Macleods Pharmaceuticals Ltd.
Plot No.8, Ganesh Indl. Estate, Kachigam, Daman - 396 210

MACLEODS

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)	Any secondary spot in the chromatogram obtained with solution (1) should not more intense than the spot in the chromatogram obtained with solution (2)	No secondary spot in the chromatogram obtained with solution (1) with reference to the spot in the chromatogram obtained with solution (2)
	(By HPLC)		
	Pyrazin-2-carboxylic Acid	Not more than 0.20	0.14
	Any other single Impurity	Not more than 0.10	0.02
	Total impurity	Not more than 0.50	0.17
12	**Assay** as Pyrazinamide $C_5H_5N_3O$		
	BY UV		
	mg per tablet	380.0 to 420.0	400.55
	% label claim	95.0 to 105.0	100.1
	By HPLC		
	mg per tablet	380.0 to 420.0	392.45
	% label claim	95.0 to 105.0	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
Sign & Date	22/06/12	22/06/12	22/06/12
	A. R. Bhosale	**C. B. Patil**	**S. J. Patil**

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