

**HiMedia Laboratories Private Limited**

C-40, Road No.21Y, MIDC, Wagle Ind. Area,Thane(W) - 400604

Website : www.himedialabs.com, Email : info@himedialabs.com

**Certificate of Analysis , Quality and Conformity**

|                             |                                                                                                |                            |
|-----------------------------|------------------------------------------------------------------------------------------------|----------------------------|
| <b>Material Code : M036</b> | <b>Material Name :</b><br>*B12 Assay Medium(Using L.leichmanni)<br>(*Vitamin B12 Assay Medium) | <b>Lot No : 0000647507</b> |
| <b>AR No.: 40001477710</b>  | <b>Date of Report : 2024-06-03</b>                                                             | <b>Exp. Date : 2026-10</b> |

| TEST                                                                                             | SPECIFICATIONS                                                                                                                                                                                                                             | RESULTS                       |
|--------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| <b><u>Appearance</u></b><br>1 Colour of Powder<br>2 Consistency<br>3 Nature                      | Cream to yellow<br>homogeneous<br>having a tendency to form soft lumps<br>which can be easily broken down to<br>powder form.                                                                                                               | Cream<br>Complies<br>Complies |
| <b><u>Colour and Clarity of prepared medium</u></b><br>1 Colour of Medium<br>2 Clarity of Medium | Light amber coloured<br>clear solution that may contain a slight<br>precipitate.                                                                                                                                                           | Complies<br>Complies          |
| <b>Reaction</b><br><br><b>pH</b>                                                                 | Reaction of 8.5% w/v aqueous solution at<br>25°C.<br><br>5.90 - 6.30                                                                                                                                                                       | <br><br>6.11                  |
| <b><u>Cultural Response</u></b><br>1 Cultural Response                                           | Microbiological assay of Vitamin B12 is<br>carried out using Lactobacillus leichmanni<br>ATCC 7830 after an incubation at 35-37°C<br>for 18-24 hours.                                                                                      | Complies                      |
| <b><u>Growth</u></b><br>1 Growth                                                                 | Gradual increase in growth with increasing<br>USP Cyanocobalamin reference standard<br>levels of 0.0, 0.025, 0.050, 0.075, 0.1, 0.125,<br>0.150 and 0.2 ng per assay tube is recorded<br>as equivalent increase in absorbance at<br>620nm. | Complies                      |

Information for BSE/TSE Risk The material was subjected to pH <= 7.0 and/or a temperature in excess of 75°C for no less than 2 hours during the manufacturing process. The bovine raw material for this product was collected entirely from Indian Origin animals in a licensed based establishment. The animals are inspected under a Govt. approved veterinarian's supervision and were apparently free from infectious and contagious diseases. BSE (Bovine Spongiform Encephalopathy)/ TSE (Transmissible Spongiform Encephalopathy) and dioxine are not known to exist in India. This material does not contain, nor is derived from the specific risks material as defined in The Maharashtra Animal Preservation Act Govt. of Maharashtra, India.

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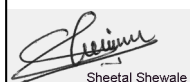
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| TEST | SPECIFICATIONS | RESULTS |
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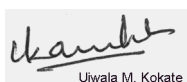
**STATUS OF THE MATERIAL : APPROVED**

This is to certify that this lot passes and it confirms to the above mentioned tests and specifications . The information given here is believed to be correct and accurate, however, both the information and products are offered without warranty for any particulars use, other than that specified in the current HiMedia manual or product sheets.

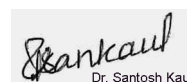
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**Microbiologist/Sr.Executive Microbiologist**



**Asst./Dy/QC Manager**



**Dy/QA Manager**