

Krishnadham

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(Govt. Recognised Export House)

**CERTIFICATE OF ANALYSIS**

CAUTION:
250 kg

CERTIFICATE OF ANALYSIS			
Product	MEBENDAZOLE. EP	[POLYMORPH "C"]	Q.C. Report No. : QC/FPI - 177
Batch No.	1771112 - WC		Date of Receipt : 26.11.2012
Date of Mfg	NOVEMBER - 2012.		Date of Analysis : 27.11.2012
Re test Date	OCTOBER - 2017.		Batch Size : 1000.0 Kgs
			Qty. Sample : 60.0 gms
RESULT OF ANALYSIS			
Sr. No.	TEST	OBSERVATION	SPECIFICATION
1	Characters	White amorphous powder almost odourless. It shows polymorphism	White to almost white amorphous powder almost odourless. It shows polymorphism
2	Solubility	Complies	Freely soluble in Formic acid
3	Identification (I.R.)	Complies	The IR absorption Spectrum of KBr Dispersion of the sample exhibits maxima at the same Wave length as that a similar preparation of mebendazole polymorph EP CRS
4	Related substances [HPLC]	Complies	Total Impurities NMT- 1.0%
	I) Impurities G	Not detected	NMT -0.50 %
	II) Any others Impurity	Complies	NMT 0.25 %
	III) Total Impurity	Complies	Total Impurities NMT- 1.0%
5	Loss on drying (%w/w)	0.26%.	NMT - 0.50 %
6	Sulphated ash (%w/w)	0.068%.	NMT - 0.10 %
7	Heavy Metals	Complies	NMT - 0.002 %
8	Melting point	258 - 292 °C	255 °C - 295°C
9	Particle Size	Complies	90% <75 Microns
10	Color of Solution	Complies	NMT - 0.30 @ 400nm
11	Assay	99.55%.	99.0 to 101.0 %
12	Residual solvents	Complies	
	I) Methanol	Complies	NMT: 3000.0 PPM
	II) N,N,DMF	Complies	NMT: 880.0 PPM
	III) Acetic acid	Not detected	NMT: 5000.0 PPM
	IV) Benzene	Not detected	NMT: 2.0 PPM
Remarks	Pass / Fail		
	The IR graph of this batch indicates the presence of polymorph "C"		
Report:	In the opinion of the undersigned the sample referred to above is of / is not of standard quality as defined in the Act & Rules made thereunder of EP		
Hemant Analysed By A. M. M. Checked By L. J. M. Approved By			

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ISO 9001:2008
Registered
GMS/C1144/0995



QMS 804
A MEMBER
OF IAF MLA



ISO 14001:2004 Registered E0139



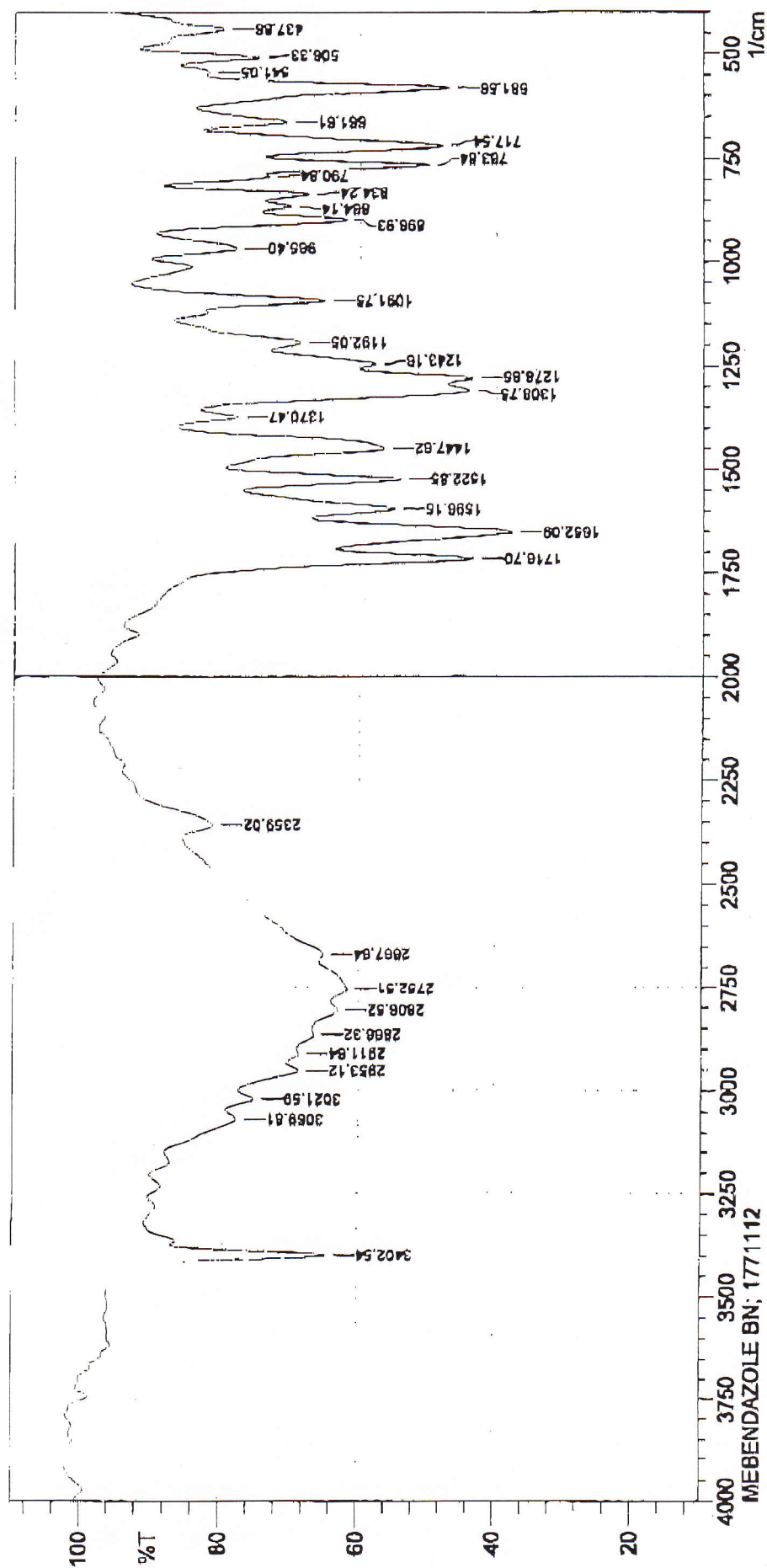
ISO 9001:2008 Registered E0139

(ISO 9001-2008 & ISO 14001-2004 Certified Company)

K A MALLE PHARMACUTICALS LTD.

D:\R 2012\NOVEMBER-2012\MEBENDAZOLE BN; 1771112.smf

12/4/2012 1:16:35 PM



Comment;

MEBENDAZOLE BN; 1771112

Resolution;

No. of Scans;

Apodization;

Date/Time; 12/4/2012 1:16:35 PM

User; qc1

Checked By:

Analysis By: