



KWALITY PHARMACEUTICALS LIMITED
1-A, INDUSTRIAL AREA , RAJA KA BAGH, TEHSIL NURPUR, KANGRA-176201
(INDIA)

DEPARTMENT : QUALITY CONTROL

FINISHED PRODUCT COA

Product Name	HYDRONCO 500- Hydroxyurea Capsules IP 500 mg	A. R. Number	KPL3/QC/AR/FP/2026/251
Batch Number	OC0199	Sample Received on	21/04/2026
Date of Mfg.	03/2026	Batch Size	25000 Capsules
Date of Exp.	02/2029	Specification No.	KPL3/SPC/CS/030-00
Date of Analysis	22/04/2026	Date of Release	18/05/2026

Sr. No	Test	Specification	Result
1.	Description	Pink colored body & Grey colored cap size "0" capsule filled with white to off white granular powder.	Pink colored body & Grey colored cap size "0" capsule filled with white granular powder.
2.	Identification		
	A. BY HPLC	In the assay, the principal peak in the chromatogram obtained with test solution should be correspond to that the principal peak in the chromatogram obtained with standard solution.	In the assay, the principal peak in the chromatogram obtained with test solution is correspond to that the principal peak in the chromatogram obtained with standard solution.
	B. By IR	The infrared spectrum obtained from sample shall exhibit maxima only at same wavelength with the spectrum obtained from reference standard.	The infrared spectrum obtained from sample is exhibit maxima only at same wavelength with the spectrum obtained from reference standard.
3.	Average filled weight	580 mg \pm 7.5% (536.5mg to 623.5mg)	578.6mg
4.	Average weight of filled Capsules	676 mg \pm 7.5% (625.3mg to 726.7mg)	675.0mg
5.	Uniformity of Filled weight	\pm 7.5 % of average filled weight.	-1.10% to +1.84%
6.	Disintegration Test	Not more than 30 minutes	04 Minute 29 Seconds
7.	Uniformity of Dosage Units	For L1 Stage, AV = NMT 15 and For L2 Stage, AV = NMT 25.	AV=5.43
8.	Dissolution	NLT 80% (Q) of the labeled amount.	Min-94.7% Max- 101.1% Avg-97.8%
9.	Microbial Enumeration Test:		
	Total Aerobic Microbial count	NMT 1000 cfu/gm	30 cfu/gm
	Total yeasts/moulds Count	NMT 100 cfu/gm	<10 cfu/gm
	Test for specified pathogens:		
	E-coli	Should be absent per gram	Absent
Salmonella sp.	Should be absent per 10 gram	Absent/ 10gram	

Prepared By Sign./Date	<i>Kulbhushan</i> 18/05/2026	Reviewed By Sign./Date	<i>Raj Kumar</i> 18/05/2026	Approved By Sign./Date	<i>Akhil Sharma</i> 18/05/2026
Name	Kulbhushan	Name	Raj Kumar	Name	Akhil Sharma
Designation	Executive	Designation	Asst. Manager	Designation	Manager QA



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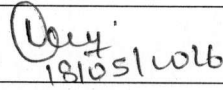
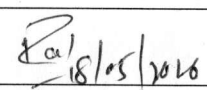
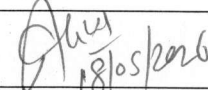
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	<i>Pseudomonas aeruginosa</i>	Should be absent per gram	Absent	
	<i>Staphylococcus aureus</i>	Should be absent per gram	Absent	
10.	Assay: Each hard gelatin capsules contains:			
	Active Ingredient	Label Claim	Limit	Result
	Hydroxyurea IP	500.0 mg	90.0% to 110.0%	101.5%

Remarks: In the opinion of undersigned the product complies/~~does not comply~~ with IP/BP/USP/In House specification.

Prepared By Sign./Date	 18/05/2026	Reviewed By Sign./Date	 18/05/2026	Approved By Sign./Date	 18/05/2026
Name	Kulbhushan	Name	Raj Kumar	Name	Akhil Sharma
Designation	Executive	Designation	Asst. Manager	Designation	Manager QA