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Valid From: 22/08/24	Quantum Drugs & Chemicals Manamadurai	Department: Quality Control
Supersedes: FM/QC/4001/06	**FINISHED PRODUCT SPECIFICATION**	SPC No: FM/QC/4001/07
	TITLE : CHLORPROPAMIDE-BP/EP/IP/USP	Page 1 of 6

CHLORPROPAMIDE-BP :

S. No	Tests	Standards
1.	Appearance	A white or almost 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.	Ultraviolet and Visible Absorption Spectrophotometry	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 Spectrophotometry	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 (at 100°C to 105 ° C)	Not more than 0.5 %
6.	Sulphated Ash	Not more than 0.1 %
7.	Assay by Titration (ODB)	99.0 to 101.0 %

	Prepared by:	Reviewed by:	Approved by:	Authorized by:
Name:	K.Dinakaraja	P.Muthuramalingam	K Soundararajan	M.B. Vijay Babu
Designation:	QC Executive	QC Manager	QA Manager	General Manager
Signature:				
Date:	20/08/24	21/08/24	22/08/24	22/08/24

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CHLORPROPAMIDE-EP :

S. No	Tests	Standards
1.	Appearance	A white or almost 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.	Ultraviolet and Visible Absorption Spectrophotometry	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 Spectrophotometry	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(at 100°C to 105 ° C)	Not more than 0.5 %
6.	Sulphated Ash	Not more than 0.1 %
7.	Assay by Titration (ODB)	99.0 to 101.0 %

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CHLORPROPAMIDE-IP :

S. No	Tests	Standards
Physical Characteristics		
1.	Description	A white or almost white, crystalline powder.
2.Identification		
A.	Infrared absorption spectrophotometry	Compare the spectrum with the reference spectrum of Chlorpropamide CRS
B.	Chloride	A white precipitate is formed
Related substances by TLC		
3.	p-chloro benzene sulphonamide (Impurity A)	Not more than 0.3 %
	1,3 dipropylurea (Impurity B)	Not more than 0.3 %
	Any other Secondary spots	Not more than 0.3 %
4.	Heavy metals	Not more than 30 ppm
5.	Sulphated Ash	Not more than 0.1 %
6.	Loss on drying (at 105 °C)	Not more than 0.5 %
Assay		
7.	Titration (ODB)	99.0 to 101.0 %

CHLORPROPAMIDE-USP:

S.No	Tests	Standards
1.	**Identification**	
A.	Infrared Spectroscopy	Compare spectrum with the reference spectrum of USP Chlorpropamide RS
B.	Thin layer chromatography	Comparable with Chlorpropamide RS
2.	Melting Range	between126° 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 %

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Specifications - CHLORPROPAMIDE-BP/EP/USP

1.	Appearance	A white or almost 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		
(i)	Melting point	126° C to 130° C
(ii)	Melting Range	Between 126° C and 129° C
(iii)	Ultraviolet and Visible Absorption Spectrophotometry	570 to 630
(iv)	Infrared Absorption Spectrophotometry	Compare spectrum with the reference spectrum of Chlorpropamide CRS
(v)	Thin Layer Chromatography	Comparable with Chlorpropamide RS.
(vi)	Chloride	A Curdy white precipitate is formed
4.	**Related substances by TLC** p-chloro benzene sulphonamide (Impurity A)	0.3 % maximum
	p-chloro benzene sulphonyl urea	0.3 % maximum
	1,3 dipropyl urea(Impurity B)	0.3 % maximum
	Any other spots	Not more than two such spots 0.1% maximum
5.	(i) Loss on drying **(BP/EP)**	Not more than 0.5 %
	(ii) Loss on drying **(USP)**	Not more than 1.0 %
6.	Sulphated Ash	Not more than 0.1 %
7.	Residue on Ignition	NMT 0.4 %
8.	a) Assay by Titration (ODB) b) Assay by HPLC (ODB)	99.0 to 101.0 % 97.0 to 103.0 %

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HISTORY:

S.No	Date	Revision No.	Changes Made	Change Control Doc No.	Effective date
1	01/03/23	06	1. SPC Template was updated as per SOP /QC/501. 2. Administrative changes was done for better clarity 3. Specifications are separate from STP for better clarity and compliance.	CCIF/2022-23/038	01/04/23
2.	19/08/24	07	The following parameters are amended as per the changes in Indian Pharmacopoeia 2022 - Addendum 2024. 1.Description 2.Identification 3.Loss on drying	CCIF/2024-25/008	22/08/24

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