IIRT Research & Innovation

FORM 39 A

(The Drugs & cosmetics act 1940 and Rules there under)

To

CERTIFICATE OF ANALYSIS

M/s. THE MEDICAL SUPERINTENDENT ESIC HOSPITAL KOLHAPUR BEHIND CIRCUIT HOUSE TARABAI PARK KOLHAPUR MAHARASHTRA		REPORT NO. :	PHDF00092509
		Study No.:	NA
		Date of Issue:	28-10-2025
Sample Name	NIFEDIPINE SUSTAINED RELEASE TABLETS IP 20 MG		
Manufacturer By	NABROS PHARMA PVT LTD.		
Supplied By	THE MEDICAL SUPERINTENDENT		
Generic Name	Nifedipine Sustained Release Tablet IP	Batch NO.	NR018
Party Ref. No.	NA	Batch Size	NA
Mfg. Lic. No.	G/1355	Sample Qty.	60 TABLETS
Recd. Dt.	11-09-2025	Dt. Mfg.	JUN - 2025
Detl. of Product	FINISHED PRODUCT	Dt. Exp.	MAY - 2028

Reference	: IP 2022	
Description	: Orange coloured round biconvex film coated sustained release tablets plain on both side	
Identification (by TLC)	: Complies	
Average Weight	: 103.76 mg	
Uniformity of weight	: Within limits	(Limits ± 7.5%)
Dissolution (by UV)	:	
In Acid Medium	: 28.71% to 33.63%	(25.0 to 40.0%)
In Buffer Medium	: 76.38 to 84.83%	(Q NLT 60.0%)
Assay (by U.V)	: Each film coated sustained release tablet contains	

	Result	Claim	Limit	Test Method
Nifedipine	19.77 mg	20.0 mg	18.0 to 22.0 mg	IP 2022

Date of Testing: 11-09-2025 **Test Completed On: 28-10-2025**

Remarks: Party asked for above test only

28-10-2025
Date of issue

QUALITY ASSURANCE UNIT QA 28-10-2025 HAPUR

Reviewed by

Institute for Industrial Research & Toxicology Hapur 28/10/2025

Person in Charge

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To

M/s. THE MEDICAL SUPERINTENDENT ESIC HOSPITAL KOLHAPUR BEHIND CIRCUIT HOUSE TARABAI PARK KOLHAPUR MAHARASHTRA	REPORT NO. : PHDF00052509 Study No.: NA Date of Issue: 30-09-2025

Sample Name	SODIUM CHLORIDE INJ. IP (0.9% W/V)		
Manufacturer By	KLOKTER LIFESCIENCES PVT. LTD.		
Supplied By	THE MEDICAL SUPERINTENDENT		
Generic Name	Sodium Chloride Inj. IP	Batch NO.	(N)24498
Party Ref. No.	NA	Batch Size	NA
Mfg. Lic. No.	877-B(H)	Sample Qty.	2×500 ML
Recd. Dt.	11-09-2025	Dt. Mfg.	JUL - 2024
Detl. of Product	FINISHED PRODUCT	Dt. Exp.	JUN - 2026

Reference	: IP 2022		
Description	: Clear colourless liquid filled in transparent plastic container.		
Identification (by Chemically)	: Complies		
pH	: 6.42	(4.5 to 7.0)	
Nominal Volume	: 500 ml		
Extractable Volume	: 508 ml	(NLT 500 ml)	
Particulate Matter	: Free from any visible suspended partical when seen under examination with unaided eye.		
Heavy Metals	: Less than 0.3 PPM	(NMT 0.3 PPM)	
Bacterial Endotoxins	: Less than 0.5 EU/mg	(NMT 0.5 EU/mg)	
Sterility	: Complies		
Assay (by Chemically)	:		

	Result	Claim	Limit	Test Method
Sodium Chloride	0.912% w/v	0.9% w/v	0.85 to 0.95% w/v	IP 2022

Date of Testing: 11-09-2025 **Test Completed On: 30-09-2025**

Remarks: In the opinion of the undersigned the sample referred above is of Standard Quality as defined in Drugs & Cosmetics Act 1940 & rules made there under

Complies with IP

30-09-2025
Date of issue

Reviewed by Nisha 30-09-2025

Person in Charge

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		Study No.:	NA
		Date of Issue:	22-09-2025
Sample Name	FOLIC ACID TABLETS IP 5 MG		
Manufacturer By	HINDUSTAN LABORATORIES LIMITED		
Supplied By	THE MEDICAL SUPERINTENDENT		
Generic Name	Folic Acid Tablet IP	Batch NO.	TFN25012AL
Party Ref. No.	NA	Batch Size	NA
Mfg. Lic. No.	KD-311	Sample Qty.	60 TABLETS
Recd. Dt.	11-09-2025	Dt. Mfg.	JUL - 2025
Detl. of Product	FINISHED PRODUCT	Dt. Exp.	JUN - 2027

Reference	: IP 2022		
Description	: Light yellow coloured round biconvex uncoated tablet having scored on one side.		
Identification (A by TLC)	: Complies		
Identification (B by Chemically)	: Complies		
Average Weight	: 98.02 mg		
Uniformity of content (by HPLC)	: 94.48 to 104.87%	(85.0 to 115.0%)	
Hydrolycis Products (by HPLC)	: Not Detected		
Dissolution (by HPLC)	: 89.83 to 98.87%	(Q NLT 75%)	
Assay (by HPLC)	: Each uncoated tablet contains.		

