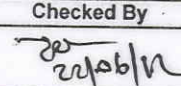


Macleods Pharmaceuticals Ltd. Plot No.8, Ganesh Indl. Estate, Kachigam, Daman - 396 210					
CERTIFICATE OF ANALYSIS					
Product		PYRAZINAMIDE 400 (Pyrazinamide Tablets BP 400 mg)		A. R. No.	
				FT-0333/12	
Batch No.		HPH201		Batch Size	
				4,50,000 Tablets	
Packing Batch No.		HPH201A		Packing Batch Size	
				2,00,000 Tablets	
Mfg. Date		05/2012		Exp. Date	
				04/2015	
Date of Analysis		29/05/2012		Date of Report	
				12/06/2012	
STP No.		C/STP/WP000483-00			
Sr. No.	Test	Specification	Result		
1	Description	White circular, flat, beveled edged uncoated tablets having plain surface on both side.	White circular, flat, beveled edged uncoated tablets having plain surface on both side.		
2	Identification A. By Infrared Absorption	The Infrared absorption spectrum of the residue in potassium bromide should be concordant with the reference spectrum of pyrazinamide working standard.	The Infrared absorption spectrum of the residue in potassium bromide is concordant with the reference spectrum of pyrazinamide working standard.		
3	Average weight (mg)	453.0 ± 2.5 % (441.68 to 464.33)	446.0		
4	Uniformity of weight (%)	Not more than two of the individual weights should deviate from the average weight by more than ± 5.0 % and none deviate by more than ± 10.0 %.	Min : -4.28 Max : 3.14		
5	Diameter (mm)	12.00 ± 0.20 (11.80 to 12.20)	Min : 12.05 Max : 12.08		
6	Hardness (N)	40 to 125 N	Min : 50.91 Max : 80.05		
7	Friability (% w/w)	Not more than 1.0	0.29		
8	Disintegration (Min)	Not more than 15	01 min 05 sec		
9	Dissolution for Pyrazinamide (% of labeled amount in 15 minutes)	Not less than 85	1) 97.3 3) 100.3 5) 96.3 2) 99.3 4) 97.3 6) 98.6		
10	Loss on Drying (% w/w)	Not more than 5.0	3.7		
11	Related Substances (By TLC) (By HPLC) Pyrazin-2-carboxylic Acid Any other single Impurity Total impurity	Any secondary spot in the chromatogram obtained with solution (1) should not more intense than the spot in the chromatogram obtained with solution (2) Not more than 0.20 Not more than 0.10 Not more than 0.50	No secondary spot in the chromatogram obtained with solution (1) with reference to the spot in the chromatogram obtained with solution (2) 0.14 0.02 0.17		
12	Assay as Pyrazinamide C ₅ H ₅ N ₃ O BY UV mg per tablet % label claim By HPLC mg per tablet % label claim	380.0 to 420.0 95.0 to 105.0 380.0 to 420.0 95.0 to 105.0	400.55 100.1 392.45 98.1		
Remark : The product Complies / Does not comply as per Finished Product specification No.C/SPC/WP000483R-00					
Prepared By		Checked By		Approved By	
 A. R. Bhosale		 C. B. Patil		 S. J. Patil	
Sign & Date					

FRM/QCD/023/F3/00

