

CERTIFICATE OF ANALYSIS

PRODUCT: ACETAZOLAMIDE EP			
Batch No.	: 23AC000159	Inspection Lot No.	: 40000040286
Mfg. Date	: October 2023	Quantity Supplied	: 25.0 Kg
Expiry Date	: September 2028	Date of Release	: 03/11/2023

S.No.	Test	Observation	Specification	Method Reference
1.	Description	A white, crystalline powder.	A white or almost white, crystalline powder.	Ph.Eur
2.	Solubility	Very slightly soluble in water, slightly soluble in ethanol (96%v/v), It dissolves in dilute solution of alkali hydroxides.	Very slightly soluble in water, slightly soluble in ethanol (96%v/v), It dissolves in dilute solution 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	0.003% w/v solution in 0.01M sodium hydroxide shows an absorption maximum at 240.5 nm and the specific absorbance is 171.1 When examined between 230 nm and 260 nm. And 0.00075% w/v solution in 0.01M sodium hydroxide shows absorption maximum at 292.2 nm and the specific absorbance is 603.0 When examined between 260 nm and 350 nm.	0.003% w/v solution in 0.01M sodium hydroxide shows an absorption maximum at 240 nm and the specific absorbance should be between 162 to 176. When examined between 230 nm and 260 nm. And 0.00075% w/v solution in 0.01M sodium hydroxide shows absorption maximum at 292 nm and the specific absorbance should be between 570 to 620. When examined between 260 nm and 350 nm.	Ph.Eur <2.2.25>
5.	Identification By chemical test	The lead acetate paper turn a Brownish-black	The lead acetate paper should turn to Brownish-black	Ph.Eur
6.	Identification By chemical test	A greenish blue precipitate is formed.	A greenish blue precipitate should be formed.	Ph.Eur

Prepared by	Checked by	Approved by
<i>Sandip Girase</i> 25/11/2023	<i>Chakradhar Patil</i> 25/11/2023	<i>Hemant Patel</i> 25/11/2023
Sandip Girase Sr. Officer - QA	Chakradhar Patil Jr. Executive - QA	Hemant Patel Asst. Manager - QA

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7.	Appearance of solution (10% w/v solution in 1M sodium hydroxide)	The solution is less opalescent than reference suspension II and less intensely coloured than reference solution Y ₅ and BY ₅	The solution should not be more opalescent than reference suspension II and not more intensely coloured than reference solution Y ₅ or BY ₅	Ph.Eur <2.2.1> Ph.Eur <2.2.2 Method II>
8.	Related substances (% w/w, by HPLC) Impurity A	0.01	Not more than 0.15	Ph.Eur <2.2.29>
9.	Related substances (% w/w, by HPLC) Impurity B	0.02	Not more than 0.15	Ph.Eur <2.2.29>
10.	Related substances (% w/w, by HPLC) Impurity C	Not detected	Not more than 0.15	Ph.Eur <2.2.29>
11.	Related substances (% w/w, by HPLC) Impurity D	Below limit of quantification	Not more than 0.15	Ph.Eur <2.2.29>
12.	Related substances (% w/w, by HPLC) Impurity E	Not detected	Not more than 0.15	Ph.Eur <2.2.29>
13.	Related substances (% w/w, by HPLC) Impurity F	0.01	Not more than 0.15	Ph.Eur <2.2.29>
14.	Related substances (% w/w, by HPLC) Any other known impurity	Not detected	Not more than 0.10	Ph.Eur <2.2.29>
15.	Related substances (% w/w, by HPLC) Any unknown impurity	Below reporting threshold	Not more than 0.10	Ph.Eur <2.2.29>
16.	Related substances (% w/w, by HPLC) Total impurities	0.05	Not more than 0.6	Ph.Eur <2.2.29>
17.	Sulfates (ppm)	Less than 500	Not more than 500	Ph.Eur <2.4.13>
18.	Loss on drying (% w/w, at 105°C)	0.19	Not more than 0.5	Ph.Eur <2.2.32>

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Sandip Girase	Chakradhar Patil	Hemant Patel
Sr. Officer - QA	Jr. Executive - QA	Asst. Manager - QA

Works at: CTX Lifesciences Pvt. Ltd., Block No: 251-252, Sachin-Magdalla Road

GIDC - Sachin, Surat - 394230, Gujarat, India. Tel: +91-261-2399669, fax: +91-261-2398547.

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19.	Sulphated ash (% w/w)	0.03	Not more than 0.1	Ph.Eur <2.4.14>
20.	Residual solvent (µg/g, by GC-HS) Methanol	188	Not more than 1000	In house
21.	Residual solvent (µg/g, by GC-HS) Acetone	Not detected	Not more than 1000	In house
22.	Residual solvent (µg/g, by GC-HS) N,N-Dimethyl formamide	Not detected	Not more than 880	In house
23.	Assay (% w/w by titrimetry as $C_4H_6N_4O_3S_2$ on dried basis	100.8	Not less than 98.5 and not more than 101.0	Ph.Eur <2.2.20>

Remark: The Product Complies to above Specifications.

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