

Quantum Drugs & Chemicals

Reg.Off:25,Bharathi Ula Road, Race Course, Madurai-625002, Tamilnadu, India.
Tel:++91(452)4345115/4345116 FAX:91(452)2568580 e-mail:quantumdrugs@gmail.com

CERTIFICATE OF ANALYSIS

Product : **TOLBUTAMIDE BP**
Batch No : TB/EXP-
Quantity :

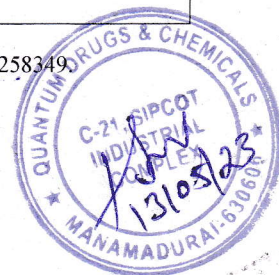
Mfg. Month :
Exp. Month :

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	IDENTIFICATION	
A.	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	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(Impurity A) 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	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



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CERTIFICATE OF ANALYSIS

Product : **TOLBUTAMIDE EP**
Batch No : TB/EXP-
Quantity:

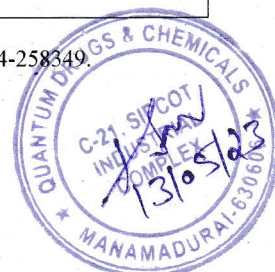
Mfg. Month :
Exp. Month :

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	IDENTIFICATION	
A.	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	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(Impurity A) 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	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

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CERTIFICATE OF ANALYSIS

Product : **TOLBUTAMIDE USP**
Batch No : TB/EXP
Quantity :

Mfg. Month :
Exp. Month :

Sl. No	Tests	Standards
1	Identification Infrared Absorption	Compare spectrum with the reference spectrum of USP Tolbutamide RS
2	Melting Range	between 126° C and 130° C
3	Loss on drying	Not more than 0.5 %
4	Selenium	0.003 %
5	Limits of Non Sulphonyl urea	Dissolve 500 mg in 10 ml of 0.5N Ammonium hydroxide: not more than a faint opalescence occurs.
6	Assay by HPLC (ODB)	97.0 to 103.0 %

REMARKS: THE ABOVE PRODUCT CONFORMS TO SPECIFICATIONS OF TOLBUTAMIDE USP

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<i>Name:</i>			
<i>Designation:</i>			
<i>Signature:</i>			
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