22, 2021
Reviewed By: 	Title: QC Manager	Date: July 22, 2021
Approved By: 	Title: QA Manager	Date: July 22, 2021

Dextran Products, Scarborough, Ontario, M1L 2H5, Canada




FINISHED PRODUCT SPECIFICATIONS

<u>TEST</u>	<u>SPECIFICATION</u>
Appearance:	White to slightly off-white powder
Colour of Solution at 375nm (6% Solution)	NMT 0.15 OD Units
Specific Rotation $[\alpha]^{20}_D$ (2% Solution)	Between +195° and +203°
pH (6% Solution)	4.5 to 7.0
Loss on Drying	NMT 7.0%
Ash Content	NMT 2.0%
Intrinsic Viscosity at 37°C (1% Solution)	0.26 to 0.32
Cold Water Solubility (1% Solution)	Soluble in cold water

Written By: 	Title: Analytical Chemist	Date: July 22, 2021
Reviewed By: 	Title: QC Manager	Date: July 22, 2021
Approved By: 	Title: QC Manager	Date: July 22, 2021




FINISHED PRODUCT SPECIFICATIONS

<u>TEST</u>	<u>SPECIFICATION</u>
Appearance:	White to slightly off-white powder
Colour of Solution at 375nm (6% Solution)	NMT 0.15 OD Units
Specific Rotation $[\alpha]^{20}_D$ (2% Solution)	Between +195° and +203°
pH (6% Solution)	4.5 to 7.0
Loss on Drying	NMT 7.0%
Ash Content	NMT 2.0%
Intrinsic Viscosity at 37°C (1% Solution)	0.32 to 0.37
Cold Water Solubility (1% Solution)	Soluble in cold water

Written By: 	Title: Analytical Chemist	Date: July 22, 2021
Reviewed By: 	Title: QC Manager	Date: July 22, 2021
Approved By: 	Title: QA Manager	Date: July 22, 2021

FINISHED PRODUCT SPECIFICATIONS

<u>TEST</u>	<u>SPECIFICATION</u>
Appearance:	White to slightly off-white powder
Colour of Solution at 375nm (6% Solution)	NMT 0.15 OD Units
Specific Rotation $[\alpha]^{20}_D$ (2% Solution)	Between +195° and +203°
pH (6% Solution)	4.5 to 7.0
Loss on Drying	NMT 7.0%
Ash Content	NMT 2.0%
Intrinsic Viscosity at 37°C (1% Solution)	0.40 to 0.50
Cold Water Solubility (1% Solution)	Soluble in cold water

Written By:		Title: Analytical Chemist	Date: July 22, 2021
Reviewed By:		Title: QC Manager	Date: July 22, 2021
Approved By:		Title: QA Manager	Date: July 22, 2021

FINISHED PRODUCT SPECIFICATIONS

<u>TEST</u>	<u>SPECIFICATION</u>
Appearance:	White to slightly off-white powder
Colour of Solution at 375nm (6% Solution)	NMT 0.15 OD Units
Specific Rotation $[\alpha]_{20}^D$ (2% Solution)	Between +195° and +203°
pH (6% Solution)	4.5 to 7.0
Loss on Drying	NMT 7.0%
Ash Content	NMT 2.0%
Intrinsic Viscosity at 37°C (1% Solution)	0.56 to 0.70
Cold Water Solubility (1% Solution)	Soluble in cold water

Written By: <i>GG</i>	Title: Analytical Chemist	Date: July 22, 2021
Reviewed By: <i>M</i>	Title: QC Manager	Date: July 22, 2021
Approved By: <i>GM</i>	Title: QA Manager	Date: July 22, 2021