12



Pell Tech Health Care Pvt Ltd

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

CERTIFICATE OF ANALYSIS

| Mfg. Lic. No. Spec. No. | | KD-622 FPS/FG751/05 | Sampled By Sample Approv | : KADAM KIRAN BAI |
|--|----------|------------------------------|--------------------------|-------------------|
| Sample Type | | Finished Product | Sample Qty. | : 300.000 Nos |
| Batch Size | <u>:</u> | 600000 Nos | Sampled Date | : 18/08/2019 |
| Batch | : | 75119F08 | Exp. Date | : May,2021 |
| Analysis Date | : | 18/08/2019 | Mfg. Date | : Jun,2019 |
| | | | Completion Dt | : 31/08/2019 |
| Product : FG751 ATENOLOL TABLETS USP 50 mg | | AR No :2019-20/QCP/FGR/00381 | | |

| Spec | e. No. : FPS/FG751/05 | Sample Approved | | |
|------------------------|--|--|--|--|
| SR. No. | Test | Specification | Observation | |
| 1 | Description | White circular flat uncoated tablets having break line on one side and plain on other side of each tablets. | White circular flat uncoated tablets having break line on one side and plain on other side of each tablets. | |
| 2 | Identification Identification A Identification B | The IR absorption spectrum of a Atenolol of the Sample solution corresponds to that of the Standard solution. The retention time of the Atenolol peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. | The IR absorption spectrum of a Atenolol of the Sample solution corresponds to that of the Standard solution. The retention time of the Atenolol peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. | |
| 3 Weight of 20 tablets | | 3.60gm +/- 3% (3.492gm - 3.708gm) | 3.53 gm | |
| 4 | Average weight of tablets | 180mg +/- 5%(171.0mg - 189.0mg) | 176.28 mg | |
| 5 | Uniformity of weight | +/- 5% of average weight of tablets | Complies | |
| 6 | Diameter | 8.0mm ± 0.5mm (7.5mm - 8.5mm) | 8.14 mm | |
| 7 | Thickness | 2.80mm ± 0.5mm (2.30mm - 3.30mm) | 3.02 mm | |
| 8 | Hardness | Between 3.0 - 9.0kg/cm2 | 5.175 kg/cm2 | |
| 9 | Friability | Not more than 1.0% w/w | 0.31 % Max. 08 Minutes 49 Seconds | |
| 10 11 | Disintegration Time Dissolution Drug release in buffer pH 4.6 after 30mins | Not more than 15mins Not less than 80% (Q) of the labeled amount dissolved in 0.1N Acetate Buffer in pH 4.6 in 30 mins | 95.2% ASSURANCE | |
| 12 | Uniformity of dosage units (by weight) | L1 Not more than 15 | 7.2 PROBLE STANDS | |
| Date | lysed By July 3/107/101/2019 | Checked By 31/0 2/2019 | Approved By Date: Page 1 of 2 | |



Pell Tech Health Care Pvt Ltd

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

CERTIFICATE OF ANALYSIS

| Product :FG751 ATENOLOL TABLETS USP 50 mg | | AR No :2019-20/QCP/FGR/00381 | | | |
|---|------------|------------------------------|---------------|---|-----------------|
| | | | Completion Dt | Π | 31/08/2019 |
| Analysis Date | <u> </u> : | 18/08/2019 | Mfg. Date | : | Jun,2019 |
| Batch | <u> </u> : | 75119F08 | Exp. Date | : | May,2021 |
| Batch Size | : | 600000 Nos | Sampled Date | : | 18/08/2019 |
| Sample Type | : | Finished Product | Sample Oty. | : | 300,000 Nos |
| Mfg. Lic. No. | : | KD-622 | Sampled By | : | KADAM KIRAN BAL |
| Spec. No. : FPS/FG751/05 Sample Approved | | | | | |

ASSAY CONTENT

| ı | | 1 | · | | |
|-----|------------------------|----------------------|----------------------|---------|---------------------------|
| 4 | Name of the ingredient | Label contents | Actual contents | Potency | Limit |
| | | Each uncoated tablet | Each uncoated tablet | (%) | |
| İ | | contains | contains | , , | |
| | Atenolol USP | 50mg | 49.981 mg | 100.0 % | Between 45.0mg - 55.0mg |
| | | | | | (90.0% - 110.0%) of label |
| | | | | | claim |
| -11 | | | | | |

Conclusion: The conclusion of the undersigned about the above mentioned product Complies as per United State

Pharmacopoeia Laid down specification and is of a standard quality mentioned there-in and released for Packing / Distribution.

20009674



| Analysed By | is. | Checked By | 2 | Approved By | (15000 Show |
|--------------|--------------|------------|------------|-------------|-------------|
| Date | 3110813018 | Date: | 31/08/2019 | Date : | 7/08/120 |
| Format No. Q | C/01-039/F01 | | | | Page 2 of 2 |