

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

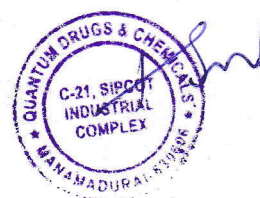
CERTIFICATE OF ANALYSIS

Product : **CHLORPROPAMIDE BP**
Batch No : CP/EXP-
Quantity :

Mfg. Month :
Exp. Month :

Sl. No	Tests	Standards	
1.	Appearance	A White, crystalline powder.	
2.	Solubility	Practically insoluble in water, freely soluble in acetone and in methylene chloride, soluble in alcohol. It dissolves in dilute solutions of alkali hydroxides.	
3.	IDENTIFICATION		
A.	Melting point	126° C to 130° C	
B.	UV and visible absorption	Dissolve 0.10g in methanol R and dilute to 50.0 ml with the same solvent. Dilute 5.0 ml of the solution to 100.0 ml with 0.01 M hydrochloric acid. Dilute 10.0 ml of the solution to 100.0 ml with 0.01 M hydrochloric acid. Examined between 220 nm and 350 nm, the solution shows an absorption maximum at 232 nm. The specific absorption at the maximum is 570 to 630.	
C.	Infrared Absorption	Compare spectrum with the reference spectrum of Chlorpropamide CRS	
D.	Chloride	A Curdy white precipitate is formed	
4.	Related substances by TLC		
	p-chloro benzene sulphonamide (Impurity A)	Not more than 0.3 %	
	1,3-dipropylurea (Impurity B)	Not more than 0.3 %	
	Any other spots	Not more than 0.3 %	
		Not more than two such spots 0.1%	
5.	Loss on drying	Not more than 0.5 %	
6.	Sulphated Ash	Not more than 0.1 %	
7.	Assay by Titration (ODB)	99.0 to 101.0 %	
REMARKS: THE ABOVE PRODUCT CONFORMS TO SPECIFICATIONS OF CHLORPROPAMIDE 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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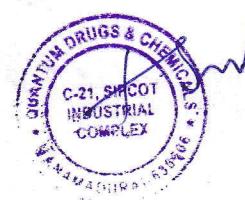
CERTIFICATE OF ANALYSIS

Product : **CHLORPROPAMIDE EP**
Batch No : CP/EXP-
Quantity :

Mfg. Month :
Exp. Month :

S. No	Tests	Standards	
1.	Appearance	A White, crystalline powder.	
2.	Solubility	Practically insoluble in water, freely soluble in acetone and in methylene chloride, soluble in alcohol. It dissolves in dilute solutions of alkali hydroxides.	
3.	IDENTIFICATION		
A.	Melting point	126° C to 130° C	
B.	UV and visible absorption	Dissolve 0.10g in methanol R and dilute to 50.0 ml with the same solvent. Dilute 5.0 ml of the solution to 100.0 ml with 0.01 M hydrochloric acid. Dilute 10.0 ml of the solution to 100.0 ml with 0.01 M hydrochloric acid. Examined between 220 nm and 350 nm, the solution shows an absorption maximum at 232 nm. The specific absorption at the maximum is 570 to 630.	
C.	Infrared Absorption	Compare spectrum with the reference spectrum of Chlorpropamide CRS	
D.	Chloride	A Curdy white precipitate is formed	
4.	Related substances by TLC		
	p-chloro benzene sulphonamide (Impurity A)	Not more than 0.3 %	
	1,3-dipropylurea (Impurity B)	Not more than 0.3 %	
	Any other spots	Not more than 0.3 %	
		Not more than two such spots 0.1%	
5.	Loss on drying	Not more than 0.5 %	
6.	Sulphated Ash	Not more than 0.1 %	
7.	Assay by Titration (ODB)	99.0 to 101.0 %	
REMARKS: THE ABOVE PRODUCT CONFORMS TO SPECIFICATIONS OF CHLORPROPAMIDE EP			
	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.



CERTIFICATE OF ANALYSIS

Product : **CHLORPROPAMIDE USP**
 Batch No : CP/EXP-
 Quantity :

Mfg. Month :
 Exp. Month :

S. No	Tests	Standards
1	Identification	
	A. Infrared Absorption	Compare spectrum with the reference spectrum of USP Chlorpropamide RS
	B. Thin Layer Chromatography	Comparable with Chlorpropamide RS
2	Melting Range	Between 126° C and 129° C
3	Loss on drying (in vacuum at 60 ° C for 2 hours)	Not more than 1.0 %
4	Residue on ignition	Not more than 0.4 %
5	Selenium	0.003 %
6	Assay by HPLC (ODB)	97.0 to 103.0 %
REMARKS: THE ABOVE PRODUCT CONFORMS TO SPECIFICATIONS OF CHLORPROPAMIDE USP		
	<i>Prepared by:</i>	<i>Reviewed by:</i>
<i>Name:</i>		<i>Approved by:</i>
<i>Designation:</i>		
<i>Signature:</i>		
<i>Date:</i>		

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