



CERTIFICATE OF ANALYSIS

Name Of Product : Paracetamol Tablets BP 500 MG
Brand Name : ---
Batch No. : 18143
Mfg. Date : OCT. 2016
Exp. Date : SEP. 2019
Batch Size : 600000 Tablets
A. R. No. : 40000139780
Released Qty. : 597000 Tablets Release Date : 04/11/2016

TEST	SPECIFICATION	RESULT	REMARKS
Description	White flat circular uncoated tablets having beveled edge with break line and "P/500" embossed on upper side and plain on other side	Conforms	Complies
Identification by IR	The infrared absorption spectrum of sample should be concordant with the infrared absorption spectrum of paracetamol standard.	Conforms	Complies
Identification by chemical test	A violet colour is produced slowly which does not turn red.	Conforms	Complies
Identification by melting point	About 169°C	169.7 °C	Complies
Average weight	570.0 mg ± 2 % (558.6– 581.4 mg)	573.3 mg	Complies
Diameter	12.70 mm ± 0.2 mm (12.50 mm to 12.90 mm)	12.7 mm	Complies
Thickness	3.6 to 4.3 mm	3.7 mm	Complies
Friability	NMT 1.0 %.	0.3 %	Complies
Disintegration	NMT 15 minutes	04 minutes	Complies
Hardness	5-12 KP	11.0 KP	Complies
Weight Variation of Individual Tablets	570.0 mg ± 5 % (541.5– 598.5)	Min: -1.2 % Max: +1.0 %	Complies
Weight of 20 tablets	11.400 g ± 2% (11.172 – 11.628 g)	11.465 g	Complies

Page 1 of 2

Flamingo Pharmaceuticals Ltd.

CIN : U51900MH1985PLC036572

Corporate Office : 7/1, Corporate Park, Sion-Trombay Road,
P. O. Box No. : 27257, Chembur, Mumbai-400 071. INDIA

E-mail : ashf@flamingopharma.com
Website : www.flamingopharma.com

Phone : 91 - 22 - 3000 9300
Fax : 91 - 22 - 2523 3085



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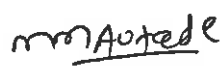
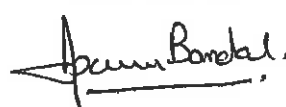
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TEST	SPECIFICATION	RESULT	REMARKS
Dissolution	Not less than 75% (Q) of the labeled amount is dissolved in 45 MIN.	Min: 100 %	Complies
		Max: 101 %	
		Mean 101 %	
Assay	95 – 105% of label claim	99.3 %	Complies
	475.0 – 525.0 mg of Paracetamol per tablet	496.5 mg/tab	
Related Substances	4-aminophenol Not more than 0.1%.	Not Detected	Complies
	4-chloroacetanilide Not more than 10 ppm	Not Detected	Complies
	Other additional impurity Not more than 0.25%.	0.01 %	Complies
Microbial Limit Tests *	a) Total viable aerobic count		
	- Bacteria Not more than 1000 cfu / g	<10 cfu / g	Complies
	- Fungi Not more than 100 cfu / g	<10 cfu / g	Complies
	b) Escherichia Coli Absent	Absent	Complies

Buyer : BLESSINGS INTERNATIONAL

Remarks: The sample complies as per above specification.

* Test to be performed for all three validation batches and after annually.

Analyzed By	Checked By	Approved By	Authorized By
			
Bhushan Shigwan	Rupali Ghadigaonkar	Mahesh Autade	Aparna Bandal
Analyst	Officer	Head - QC	Head - Quality
Date: 04/11/16	Date: 04/11/16	Date: 04/11/16	Date: 04/11/16