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Succeed with Quality



# CERTIFICATE

Quality Austria Certification GmbH awards this **qualityaustria** certificate to the following organisation:

This **qualityaustria** certificate confirms the application and further development of an effective

**HIMEDIA**

**HiMedia Laboratories Pvt. Ltd.**

Plot No. C40, Road - 21Y, WAGLE Industrial Estate,  
Thane (West) - 400604 Maharashtra, India

**QUALITY MANAGEMENT SYSTEM**

complying with the requirements of standard

**ISO 13485:2016**

Medical devices - Quality management systems -  
Requirements for regulatory purposes

Quality Austria Certification GmbH is accredited according to the Austrian Accreditation Act by the BMWFV (Federal Ministry of Science, Research and Economy).

Quality Austria is accredited as an organisation for environmental verification by the BMLFUW (Federal Ministry of Agriculture, Forestry, Environment and Water Management).

Quality Austria is authorized by the VDA (Association of the Automotive Industry).

For accreditation registration details please refer to the applicable decisions or recognition documents.

Quality Austria is the Austrian member of IQNet (International Certification Network).



Design, Development & Manufacturing of Biosciences Products for application in Microbiology, Cell Biology & Molecular Biology Products.

Registration No.: M-00391/0

Date of initial issue: 28 February 2022

Valid until: 27 February 2028

The validity of the **qualityaustria** certificate will be maintained by annual surveillance audits and one renewal audit after three years.

Vienna, 10 March 2025

Quality Austria Certification GmbH,  
AT-1010 Vienna, Zelinkagasse 10/3



**qualityaustria**

MEMBER OF



Dok. Nr. FO\_24\_028

b9848bfe-d23d-4edf-91e0-8d0d63d0b1ae

The current validity of the certificate is documented exclusively on the Internet under <http://www.qualityaustria.com/en/cert>

Mag. Christoph Mondl  
CEO

Mag. Dr. Werner Paar  
CEO

Ing. Christoph Baumgartner, MSc, MBA  
Authorised representative,  
management Customer Service Center



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**HIMEDIA**

**HiMedia Laboratories Pvt. Ltd.**

Plot No. C40, Road - 21Y, WAGLE Industrial Estate,  
Thane (West) - 400604 Maharashtra, India

**QUALITY MANAGEMENT SYSTEM**  
complying with the requirements of standard  
**ISO 9001:2015**

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Quality Austria is authorized by the VDA (Association of the Automotive Industry).

For accreditation registration details please refer to the applicable decisions or recognition documents.

Quality Austria is the Austrian member of IQNet (International Certification Network).



Design, Development & Manufacturing of Microbiology, Cell Biology, Plant Tissue Culture & Molecular Biology Products and Trading of Allied Plastic-ware, Lab Aid Instrument and Consumables (Sterile Disposable Petri Dishes, Sterile Swabs, Sterile Loops and Spreaders)

Registration No.: Q-27302/0

Date of initial issue: 28 February 2022

Valid until: 27 February 2028

Vienna, 10 March 2025

The validity of the **qualityaustria** certificate will be maintained by annual surveillance audits and one renewal audit after three years.

Quality Austria Certification GmbH,  
AT-1010 Vienna, Zelinkagasse 10/3



**qualityaustria**

MEMBER OF



Dok. Nr. FO\_24\_028

ffc93e2-26e1-4a0d-9e33-43e35e833781

The current validity of the certificate is documented exclusively on the Internet under <http://www.qualityaustria.com/en/cert>

Mag. Christoph Mondl  
CEO

Mag. Dr. Werner Paar  
CEO

Ing. Christoph Baumgartner, MSc, MBA  
Authorised representative,  
management Customer Service Center

# CERTIFICATE OF ANALYSIS

**AL007G**


HiGlutaXL™ Dulbecco's Modified Eagle Medium, High Glucose  
w/ 4.5gms Glucose per litre, L-Alanyl-L-Glutamine, Sodium pyruvate and  
Sodium bicarbonate

