Quantum Drugs & Chemicals

Reg.Off:25,Bharathi Ula Road, Race Course, Madurai-625002, Tamilnadu, India.
Tel:++91(452)4345116/2569019 FAX:91(452)2568580 e-mail:quantumdrugs@gmail.com

CERTIFICATE OF ANALYSIS

Product : **TOLBUTAMIDE BP** Mfg. Date :
Batch No : TB/EXP- Exp. Date :
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.	BY UV	Test solution (a) Dissolve 25.0 mg in methanol 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. 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.	BY IR	Should comply the test
D.	MELTING POINT AFTER RECRYSTALLISATION	135°C to 140°C
4	APPEARANCE OF SOLUTIONS	Dissolve 0.2gm in 5ml of dilute Sodium hydroxide and 5ml of water. The solution is clear and colorless.
5	pH	4.5 to 5.5
6	RELATED SUBSTANCES(BY HPLC) i Unspecified impurities ii Total	 Not more than 0.1% Not more than 0.3%
7	HEAVY METALS	Not more than 10 ppm
8	LOSS ON DRYING	Not more than 0.50%
9	SULPHATED ASH	Not more than 0.10%
10	ASSAY (ODB)	99.0% to 101.0%

REMARKS: THE ABOVE PRODUCT CONFORMS TO SPECIFICATIONS OF TOLBUTAMIDE BP

	Analysed by:	***Checked 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

08/02/19

Quantum Drugs & Chemicals

Reg.Off:25,Bharathi Ula Road, Race Course, Madurai-625002, Tamilnadu, India.
Tel:++91(452)4345116/2569019 FAX:91(452)2568580 e-mail:quantumdrugs@gmail.com

CERTIFICATE OF ANALYSIS

Product : **TOLBUTAMIDE EP** Mfg. Date :
Batch No : TB/EXP- Exp. Date :
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.MELTING POINT	126°C to 130°C
	B. BY UV and visible absorption	Test solution (a) Dissolve 25.0 mg in methanol and dilute to 100.0ml with the same solvent. Test solution (b) Dilute 10.0 ml of the test solution (a) to 250.0 ml with methanol. Spectral range: 245 - 360 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 of recrystallisation	135°C to 140°C
4.	Appearance of Solution	Dissolve 0.2gm 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
	Related Substances :By HPLC Unspecified impurities Total	 Not more than 0.1% Not more than 0.3%
7.	Heavy metals	Not more than 10 ppm
8.	Loss on drying	Not more than 0.50%
9.	Sulphated Ash	Not more than 0.10%
10.	Assay (ODB)	99.0 to 101.0 %
REMARKS: THE ABOVE PRODUCT CONFORMS TO SPECIFICATIONS OF TOLBUTAMIDE EP		

	Analysed by:	*Checked 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

28/02/15

Quantum Drugs & Chemicals

Reg.Off:25,Bharathi Ula Road, Race Course, Madurai-625002, Tamilnadu, India.
Tel:++91(452)4345116/2569019 FAX:91(452)2568580 e-mail:quantumdrugs@gmail.com

CERTIFICATE OF ANALYSIS

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

S. No	Tests	Standards
1	**Identification** Infrared Absorption	Compare spectrum with the reference spectrum of USP Tolbutamide RS
2	Melting Range	between126° C and 130° C
3	Loss on drying	Not more than 0.50 %
4	Selenium	Not more than 0.003 %
5	Heavy metals	Not more than 0.002 %
6	Limits of Non Sulphonylurea	Dissolve 500 mg in 10 ml of 0.5N Ammonium hydroxide :not more than a faint opalescence occurs.
7	Assay by HPLC (ODB)	97.0 to 103.0 %
Additional Tests		
8	Appearance	AWhite, Crystalline powder
9	Odor	Practically odorless
10	Solubility	Practically insoluble in water, soluble in acetone and in alcohol. It dissolves in dilute solutions of alkali hydroxides.
REMARKS: THE ABOVE PRODUCT CONFORMS TO SPECIFICATIONS OF TOLBUTAMIDE USP		

	Analysed by:	*Checked 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

08/04/15