



a bio-quest for ever

YASHRAJ BIOTECHNOLOGY LIMITED

An ISO 9001:2000 Certified Quality Assurance System

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| Doc. No: F/YBL/QC-01 | Rev: 02 | Date: 15-05-09 |
| Supersedes : F/YBL/QA-01 | Rev: 00 | Date: 01-08-05 |

CERTIFICATE OF ANALYSIS

Date of Certificate: 15-05-09 Certificate No: QF0313

Description of Product: **Hepatitis B Surface Antigen-ad type (HBsAg-Ad)**
Liquid (Aseptically Filtered) in 50 mM Phosphate, 150 mM NaCl
(pH 7.2 - 7.6) 0.09% Sodium Azide
Heat Inactivated at 60°C for 15 hours

Batch No.: FHBd0090 Product Code: FHBd Grade: High Pure (>99%)

Origin: Human Blood Manufacturing: May 09 Expiry: Apr 12

| Sr. No. | Test | Test Method | Acceptance Criteria | Observation |
|---------|--|--|--------------------------|-------------|
| 01 | Identification | ELISA | Positive for HBsAg | Passes |
| 02 | HBsAg Content | BIORAD (Against PEI Standard) | 2- 4 mg/ml | 2.30 mg/ml |
| 03 | Total Protein | OD ₂₈₀ -OD ₃₂₀ | As observed | 2.32 mg/ml |
| 04 | 'Ad' subtype-Purity | ELISA | >99 % | Passes |
| 05 | Purity Profile | SDS-PAGE | Match Internal Ref. Std. | Passes* |
| 06 | Aggregation | Gel Filtration | < 9% | 7.95 % |
| 07 | Bio-burden | Plate Count | < 10 CFU/ml | Passes |
| 08 | Viral Marker Test For Anti-HIV I & II And Anti-HCV | ELISA (US FDA Approved BIORAD & Ortho clinical Diagnostics) | Negative | Passes |
| 09 | Absence of Viral DNA /RNA for HIV I and HCV | PCR | Negative | Passes* |

Opinion: The batch [FHBd0090](#) conforms to the release specifications for Hepatitis B Surface Antigen-ad subtype High Pure (Code: FHBd). (* Soft copy available on request)

Suitability: For raising antibodies (request azide free), as primary antigen and/or preparation of controls & calibrators

Recommended Storage: 2-8° C or -20°C in working aliquots to avoid repeated freeze-thaw

Sanjeev Kumar Gupta, Ph.D.
Manager -Quality Assurance & Regulatory Affairs

Caution: This product is not for human consumption. Use only in In-Vitro research or products. All bio-safety precautions must be practiced while handling.

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