



Pell Tech Health Care Pvt Ltd

Plot No. 20B, Tansa Farm Estate, Bhiwandi-Wada Road, Wada, Thane, Maharashtra - 421312

CERTIFICATE OF ANALYSIS

Product : FG762 ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg		AR No : 2019-20/QCP/FGR/00377	
Analysis Date : 18/08/2019		Completion Dt	: 21/08/2019
Batch	: 76219E08	Mfg. Date	: May, 2019
Batch Size	: 400000 Nos	Exp. Date	: Apr, 2022
Sample Type	: Finished Product	Sampled Date	: 18/08/2019
Mfg. Lic. No.	: KD-622	Sample Qty.	: 300.000 Nos
Spec. No.	: FPS/FG762/04	Sampled By	: KADAM KIRAN BAL
		Sample Approved	

SR. No.	Test	Specification	Observation
1	Description	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.
2	Identification	In the Assay, the principal peak in the chromatogram obtained with test solution corresponds to the peak due to Esomeprazole magnesium in the chromatogram obtained with the reference solution.	In the Assay, the principal peak in the chromatogram obtained with test solution corresponds to the peak due to Esomeprazole magnesium in the chromatogram obtained with the reference solution.
3	Weight of 20 tablets	1.85gm \pm 5% (1.7575gm to 1.9425gm)	1.88 gm
4	Average weight of tablets	92.5mg \pm 7.5% (85.5625mg - 99.4375mg)	93.94 mg
5	Uniformity of weight	\pm 7.5% of Average weight	Complies
6	Thickness	2.90 mm \pm 0.5mm (2.40mm - 3.40mm)	2.64 mm
7	Diameter	6.10 mm \pm 0.5mm (5.60mm - 6.60mm)	6.35 mm
8	Disintegration Test A) 0.1N HCl for 2hrs B) In mixed phosphate buffer pH 6.8 for 45 min	No any fragments Not more than 45 mins	No any fragments Max. 04 Minutes 35 Seconds
9	Dissolution Release in 0.1M HCL after 2hrs Released in buffer pH 6.8 after 45 mins	Not more than 10.0% of the labelled amount of Esomeprazole released. Not less than 75%(Q) of the labelled amount of Esomeprazole is released.	0.0% 99.7%
10	Uniformity of dosage units (by Content uniformity)	Between 85.0% and 115.0%	105.49%
11	Organic impurities Omeprazole sulfone	Not more than 0.5%	0.126%

Analysed By	Checked By	Approved By
Date	Date:	Date :



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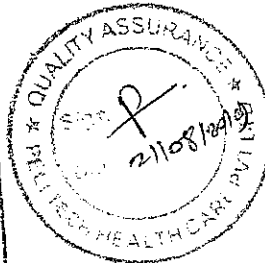
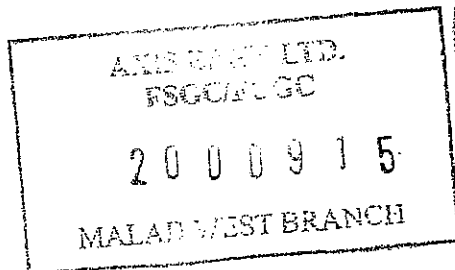
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Spec. No.	: FPS/FG762/04	Sample Approved	
Any other individual impurity		0.059%	
Total impurities		0.457%	
Not more than 0.2%			
Not more than 2.0%			

ASSAY CONTENT

Name of the ingredient	Label contents Each enteric coated tablet contains:	Actual contents Each enteric coated tablet contains:	Potency (%)	Limit
Esomeprazole Magnesium USP equivalent to Esomeprazole	20mg	20.167 mg	100.83%	Between 90.0% to 110.0% of labelled amount (Between 18.0mg to 22.0mg)

Conclusion : The conclusion of the undersigned about the above mentioned product **Complies** as per In-house Specification Laid down specification and is of a standard quality mentioned there-in and released for Packing / Distribution.



Analysed By	<u>9</u>	Checked By	<u>81</u>	Approved By	<u>[Signature]</u>
Date	21/08/2019	Date:	21/08/2019	Date :	21/08/2019