Lot Number : **0000745799**  
QC Test Date : 10.02.2026  
Expiry Date : 31.08.2027  
Release Date : 27.02.2026  
Store at : 2° - 8° C

TEST	SPECIFICATIONS	RESULTS
Appearance	Red colored, clear solution.	Complies
pH	7.00 - 7.60	7.31
Osmolality in mOsm/Kg H <sub>2</sub> O	320mOsm* - 360mOsm*	351mOsm*
Sterility	No bacterial or fungal growth is observed after 14 days of incubation, as per USP specification.	Complies
Cultural Response	The growth promotion capacity of the medium is assessed qualitatively by analyzing the cells for the morphology and quantitatively by estimating the cell counts and comparing it with a control medium.	Complies
<b>Endotoxin content</b>		
Endotoxin Content	NMT 1EU/ml	Complies

\*Expressed in mOsm/Kg H<sub>2</sub>O

Status of the material : **APPROVED**



Jyotsana Labad

Department, Quality Control  
Cell Biology



Rajat Singh

Department, Quality Assurance  
Cell Biology

This is to certify that this lot passes and conforms to the above mentioned tests and specifications. User must ensure suitability of the product in their application prior to use.

This document has been produced electronically

# CERTIFICATE OF ANALYSIS

## TL1010


Hank's Balanced Salt Solution 1X  
w/ Sodium bicarbonate  
w/o Phenol red

Lot Number : **0000746200**  
QC Test Date : 12.02.2026  
Expiry Date : 29.02.2028  
Release Date : 21.03.2026  
Store at : 15° - 30° C

TEST	SPECIFICATIONS	RESULTS
Appearance	Colorless, clear solution	Complies
pH	7.10 - 7.70	7.62
Osmolality in mOsm/Kg H <sub>2</sub> O	265mOsm* - 305mOsm*	273mOsm*
Sterility	No bacterial or fungal growth is observed after 14 days of incubation, as per USP specification.	Complies
Toxicity test	Passes	Complies
Endotoxin Content	NMT 1EU/ml	Complies

\*Expressed in mOsm/Kg H<sub>2</sub>O

Status of the material : **APPROVED**



Jyotsana Labad

Department, Quality Control  
Cell Biology



Rajat Singh

Department, Quality Assurance  
Cell Biology

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# CERTIFICATE OF ANALYSIS

**TL1006**


Dulbecco's Phosphate Buffered Saline 1X  
w/o Phenol red, Calcium and Magnesium

Lot Number : **0000748549**  
 QC Test Date : 25.02.2026  
 Expiry Date : 29.02.2028  
 Release Date : 12.03.2026  
 Store at : 15°- 30° C

TEST	SPECIFICATIONS	RESULTS
Appearance	Colorless, clear solution	Complies
pH	7.20 - 7.80	7.49
Osmolality in mOsm/Kg H <sub>2</sub> O	265mOsm* - 305mOsm*	277mOsm*
Sterility	No bacterial or fungal growth is observed after 14 days of incubation, as per USP specification.	Complies
Toxicity test	Passes	Complies
Endotoxin content	NMT 1EU/ml	Complies

\*Expressed in mOsm/Kg H<sub>2</sub>O

Status of the material : **APPROVED**



Jyotsana Labad

Department, Quality Control  
Cell Biology



Rajat Singh

Department, Quality Assurance  
Cell Biology

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# CERTIFICATE OF ANALYSIS

## AL007S


Dulbecco's Modified Eagle Medium (DMEM), High glucose  
w/ 4.5gms Glucose per litre, 1mM Sodium pyruvate, L-Glutamine and 1.5gms per litre  
of Sodium bicarbonate

Lot Number : **0000752750**  
QC Test Date : 18.03.2026  
Expiry Date : 31.03.2027  
Release Date : 08.04.2026  
Store at : 2° - 8° C

