CTX LIFESCIENCES

CERTIFICATE OF ANALYSIS

PRODUCT : HYDROCHLOROTHIAZIDE IP			
Batch No. : 16HZ000110		A. R. No. : FG1600139	
Mfg. Date : January 2016		Quantity Supplied : 250.0 Kg	
Expiry Date : December 2020		Date of Release : 07/02/2016	

S.No.	Tests	Observations	Specifications
1.	Description	White, odourless crystalline powder.	White or almost white, crystalline powder, odourless.
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.
3	Identification		
	a) By IR	IR spectrum of sample recorded as ATR exhibits transmission minima (absorption maxima) at the same wavenumbers to those in the spectrum obtained with the Hydrochlorothiazide working standard.	IR spectrum of sample recorded as KBr/ATR should exhibit transmission minima (absorption maxima) at the same wavenumbers to those in the spectrum obtained with the Hydrochlorothiazide working standard.
	b) By TLC	The principal spot in the chromatogram obtained with test solution corresponds to that in the chromatogram obtained with the reference solution.	The principal spot in the chromatogram obtained with test solution should correspond to that in the chromatogram obtained with the reference solution.
4.	Acidity /Alkalinity	0.24 ml of 0.01 M hydrochloric acid is required to change the colour of indicator to red.	Not more than 0.4 ml of 0.01M hydrochloric acid is required to change the colour of indicator to red.
5.	Chloride (ppm)	Less than 100	Not more than 100
6.	Sulphated ash (% w/w)	0.03	Not more than 0.1
7.	Loss on drying (% w/w, determined on 1.0 g at 105°C, for 1 hr.)	0.19	Not more than 0.5

Prepared by	Checked by	Approved by
27/02/2016	27/02/2016	27/02/2016
Officer - QA	Sr. Executive – QA	Asst. Manager – QA

Works at: CTX Lifesciences (P) Ltd, Block No: 251-252, Sachin Magdalla Road

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S.No.	Tests	Observation	Specification
8.	Related Compound (% w/w ,by HPLC)		
	Benzothiadiazine related compound A/Impurity B	0.06	Not more than 0.5
	Chlorothiazide/Impurity A	0.09	Not more than 0.5
	5-chlorohydrochlorothiazide	Below limit of quantification	Not more than 0.5
	Hydrochlorothiazide Dimer/Impurity C	0.02	Not more than 0.5
	Any unknown impurity	Below reporting threshold	Not more than 0.5
	Total impurities	0.17	Not more than 1.0
9.	Assay (By HPLC, % w/ w, as $C_7H_8ClN_3O_4S_2$ on dried basis)	100.0	Not less than 98.0 and Not more than 102.0
Additional Test			
10.	Residual Solvent (µg/g , By GC)		
	Methyl Isobutyl Ketone	Not detected	Not more than 1000
	Additional solvent Benzene*	Not detected	Not more than 2

*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.

Remark: The Product Complies to above Specifications.

Prepared by	Checked by	Approved by
27/02/2016	27/02/2016	27/02/2016
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