



Certificate of Analysis

Becton Dickinson and Company
BD Diagnostic Systems
1475 Athens Highway
Grayson GA 30017-1538 US

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Product Name : Dropper Adjuvant Complete H37Ra
Catalog Number : 231131 **Manufacture Date** : 2016/02/24
Batch Number : 6056589
Expiration Date : 2019/02/23

Description: A suspension of light mineral oil and mannide monooleate.

Suitable for use as an immunopotentiating agent. Complete adjuvants contain a mixture of Mycobacterium sp..

The Mycobacterium powder, a component of this adjuvant, consists of pure dried cells of Mycobacterium butyricum or M. tuberculosis as applicable to the product - there are no additives. BD kills the Mycobacterium cells using a steam autoclave. The autoclave cycle has been validated using an overkill method according to the applicable standards. During production of the material, the autoclave charts are reviewed by Production personnel for adequacy. The records are then independently reviewed by Quality Assurance personnel to assure the load parameters were met or exceeded. This certifies that the product is non-viable.

Appearance: Yellow, oily liquid.
(a heat killed bacterial suspension present in complete adjuvants)

Storage: 15-30 degrees celsius

Characteristic	Unit	Value	Lower Limit	Upper Limit
Viscosity	CST	12.28	10.00	14.00
Density in g/ml		0.85	0.79	0.85
Bioburden passed	-	OK	-	-- -
Emulsion Preperati	-	OK	-	-- -

Animal source	Country of Origin	Tissue Category		
		BIC	SIC	ABC
Leporine	USA	IV	IV	IB

The Batch Number on this certificate is synonymous with the Lot Number shown on the product label.

BD Diagnostics - Diagnostic Systems products are manufactured in ISO 9001:2008 Registered facilities. In addition, BD Diagnostics - Diagnostic Systems facilities are registered with the United States Food and Drug Administration (FDA), are regulated by the FDA's Quality System Regulations (QSRs), and are also ISO 13485:2003 Registered.

Creation Date: 2016/03/31 13:24:18



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This product met BDDS stringent quality standards at time of batch/lot release. Any test results reported on this certificate were obtained at time of release. This material is not for human or animal consumption.

BD Diagnostics - Diagnostic Systems' Certificates of Analysis (COA) typically contain animal origin information when products are manufactured using materials of animal origin. This information may be contained in the animal source table and/or in one or more of the additional paragraphs found on the COA. Following Quality Control release, the COA is created and published at <http://www.bd.com/regdocs>. For each batch of finished product that contains animal origin raw materials, the COA shows the animal origin data from the individual lots of animal origin raw materials used, as provided by the raw material suppliers.

At times, suppliers notify BD Diagnostics - Diagnostic Systems of new and/or additional information they have received from their raw material suppliers that modifies the animal origin information for lots previously provided to BD. See "COA Animal Origin Information Position Statement" located at <http://www.bd.com/regdocs> under "Position Statements" for the impact that retrospective information has on COAs and on customers enrolled in the BDDS and BDAB Automated Change Notification Program.

For complete details on animal origin information, refer to "BD Position Statement - BD Diagnostic-Diagnostic Systems, COA Animal Origin Information Position Statement", at <http://www.bd.com/regdocs> under "Position Statements".

Manufacturer is Becton Dickinson and Company, 7 Loveton Circle, Sparks, MD 21152 USA. To determine location of manufacturing for this product, please see www.bd.com/ds/technicalCenter/regulatory.asp.

Charlotte Dannenfelser
BD Life Sciences - Diagnostic Systems
Quality Director, Microbiology
Signature Date: 2016/03/31