TEST	SPECIFICATIONS	RESULTS
Appearance	Orangish red colored, clear solution	Complies
pH	7.00 - 7.60	7.29
Osmolality in mOsm/Kg H <sub>2</sub> O	285mOsm* - 325mOsm*	310mOsm*
Sterility	No bacterial or fungal growth is observed after 14 days of incubation as per USP specification.	Complies
Cultural Response	The growth promotion capacity of the medium is assessed qualitatively by analyzing the cells for the morphology and quantitatively by estimating the cell counts.	Complies
<b>Endotoxin content</b>		
Endotoxin Content	NMT 1EU/ml	Complies

\*Expressed in mOsm/Kg H<sub>2</sub>O

Status of the material : **APPROVED**



Jyotsana Labad



Rajat Singh

Department, Quality Control  
Cell Biology

Department, Quality Assurance  
Cell Biology

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## HiGlutaXL™ Dulbecco's Modified Eagle Medium, High Glucose

With 4.5gms Glucose per litre, L-Alanyl-L-Glutamine, Sodium pyruvate and Sodium bicarbonate

**Product Code: AL007G**

### Product Description:

HiGlutaXL™ medium contains the stabilised dipeptide form of L-glutamine, L-alanyl-L-glutamine. HiGlutaXL™ medium offers several advantages over the conventional glutamine containing media. Dipeptide form prevents the intramolecular cyclization reaction, thus preventing toxic build-up of ammonia. L-alanyl-L-glutamine incorporates L-alanine that protects the alpha amino acid group. Aminopeptidases within the cell break the dipeptide, gradually releasing both L-glutamine and L-alanine for use by the cell. The gradual release of L-glutamine obviates the need to supplement L-glutamine frequently and allows liquid media to be stored at 4°C for longer periods.

AL007G is HiGlutaXL™ Dulbecco's Modified Eagle Medium with 4.5gms glucose per liter, L-alanyl-L-glutamine, sodium pyruvate and sodium bicarbonate. Users are advised to review the literature for recommendations regarding medium supplementation and physiological growth requirements specific for different cell lines.

### Composition:

Ingredients	mg/L
<b>INORGANIC SALTS</b>	
Calcium chloride dihydrate	265.000
Ferric nitrate nonahydrate	0.100
Magnesium sulphate anhydrous	97.720
Potassium chloride	400.000
Sodium bicarbonate	3700.000
Sodium chloride	6400.000
Sodium dihydrogen phosphate anhydrous	109.000
<b>AMINO ACIDS</b>	
Glycine	30.000
L-Alanyl-L-Glutamine	868.000
L-Arginine hydrochloride	84.000
L-Cystine dihydrochloride	62.570
L-Histidine hydrochloride monohydrate	42.000
L-Isoleucine	105.000
L-Leucine	105.000

L-Lysine hydrochloride	146.000
L-Methionine	30.000
L-Phenylalanine	66.000
L-Serine	42.000
L-Threonine	95.000
L-Tryptophan	16.000
L-Tyrosine disodium salt dihydrate	103.790
L-Valine	94.000
<b>VITAMINS</b>	
Choline chloride	4.000
D-Ca-Pantothenate	4.000
Folic acid	4.000
Nicotinamide	4.000
Pyridoxal hydrochloride	4.000
Riboflavin	0.400
Thiamine hydrochloride	4.000
i-Inositol	7.200
<b>OTHERS</b>	
D-Glucose	4500.000
Phenol red sodium salt	15.900
Sodium pyruvate	110.000

### Quality Control:

#### Appearance

Red colored, clear solution.

#### pH

7.00 -7.60

#### Osmolality in mOsm/Kg H<sub>2</sub>O

320.00 -360.00

#### Sterility

No bacterial or fungal growth is observed after 14 days of incubation, as per USP specification.

#### Cultural Response

The growth promotion capacity of the medium is assessed qualitatively by analyzing the cells for the morphology and quantitatively by estimating the cell counts and comparing it with a control medium.

**Endotoxin Content**

NMT 1EU/ml

**Storage and Shelf Life:**

Store at 2-8 °C away from bright light.

Shelf life is 18 months.

Use before expiry date given on the product label.

