Holden Medical Laboratories Pvt. Ltd.
C35, C36 & C37, MIDC, Malegaon, Sinnar, Nashik -422113.
QUALITY CONTROL DEPARTMENT

RAW MATERIAL – CERTIFICATE OF ANALYSIS

Format No.: HML_QC_ RMCOA_14_04_01
Effective Date: 01/04/14
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Name of Raw Material	:	Hydrochlorothiazide BP	**A.R. No.**	:	RM/271/20-21
Batch No.	:	20HZ00721	**Invoice No. / Dt.**	:	310201601/09/11/20
Qty. Received	:	17X 25 Kg 01X 24.950 Kg	**Manufacturer**	:	CTX Lifesciences Pvt. Ltd.
Mfg. Date	:	Oct-20	**Supplier**	:	CTX Lifesciences Pvt. Ltd.
Exp. Date	:	Sep-25	**Sample Qty.**	:	49.0 gm
Released Date	:	14/12/20	**Sampled by**	:	MPK

TESTS		**RESULTS**	**LIMITS**
Appearance	:	White, crystalline powder.	White or almost white, crystalline powder.
Solubility	:	Very slightly soluble in water, soluble in acetone, sparingly soluble in ethanol (96 per cent).It dissolves in dilute solutions of alkali hydroxides.	Very slightly soluble in water, soluble in acetone, sparingly soluble in ethanol (96 per cent).It dissolves in dilute solutions of alkali hydroxides.
Identification	:	B] Complies	B] By Infrared absorption Spectrophotometry
Acidity or Alkalinity	:	0.1 ml of 0.01 M hydrochloric acid is required to change the colour of the indicator to red.	NMT 0.4 ml of 0.01 M hydrochloric acid is required to change the colour of the indicator to red.
Related substances	:		
Impurities A,C		Not detected	NMT 0.5 %
Impurity B		Below disregard limit	NMT 0.5 %
Unspecified Impurities		Below disregard limit	NMT 0.1 %
Total Impurities		Nil	NMT 1.0 %
Chlorides	:	Complies	NMT 100 PPM
Loss on drying in an oven at 105^0 C	:	0.08 %	NMT 0.5 %
Sulfated ash	:	0.05 %	NMT 0.1 %
Assay	:	99.46 %	97.5 % to 102.0 % on dried basis
Residual Solvent			
Methyl Isobutyl Ketone		Not detected	NMT 1000 PPM
Benzene		Not detected	NMT 2 PPM

REMARKS: The above sample **complies** with BP standards.

Analysed by
Date: 14/12/20

Checked by
14/12/20.

Approved by
14/12/20.

Note: If signature & entries in blue ink it indicates that it is an original document.

CERTIFICATE OF ANALYSIS

PRODUCT : HYDROCHLOROTHIAZIDE BP			
Batch No.	: 20HZ00721	Inspection Lot No.	: 40000019521
Mfg. Date	: October 2020	Quantity Supplied	: 449.95 Kg
Expiry Date	: September 2025	Date of release	: 24/10/2020

S.No.	Tests	Observations	Specifications	Method Reference
1.	Description	White, crystalline powder.	White or almost white, crystalline powder.	BP
2.	Solubility	Soluble in acetone, sparingly soluble in ethanol (96%), very slightly soluble in water, It dissolves in dilute solutions of alkali hydroxides.	Soluble in acetone, sparingly soluble in ethanol (96%), very slightly soluble in water, It dissolves in dilute solutions of alkali hydroxides.	BP
3.	Identification By IR	Infrared spectrum of the test is Concordant with the infrared spectrum of the standard obtained in the same manner.	Infrared spectrum of the test should Concordant with the infrared spectrum of the standard obtained in the same manner.	BP<2.2.24>
4.	Identification By UV	The ratio of absorbance measured at the maximum at 273.2 nm to that measured at 322.1 nm is 5.6	The ratio of absorbance measured at the maximum at 273 nm to that measured at 323 nm should be between 5.4 and 5.7	BP<2.2.25>
5.	Acidity /Alkalinity	0.25 ml of 0.01M hydrochloric acid is required to change the color of indicator to red.	Not more than 0.4 ml of 0.01M hydrochloric acid is required to change the color of indicator to red.	BP
6.	Related Substances (By HPLC, % w/w) Impurity A	0.04	Not more than 0.5	BP <2.2.29>
7.	Related Substances (By HPLC, % w/w) Impurity B	0.05	Not more than 0.5	BP <2.2.29>
8.	Related Substances (By HPLC, % w/w) Impurity C	0.01	Not more than 0.15	BP <2.2.29>
9.	Related Substances (By HPLC, % w/w) 5-chlorohydrochlorothiazide	Below detection limit	Not more than 0.10	BP <2.2.29>
10.	Related Substances (By HPLC, % w/w) Any other	Below reporting threshold	Not more than 0.10	BP <2.2.29>

Prepared by	Checked by	Approved by
04/11/2020	04/11/2020	04/11/2020
Chhatrasinh Girase	**Hemant Patel**	**Chetan Modi**
Assistant – QA	**Asst. Manager – QA**	**Asst. Manager – QA**

Works at: CTX Lifesciences (P) Ltd, Block No: 251-252, Sachin Magdalla Road
GIDC - Sachin, Dist: - Surat (Gujarat) India. Tel: +91-261-2399669, fax: +91-261-2398547.

CTX IPESCIENCES

CERTIFICATE OF ANALYSIS

PRODUCT : HYDROCHLOROTHIAZIDE BP			
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S.No.	Tests	Observations	Specifications	Method Reference
11.	Related Substances (By HPLC, % w/w) Total	0.10	Not more than 1.0	BP <2.2.29>
12.	Chlorides (ppm)	Less than 100	Not more than 100	BP <2.4.4>
13.	Loss on drying (% w/w, determined on 1.0 g at 105°C.)	0.18	Not more than 0.5	BP<2.2.32>
14.	Sulphated ash (% w/w, determined on 1.0 g)	0.02	Not more than 0.1	BP<2.4.14>
15.	Assay (By HPLC, % w/w, as $C_7H_8ClN_3O_4S_2$ on dried basis)	100.3	Not less than 97.5 and Not more than 102.0	BP<2.2.29>
16.	Residual solvents (By GC-HS, µg/g) Methyl isobutyl ketone	Not detected	Not more than 1000	In house
17.	Content Benzene (By GC-HS, µg/g) Benzene*	Not detected	Not more than 2	In house

* Benzene is not used in process. Since it may be probable contaminant of other process solvent, the limit of residual Benzene is incorporated in the COA.

Where,
Impurity A // Chlorothiazide = 6-chloro-2H-1,2,4-benzothiadiazine-7-sulfonaminde 1,1-dioxide
Impurity B = 4-amino-6-chlorobenzene-1,3-disulphonamide (Salamide)
Impurity C = 6-chloro-N-[(6-chloro-7-sulphamoyl-2,3-dihydro-4H-1,2,4-benzothiadiazin-4-yl 1,1-dioxide)methyl]-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulphonamide 1,1-dioxide (Dimer)
5-chlorohydrochlorothiazide = 5,6-Dichloro-3,4-Dihydro-2H-1,2,4-Benzothiadiazine-7-Sulfonamide 1,1-dioxide.

Remark: The Product Complies to above Specifications.

Prepared by	Checked by	Approved by
04/11/2020	04/11/2020	04/11/2020
Chhatrasinh Girase	**Hemant Patel**	**Chetan Modi**
Assistant – QA	**Asst. Manager – QA**	**Asst. Manager – QA**