



Sanofi Aventis México S.A. de C.V.
 Acueducto del alto Lerma No 2. Zona Industrial Ocoyoacac
 C.P.52740, Ocoyoacac Estado de México
 R.F.C.: SAM951123978
 Tel. 54844400 Fax. (01) 72828781

Fecha de impresión : 23/Jun/2015

Certificado de Análisis

BENZOIL METRONIDAZOL (AARTI DRUGS)

MX110238

Lote No. : **14MX00494**

Fecha de fabricación : 31/Ago/2014
 Fecha de caducidad : 31/Jul/2019
 Método analítico : MEX-TC-R-00174
 Número de lote de inspección : 6116104 Cantidad : 1,099.880 kg
 Cumplimiento : Este lote es aceptado y cumple con las especificaciones.

Prueba	Resultados analíticos	Especificaciones
METODO ANALITICO	Corresponde	Corresponde
MEX-TC-R-00174 V. 2.0		
DESCRIPCION	Corresponde	Corresponde
POLVO CRISTALINO, BLANCO O AMARILLO CLARO.		
SOLUBILIDAD	Corresponde	Corresponde
IDENTIFICACION IR	Corresponde	Corresponde
TEMPERATURA DE FUSION	102 °C	98 a 102 °C
PERDIDA POR SECADO	0,0 %	<= 0,5 %
RESIDUOS DE IGNICION	0,0 %	<= 0,1 %
METALES PESADOS	< 20 ppm	<= 20 ppm
VALORACION	99,8 %	98,0 a 102,0 %

Proveedor : Aarti Drugs Limited
 Lote de Proveedor: MBO/14080342
 Cantidad : 1100.000 KG

Responsable de Calidad. QFB Alicia Ruiz Morales
A Ruiz 23/06/2015



Aarti Drugs Limited

Manufacturers of : Bulk Drugs & Chemicals

CORPORATE OFFICE : Plot No.109-D, Mahendra Industrial Estate,
Ground Floor, Road No.29, Sion (East), Mumbai - 400 022. (India)
Tel. : 91 22 2407 2249 • Fax : 91 22 2407 0144 / 2407 3462
Email:sales@aartidrugs.com • Website : www.aartidrugs.com

REGD. OFFICE : Plot No. N-198, MIDC, Tarapur, Tal-Palghar,
Dist. Thane - 401 506 (M.H.) INDIA Tel. : 91-2525 270259/271699
Fax : 91 2525 273368

QUALITY CONTROL CERTIFICATE OF ANALYSIS

Product Name	: Metronidazole Benzoate BP	CAS#	: 13182-89-3
Batch No.	: MBO/14080342	A. R. No.	: MBO/14/0373
Mfg. Date	: Aug- 2014	Date of Analysis	: 19-Aug-2014
Exp. Date	: Jul- 2019		

Sr. NO.	TESTS	OBSERVATIONS	SPECIFICATION
1	Appearance	White crystalline powder	White or slightly yellowish, crystalline powder
2	Solubility	Complies	Practically insoluble in water, freely soluble in methylene chloride, soluble in acetone, slightly soluble in alcohol.
3	Identification		
	A. Melting Point	101 °C	Melt Between 99 °C to 102 °C
	B. UV.	Specific Absorbance at the maximum at 232 nm =570	The light absorption in the range 220 nm and 350 nm the solution shows 2 absorption maxima, at 232 nm and 275 nm. The specific absorbance at maximum at 232 nm is 525 to 575.
	C. IR	Concordant with WRS.	Infrared absorption spectrum of sample in KBr dispersion is concordant with infrared absorption spectrum of Metronidazole Benzoate working standard or Metronidazole Benzoate reference spectrum.
	D. Primary aromatic amines test.	Complies	An intense orange or red colour precipitates produce.
4	Appearance of solution	Complies	Not more opalescent than reference suspension II and not more intensely coloured than reference solution GY ₃ .
5.	Acidity	0.05 ml.	NMT 0.25 ml of 0.02 M NaOH is required to change the colour of the indicator.
6	Related substances	BDL BDL BDL 0.01% 0.01%	Impurity A : Not more than 0.1%. Impurity B : Not more than 0.1%. Impurity C : Not more than 0.1%. Other impurity : Not more than 0.1%. Total impurities : Not more than 0.2%.
7	Heavy Metals	Less than 20 ppm	Not more than 20 ppm.
8	Sulphated Ash (%)	0.05%	Not more than 0.1%
9	Loss on drying (%)	0.13%	Not more than 0.5%
10	Assay, (%)	99.86%	Not less than 98.50% and not more than 101.0%
*INHOUSE TESTS :			
1	Particle size	Complies	30 Micron Not less than, 95%

Opinion: The material Complies / Not-comply as per BP specification.

*The material Complies / Not-comply as per In house specification.

Prepared By

Date: 19/08/2014.

Checked By:

Date: 19/08/2014.

Quality Control Head

Date: 19/08/2014.

Manufacturing site : Manjari chemical division Plot no K 40, MIDC, Tarapur (INDIA) Pin 401 506
Phone - 02525 271989, Fax No- 02525 272626