**Disclaimer :**

Revision : 02/2022

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## Dulbecco's Modified Eagle Medium (DMEM), High glucose

With 4.5 gms Glucose per litre, 1mM Sodium pyruvate, L-Glutamine, 1.5 gms per litre Sodium bicarbonate

**Product Code: AL007S**

### Product Description:

Dulbecco's Modified Eagle Medium (DMEM) is one of the most widely used modification of Eagle's medium. DMEM is a modification of Basal Medium Eagle (BME) that contains four-fold concentration of amino acids and vitamins. Additionally, the formulation also includes glycine, serine and ferric nitrate. The original formulation contains 1000 mgs/L of glucose and was originally used to culture embryonic mouse cells.

DMEM high glucose is a further modification of original DMEM and contains 4500mgs/L of glucose. The additional glucose has proved to be useful in cultivating various other cell lines including primary cultures of mouse and chicken cells as well as various normal and transformed cell lines.

AL007S is Dulbecco's Modified Eagle Medium with 4.5gms glucose per litre, L-glutamine, 1.5gms per litre sodium bicarbonate and 1mM sodium pyruvate. Users are advised to review the literature for recommendations regarding medium supplementation and physiological growth requirements specific for different cell lines.

### Composition:

Ingredients	mg/L
<b>INORGANIC SALTS</b>	
Calcium chloride dihydrate	265.000
Ferric nitrate nonahydrate	0.100
Magnesium sulphate anhydrous	97.720
Potassium chloride	400.000
Sodium bicarbonate	1500.000
Sodium chloride	6400.000
Sodium phosphate monobasic anhydrous	109.000
<b>AMINO ACIDS</b>	
Glycine	30.000
L-Arginine hydrochloride	84.000
L-Cystine dihydrochloride	62.570
L-Glutamine	584.000
L-Histidine hydrochloride monohydrate	42.000
L-Isoleucine	105.000
L-Leucine	105.000

L-Lysine hydrochloride	146.000
L-Methionine	30.000
L-Phenylalanine	66.000
L-Serine	42.000
L-Threonine	95.000
L-Tryptophan	16.000
L-Tyrosine disodium salt	103.790
L-Valine	94.000
<b>VITAMINS</b>	
Choline chloride	4.000
D-Ca-Pantothenate	4.000
Folic acid	4.000
Nicotinamide	4.000
Pyridoxal 5 phosphate	4.000
Riboflavin	0.400
Thiamine hydrochloride	4.000
i-Inositol	7.200
<b>OTHERS</b>	
D-Glucose	4500.000
Phenol red sodium salt	15.900
Sodium pyruvate	110.000

### Quality Control:

#### Appearance

Orangish red colored, clear solution.

#### pH

7.00 - 7.60

#### Osmolality in mOsm/Kg H<sub>2</sub>O

285.00 - 325.00

#### Sterility

No bacterial or fungal growth is observed after 14 days of incubation as per USP specification.

#### Cultural Response

The growth promotion capacity of the medium is assessed qualitatively by analyzing the cells for the morphology and quantitatively by estimating the cell counts.

#### Endotoxin Content

NMT 1EU/ml

**Storage and Shelf Life:**

Store at 2-8°C away from bright light.

Shelf life is 12 months.

Use before expiry date given on the product label.

**Disclaimer :**

Revision : 05/2025

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## Dulbecco's Phosphate Buffered Saline 1X

Without Phenol red, Calcium and Magnesium

**Product Code: TL1006**

### Product Description:

All media used in tissue culture have a basis of a synthetic mixture of inorganic salts known as a physiological or balanced salt solution (BSS). All the physiological salt solutions have been derived from the salt solution originally described by Sydney Ringer (1885). The first balanced salt solution to be developed specifically for supporting the metabolism of mammalian cells was Tyrode's solution. Since then many modifications have been done to obtain better buffering salt solutions and to prevent calcium precipitation.

The function of a salt solution is:

- To maintain the medium within physiological pH range.
- To maintain intracellular and extra cellular osmotic balance.
- Modified with a carbohydrate, such as glucose serves as an energy source for cell metabolism.

