Quantum Drugs & Chemicals
Reg.Off:25,Bharathi Ula Road, Race Course, Madurai-625002, Tamilnadu, India.
Tel:++91(452)4345115/4345116 e-mail:quantumdrugs@gmail.com

CERTIFICATE OF ANALYSIS

Product : **TOLBUTAMIDE BP** Mfg. Month :
Batch No : TB/EXP- Exp. Month :
Quantity :

S. No	Tests	Standards
1	Appearance	White Crystalline Powder
2	Solubility	Practically insoluble in water, soluble in acetone and in ethanol (96 per cent). It dissolves in dilute solutions of alkali hydroxides.
3 A.	IDENTIFICATION Melting point	 126 °C to 130 °C
B.	UV and visible absorption	Test solution (a) Dissolve 25.0 mg in methanol R and dilute to 100.0ml with the same solvent. Test solution (b) Dilute 10.0 ml of test solution (a) to 250.0 ml with methanol R. Spectral range: 245 - 300 nm for test solution (a); 220-235 nm for test solution (b). Absorption maxima; At 258 nm, 263 nm and 275 nm for test solution (a); at 228 nm for test solution (b). Shoulder: At 268 nm for test solution (a). Specific absorbance at the absorption maximum 480 to 520 for test solution (b) .
C.	Infrared absorption spectrophotometry	Compare spectrum with the reference spectrum of Tolbutamide CRS
D.	Melting point after recrystallisation	135 °C to 140 °C
4	Appearance of Solutions	Dissolve 0.2 g in 5ml of dilute Sodium hydroxide solution R and add 5ml of water R. The solution is clear and colorless.
5	pH	4.5 to 5.5
6	Related Substances(BY HPLC) i) Unspecified impurities ii)PTSA(ImpurityA) iii)PTSU(Impurity B) iv) Total Impurities	 Not more than 0.10% Not more than 0.10% Not more than 0.10% Not more than 0.3%
7	Loss on drying (at 105°C)	Maximum 0.5%
8	Sulphated ash	Maximum 0.1%
9	Assay by Titration (ODB)	99.0% to 101.0%

REMARKS: THE ABOVE PRODUCT CONFORMS TO SPECIFICATIONS OF TOLBUTAMIDE BP

	Prepared by:	*Reviewed by:*	*Approved by:*
Name:			
Designation:			
Signature:			
Date:			

Manufacturing Site: C-21, Sipcot Industrial Complex, Manamadurai – 630 606. India. Phone No.: ++91-4574-258349.

QUANTUM DRUGS & CHEMICALS C-21, SIPCOT INDUSTRIAL COMPLEX MANAMADURAI

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CERTIFICATE OF ANALYSIS

Product : **TOLBUTAMIDE EP** Mfg. Month :
Batch No : TB/EXP- Exp. Month :
Quantity:

S. No	Tests	Standards
1	Appearance	White Crystalline Powder
2	Solubility	Practically insoluble in water, soluble in acetone and in ethanol (96 per cent). It dissolves in dilute solutions of alkali hydroxides.
3 A.	IDENTIFICATION Melting point	 126 °C to 130 °C
B.	UV and visible absorption	Test solution (a) Dissolve 25.0 mg in methanol R and dilute to 100.0ml with the same solvent. Test solution (b) Dilute 10.0 ml of test solution (a) to 250.0 ml with methanol R. Spectral range: 245 - 300 nm for test solution (a); 220-235 nm for test solution (b). Absorption maxima; At 258 nm, 263 nm and 275 nm for test solution (a); at 228 nm for test solution (b). Shoulder: At 268 nm for test solution (a). Specific absorbance at the absorption maximum 480 to 520 for test solution (b) .
C.	Infrared absorption spectrophotometry	Compare spectrum with the reference spectrum of Tolbutamide CRS
D.	Melting point after recrystallisation	135 °C to 140 °C
4	Appearance of Solutions	Dissolve 0.2 g in 5ml of dilute Sodium hydroxide solution R and add 5ml of water R. The solution is clear and colorless.
5	pH	4.5 to 5.5
6	Related Substances(BY HPLC) i) Unspecified impurities ii)PTSA(ImpurityA) iii)PTSU(Impurity B) iv) Total Impurities	 Not more than 0.10% Not more than 0.10% Not more than 0.10% Not more than 0.3%
7	Loss on drying (at 105°C)	Maximum 0.5%
8	Sulphated ash	Maximum 0.1%
9	Assay by Titration (ODB)	99.0% to 101.0%
REMARKS: THE ABOVE PRODUCT CONFORMS TO SPECIFICATIONS OF TOLBUTAMIDE EP		

	Prepared by:	*Reviewed by:*	*Approved by:*
Name:			
Designation:			
Signature:			
Date:			

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CERTIFICATE OF ANALYSIS

Product : **TOLBUTAMIDE USP** Mfg. Month :
Batch No : TB/EXP Exp. Month :
Quantity :

Sl. No	Tests	Standards
1	**Identification** A. Infrared Spectroscopy	Compare spectrum with the reference spectrum of USP Tolbutamide RS
	B. HPLC	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.
2	Assay by HPLC (ODB)	97.0%- 103.0 %
3	Selenium	Not more than 0.003 %
4	Organic Impurities by HPLC i) Tosylurea (PTSU) ii)Tosylamide(PTSA) iii) Tolazamide iv)Any other individual impurity v) Total Impurities	 Not more than 0.1% Not more than 0.1% Not more than 0.1% Not more than 0.1% Not more than 0.3%
5	Loss on drying (dry at 105°C for 3h.)	Not more than 0.5 %

REMARKS: THE ABOVE PRODUCT CONFORMS TO SPECIFICATIONS OF TOLBUTAMIDE USP

	Prepared by:	*Reviewed by:*	*Approved by:*
Name:			
Designation:			
Signature:			
Date:			

Manufacturing Site: C-21, Sipcot Industrial Complex, Manamadurai – 630 606. India. Phone No.: ++91-4574-258349.

QUANTUM DRUGS & CHEMICALS C-21, SIPCOT INDUSTRIAL COMPLEX MANAMADURAI 630606