



# YASHRAJ BIOTECHNOLOGY LIMITED

An ISO 9001:2000 Certified Quality Assurance System

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*a bio-quest for ever*

## CERTIFICATE OF ANALYSIS

Date of Certificate: 20-04-09

Certificate No: QF0308

Description of Product: **Hepatitis B Surface Antigen-ay type (HBsAg-Ay)**  
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.: FHBBy0088

Product Code: FHBy

Grade: High Pure (>98%)

Origin: Human Blood

Manufacturing: Apr 09

Expiry: Mar 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	2.11 mg/ml
03	Total Protein	OD <sub>280</sub> -OD <sub>320</sub>	2 - 4 mg/ml	2.13 mg/ml
04	'Ay' subtype-Purity	ELISA	>99 %	Passes
05	Purity Profile	SDS-PAGE	Match Internal Ref. Std.	Passes*
06	Aggregation	Gel Filtration	< 9%	5.25 %
07	Bio-burden	Plate Count	< 10 CFU/ml	Passes
08	Viral Marker Test For Anti-HIV I & II And Anti-HCV	ELISA (BIORAD & Ortho clinical Diagnostics)	Negative	Passes
09	Absence of Viral DNA /RNA for HIV I and HCV	PCR	Negative	Passes*

**Opinion:** The batch **FHBBy0088** conforms to the release specifications for Hepatitis B Surface Antigen-ay subtype High Pure (Code: FHBy). (\* 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**

**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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