TL1006 is 1X Dulbecco's Phosphate Buffered Saline without phenol red, calcium and magnesium. It is most commonly used for washing off calcium and magnesium ions which may hinder the trypsin activity during tissue disaggregation and monolayer dispersal.

### Composition:

Ingredients	mg/L
<b>INORGANIC SALTS</b>	
Disodium hydrogen phosphate	1150.000
Potassium chloride	200.000
Potassium dihydrogen orthophosphate	200.000
Sodium chloride	8000.000

### Quality Control:

#### Appearance

Colorless, clear solution.

#### pH

7.20 - 7.80

#### Osmolality in mOsm/Kg H<sub>2</sub>O

265.00 - 305.00

#### Sterility

No bacterial or fungal growth is observed after 14 days of incubation, as per USP specification.

#### Toxicity test

Passes

#### Endotoxin content

NMT 1EU/ml

### Storage and Shelf Life:

Store at 15-30°C away from bright light.

Shelf life is 24 months.

Use before expiry date given on the product label.



CE Partner 4U, Esdoornlaan 13, 3951 DB  
Maarn The Netherlands, [www.cepartner4u.eu](http://www.cepartner4u.eu)



**Manufacturer:**

Reg. Off : HiMedia Laboratories Pvt. Ltd.,  
Plot No. C40, Road No. 21Y,  
MIDC, Wagle Industrial Area, Thane (West)  
400604, Maharashtra, India.  
Works : B-4-5-6 / MIDC, Palkhed, Dindori,  
Nashik- 422202 Maharashtra,  
India  
[www.himedialabs.com](http://www.himedialabs.com)

## Product Label Symbols

	Catalogue number for product identification.
	Batch/lot number for the batch identification.
	Date of expiry/ shelf life.
	Recommended storage temperature.
	Manufactured using accepted aseptic techniques.
	Product meets the applicable EC directives requirements.
	Product designed for use as an in vitro diagnostic medical device.
	Instructions for use.

**Disclaimer:**

Revision : 05/2025

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## Hanks' Balanced Salt Solution 1X

**With Sodium bicarbonate**  
**Without Phenol red**

**Product Code: TL1010**

### Product Description:

All media used in tissue culture have a basis of a synthetic mixture of inorganic salts known as a physiological or balanced salt solution (BSS). All the physiological salt solutions have been derived from the salt solution originally described by Sydney Ringer (1885). The first balanced salt solution to be developed specifically for supporting the metabolism of mammalian cells was Tyrode's solution. Since then many modifications have been done to obtain better buffering salt solutions and to prevent calcium precipitation.

The function of a salt solution is:

- To maintain the medium within physiological pH range.
- To maintain intracellular and extra cellular osmotic balance.
- Modified with a carbohydrate, such as glucose serves as an energy source for cell metabolism.

Hanks' balanced salt solution is designed to equilibrate with air, hence does not require CO<sub>2</sub> air mixture.

TL1010 is Hanks' balanced salt solution with sodium bicarbonate. It is designed for use with cells maintained in less CO<sub>2</sub> environment or CO<sub>2</sub> free environment. It does not contain phenol red.

### Composition:

Ingredients	mg/L
<b>INORGANIC SALTS</b>	185.410
Calcium chloride dihydrate	48.000
Disodium hydrogen phosphate	97.720
Magnesium sulphate anhydrous	

Potassium chloride	400.000
Potassium dihydrogen phosphate anhydrous	60.000
Sodium bicarbonate	350.000
Sodium chloride	8000.000
<b>OTHERS</b>	
D-Glucose	1000.000

### Quality Control:

#### Appearance

Colorless, clear solution

#### pH

7.10 -7.70

#### Osmolality in mOsm/Kg H<sub>2</sub>O

265.00 -305.00

#### Sterility

No bacterial or fungal growth is observed after 14 days of incubation, as per USP specification.

#### Toxicity test

Passes

#### Endotoxin Content

NMT 1EU/ml

### Storage and Shelf Life:

Store at 15-30 °C away from bright light.

Shelf life is 24 months.

Use before expiry date given on the product label.

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Revision: 04/2022