

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

| | | |
|-----------------------------|--|----------------------------|
| Material Code : M036 | Material Name : *B12 Assay Medium(Using L.leichmanni) (*Vitamin B12 Assay Medium) | Lot No : 0000544678 |
| AR No.: 40001259075 | Date of Report : 2022-07-21 | Exp. Date : 2024-12 |

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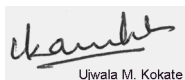
STATUS OF THE MATERIAL : APPROVED

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 particular use, other than that specified in the current HiMedia manual or product sheets.

This document has been produced electronically and is valid



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