Holden Medical Laboratories Pvt. Ltd.
Plot No: C35, C36 & C37, Malegaon, M.I.D.C.
Sinnar, Nashik- 422113, INDIA

FINISHED PRODUCT – CERTIFICATE OF ANALYSIS

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Effective Date: 01/04/19
Page No: 1 of 2

Product Name	:	Hydrochlorothiazide Tablets BP 50 mg	**A. R. No.**	:	FG/487/19-20
Batch No.	:	HE19L09	**Mfg. Date**	:	Dec.19
Batch Size	:	10.00 Lac Tablets	**Exp. Date**	:	Nov.22
Received Date	:	16/01/20	**Pack Size**	:	2X10 Tablets
Released Date	:	28/01/20	**Sample Quantity**	:	10X2X10 Tablets

SR. NO.	TESTS	RESULTS	LIMITS
1	**DESCRIPTION**	White, circular, flat, uncoated tablets having breakline on one side & plain on other side, such 10 tablets packed in Aluminium / PVC blister & such 2 blisters are further packed in printed carton along with leaflet.	White, circular, flat, uncoated tablets having breakline on one side & plain on other side, such 10 tablets packed in Aluminium / PVC blister & such 2 blisters are further packed in printed carton along with leaflet.
2	**IDENTIFICATION**	A] Complies B] The absorbances of sample & standard solution are similar as performed in assay at 273 nm.	A] The principal spot in the chromatogram obtained with solution (1) corresponds in colour and intensity to that in the chromatogram obtained with solution (2). B] The absorbance of sample & standard solution should be similar as performed in assay at 273 nm.
3	**AVG. WT.**	0.1513 gm	0.150 gm ± 5 %
4	**UNIFORMITY OF WT.**	Complies	Within ± 5 % of Avg. wt.
5	**DISINTEGRATION TIME**	2 minutes 58 seconds	NMT 15 minutes
6	**FRIABILITY**	0.08 % w/w	NMT 1.0% w/w
7	**HARDNESS**	3.0 kg / cm^2	NLT 2.5 kg/cm^2
8	**THICKNESS**	2.52 mm to 2.58 mm	2.50 mm ± 0.4 mm
9	**DIAMETER**	7.08 mm to 7.09 mm	7.10 mm ± 0.2 mm
10	**RELATED SUBSTANCES** **INDIVIDUAL IMPURITY** **TOTAL IMPURITIES**	Any secondary maximum impurity: 0.085 % 0.136 %	NMT 1.0% NMT 2.5%
11	**DISSOLUTION**	95.84 % to 99.64 %	NLT 80.0 % in 45 minutes
12	**LOSS ON DRYING**	1.80 % w/w	NMT 5.0% w/w
13	**MICROBIAL TEST**	20 CFU/gm 10 CFU/gm Absent Absent	Total Viable Count: NMT 10^3 CFU/gm Total Fungal Count: NMT 10^2 CFU/gm Escherichia coli: Should be absent Salmonella abony: Should be absent
14	**ASSAY**		

Ingredient	Label Claim	Result	Percentage	Limit
Hydrochlorothiazide BP	50 mg /Tab.	49.83 mg/Tab.	99.66 %	92.5 % to 107.5 %

Quality Control Remarks: The above sample **Complies** / ~~**Does not Comply**~~ as per BP/In-house Standards.

28/01/20 **Analysed By** **Mr.K.S.Arkhade** **QC Officer/ ~~Executive~~**	28/01/20 **Checked By** **Mrs. M.R. Shirsath** **~~QC Executive~~/ Assistant QC Manager**	28/01/20. **Approved By** **Ms. V.V. Shinde** **QC Manager**

BATCH RELEASE CERTIFICATE

Confirmation Statement by Qualified Person (QP):

Product Name: Hydrochlorothiazide Tablets BP 50 mg **Batch No: HE19L09**

I hereby confirm that the manufacturing stages referred in the Technical Quality Agreement have been carried out in full compliance with the GMP requirements and the terms described in the agreement for ensuring compliance with the requirements of the Marketing Authorisation (s). As Manufacturer we are certifying and releasing the batch for distribution.

Name, designation and signature with date of qualified person confirming the manufacturing and releasing the batch.	for 28/01/20 **Mrs. Aparna Potdar** **Qualified person (QP)** Hilden Medical Laboratories Pvt. Ltd. Q.A. Dept.