KWALITY PHARMACEUTICALS LIMITED

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

DEPARTMENT : QUALITY CONTROL

FINISHED PRODUCT COA

Product Name	Leuprolide Acetate Depot For Injection 3.75 mg/vial	**A. R. Number**	KPH/23/FPO/ 627
Batch Number	OL0439	**Sample Received on**	17/06/2023
Date of Mfg.	06/2023	**Batch Size**	3000 Vials
Date of Exp.	05/2025	**Specification No.**	KPL/SPC/IN/018-04
Date of Analysis	17/06/2023	**Date of Release**	26/07/2023

Sr. No	Test	Specification	Result
1.	**Description**		
	Before reconstitution	White or off-white coloured crystalline powder filled in clear colorless transparent tubular glass vial USP type I.	Off-white coloured crystalline powder filled in clear colorless transparent tubular glass vial USP type I.
	After reconstitution	After reconstitution with Diluent, a white or off-white color suspension produced with small microsphere suspended particles may be observed.	After reconstitution with Diluent, off-white color suspension produced with small microsphere suspended particles observed.
2.	**Identification:**		
	A. By Light absorption	The light absorption of the resulting solution exhibits a maximum between 277 and 282 nm.	The light absorption of the resulting solution exhibits a maximum at 279.941nm.
	B. By HPLC	In the Assay, the retention time of the principal peak in the chromatogram obtained with sample solution corresponds to that of the principal peak in the chromatogram obtained with standard solution.	In the Assay, the retention time of the principal peak in the chromatogram obtained with sample solution corresponds to that of the principal peak in the chromatogram obtained with standard solution.
3.	**pH**	5.0 to 7.0	5.603
4.	**Related substances (By HPLC)**		
	Impurity D	NMT 1.0 %	Not detected
	Impurity A	NMT 0.5%	0.16%
	impurity B	NMT 0.5%	0.39%
	impurity C	NMT 0.5%	Not detected
	Any other secondary peak	NMT 0.5%	0.01% BDL
	Sum of secondary peak	NMT 2.5%	0.02% BDL
5.	**Water**	NMT 5.0%	1.4849%

Prepared By Sign./Date	26/07/23	Reviewed By Sign./Date	26/07/23	Approved By Sign./Date	26/07/23
Name	Anil Pathare	Name	Bhimrao Patil	Name	Bijaylaxmi Panda
Designation	Sr. Executive	Designation	Sr. Manager	Designation	Sr. Manager

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6.	**Bacterial Endotoxins (Gel clot method)**	NMT 11.6 EU/mg	Less than 11.6 EU/mg of leuprorelin.
7.	**Sterility (Direct inoculation method)**	Should be sterile.	Sterile
8.	**Particulate matter: (Method 2, microscopic particle count test)**	≥ 10 µm: Not more than 3000 particles ≥ 25 µm: Not more than 300 particles.	12 particles 18 particles
9.	**Uniformity of Dosage Units**	For L1 Stage, AV = NMT 15 and For L2 Stage, AV= NMT 25.	AV=1.88
10.	**Assay: Each vial contains:**		

Active Ingredient	Label Claim	Limit	Result
Leuprolide acetate	3.75 mg	95.0% to 105.0%	3.93 mg 104.8%
Leuprolide as such	3.57 mg		3.74 mg 104.8%

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

Prepared By Sign./Date	26/07/23	Reviewed By Sign./Date	26/07/23	Approved By Sign./Date	26/07/23
Name	Anil Pathania	Name	Rhimrao Patil	Name	Brijendrajit Singh
Designation	Sr. Executive	Designation	Sr. Manager	Designation	Sr. Manager