

**PRODUCT: HYDROCHLOROTHIAZIDE EP**

Batch No. : 21HZ000004	Inspection Lot No. : 40000020909
Mfg. Date : December 2020	Quantity Supplied : 25.0 Kg
Expiry Date : November 2025	Date of release : 06/01/2020

S.No.	Tests	Observations	Specifications	Method Reference
1.	Description	White, crystalline powder.	White or almost white, crystalline powder.	Ph. Eur.
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.	Ph. Eur.
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.	Ph. Eur. <2.2.24>
4.	Identification By UV	The ratio of absorbance measured at the maximum at 273.2 nm to that measured at 323.1 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	Ph. Eur. <2.2.25>
5.	Acidity /Alkalinity	0.26 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.	Ph. Eur.
6.	Related Substances (By HPLC, % w/w) Impurity A	0.03	Not more than 0.5	Ph. Eur. <2.2.29>
7.	Related Substances (By HPLC, % w/w) Impurity B	0.12	Not more than 0.5	Ph. Eur. <2.2.29>
8.	Related Substances (By HPLC, % w/w) Impurity C	0.02	Not more than 0.15	Ph. Eur. <2.2.29>
9.	Related Substances (By HPLC, % w/w) 5-chlorohydrochlorothiazide	0.01	Not more than 0.10	Ph. Eur. <2.2.29>
10.	Related Substances (By HPLC, % w/w) Any other	Below reporting threshold	Not more than 0.10	Ph. Eur. <2.2.29>

Prepared by

Checked by

No lote ACOFARMA

Approved by

09/01/2021

09/01/2021

210741

09/01/2021

**Chhatrasinh Girase**
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# CERTIFICATE OF ANALYSIS

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S.No.	Tests	Observations	Specifications	Method Reference
11.	Related Substances (By HPLC, % w/w) Total	0.17	Not more than 1.0	Ph. Eur. <2.2.29>
12.	Chlorides (ppm)	Less than 100	Not more than 100	Ph. Eur. <2.4.4>
13.	Loss on drying (% w/w, determined on 1.0 g at 105°C.)	0.17	Not more than 0.5	Ph. Eur. <2.2.32>
14.	Sulphated ash (% w/w, determined on 1.0 g)	0.04	Not more than 0.1	Ph. Eur. <2.4.14>
15.	Assay (By HPLC, % w/w, as C <sub>7</sub> H <sub>8</sub> ClN <sub>3</sub> O <sub>4</sub> S <sub>2</sub> on dried basis)	100.1	Not less than 97.5 and Not more than 102.0	Ph. Eur. <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
<b>Additional Tests:</b>				
18.	Content of formaldehyde (µg/g by HPLC)	Below limit of quantification	Not more than 20	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,

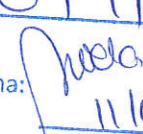
Impurity A // Chlorothiazide = 6-chloro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide

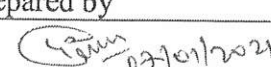
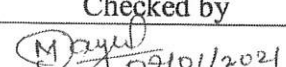
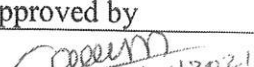
Impurity B = 4-amino-6-chlorobenzene-1,3-disulphonamide (Salamide)

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.**

Nº lote ACOFARMA:  
210741  
Firma y fecha:   
11/02/21

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 09/01/2021	 09/01/2021	 09/01/2021
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