	Result	Claim	Limit	Test Method
Folic Acid	5.17 mg	5.0 mg	4.5 to 5.75 mg	IP 2022

Date of Testing: 11-09-2025 **Test Completed On: 22-09-2025**

Remarks. In the opinion of the undersigned the sample referred above is of Standard Quality as defined in Drugs & Cosmetics Act 1940 & rules made there under

Complies with IP

22-09-2025
Date of issue

Reviewed by

Institute for Industrial Research & Toxicology ★ HAPUR ★ U.P.

22-09-2025

Person in Charge

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		Study No.:	NA
		Date of Issue:	30-10-2025
Sample Name	INDAPAMIDE SUSTAINED RELEASE TABLETS IP		
Manufacturer By	BAL PHARMA LIMITED		
Supplied By	THE MEDICAL SUPERINTENDENT		
Generic Name	Indapamide Sustained Release Tablet IP	Batch NO.	DIS44
Party Ref. No.	NA	Batch Size	NA
Mfg. Lic. No.	KTK25/294/92	Sample Qty.	60 TABLETS
Recd. Dt.	11-09-2025	Dt. Mfg.	JUN - 2025
Detl. of Product	FINISHED PRODUCT	Dt. Exp.	MAY - 2027

Reference	:	IP 2022
Description	:	White round biconvex film coated tablet
Identification (A by TLC & B by HPLC)	:	Complies
Average Weight	:	141.41 mg
Assay (by HPLC)	:	Each film coated sustained release tablet contains.

	Result	Claim	Limit	Test Method
Indapamide	1.46 mg	1.5 mg	1.425 to 1.575 mg	IP 2022

Date of Testing: 11-09-2025 — Test Completed On: 30-10-2025

Remarks: Party asked for above test only

30-10-2025
Date of issue

Reviewed by Nisha 30-10-25

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Person Incharge

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		Study No.:	**NA**
		Date of Issue:	**12-09-2025**
Sample Name	**CETIRIZINE SYRUP IP 5MG/5ML**		
Manufacturer By	**KARNATAKA ANTIBIOTICS AND PHARMACEUTICALS LTD**		
Supplied By	**THE MEDICAL SUPERINTENDENT**		
Generic Name	**Cetirizine Syrup IP**	**Batch NO.**	**CTZS25005**
Party Ref. No.	**NA**	**Batch Size**	**NA**
Mfg. Lic. No.	**L/16/1807/MNB**	**Sample Qty.**	**60×05 PCS**
Recd. Dt.	**11-09-2025**	**Dt. Mfg.**	**JUL - 2025**
Detl. of Product	**FINISHED PRODUCT**	**Dt. Exp.**	**JUN - 2027**

Reference	:	IP 2022
Description	:	Light orange coloured solution filled in amber coloured plastic bottle.
Identification (by HPLC)	:	Complies
Nominal Volume	:	60.0 ml
Average net volume	:	62.0 ml
Weight per ml	:	1.02916 gm
pH	:	5.38 (4.5 to 5.5)
Assay (by HPLC)	:	Each 5 ml contains

	Result	Claim	Limit	Test Method
Cetirizine HCl	4.91 mg	5.0 mg	4.5 to 5.5 mg	IP 2022

Date of Testing: 11-09-2025 **Test Completed On: 12-09-2025**

Remarks: In the opinion of the undersigned the sample referred above is of Standard Quality as defined in Drugs & Cosmetics Act 1940 & rules made there under

Complies with IP

12-09-2025
Date of issue

QUALITY ASSURANCE ★ HAPUR ★
12-09-2025
Reviewed by

Institute for Industrial Research & Toxicology ★ HAPUR ★
12.09.2025
Person in Charge

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		Study No.:	**NA**
		Date of Issue:	**18-09-2025**
Sample Name	**MICONAZOLE NITRATE CREAM IP 2% W/W**		
Manufacturer By	**ZENITH DRUGS LIMITED**		
Supplied By	**THE MEDICAL SUPERINTENDENT**		
Generic Name	**Miconazole Nitrate Cream IP**	**Batch NO.**	**5E40**
Party Ref. No.	**NA**	**Batch Size**	**NA**
Mfg. Lic. No.	**25/7/2001**	**Sample Qty.**	**10×15 GM**
Recd. Dt.	**11-09-2025**	**Dt. Mfg.**	**JUL - 2025**
Detl. of Product	**FINISHED PRODUCT**	**Dt. Exp.**	**JUN - 2027**

Reference	: IP 2022	
Description	: White softmass filled in printed lemi tube.	
Identification A (by Chemically)	: Complies	
Identification B (by HPLC)	: Complies	
Nominal weight	: 15.0 gm	
Average fill weight	: 15.030 gm	
Uniformity of fill weight	: Within limit	(Limits ± 9.0%)
Related Substances (by HPLC)	:	
Any secondary impurity	: Not Detected	(NMT 0.25%)
Total Impurities	: Not Detected	(NMT 0.5%)
Assay (by HPLC)	:	

	Result	Claim	Limit	Test Method
Miconazole Nitrate	1.97% w/w	2.0% w/w	1.90 to 2.10% w/w	IP 2022

Date of Testing: 11-09-2025 **Test Completed On: 18-09-2025**

Remarks: In the opinion of the undersigned the sample referred above is of Standard Quality as defined in Drugs & Cosmetics Act 1940 & rules made there under

Complies with IP

18-09-2025
Date of issue

Reviewed by Nisha 18-09-2025

18-09-2025
Person in Charge

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Sample Name	AMOXYCILLIN AND POTASSIUM CLAVULANATE TABLETS IP 625 MG		
Manufacturer By	KARNATAKA ANTIBIOTICS AND PHARMACEUTICALS LTD		
Supplied By	THE MEDICAL SUPERINTENDENT		
Generic Name	Amoxycillin & Potassium Clavulanate Tablet IP	Batch NO.	APCT25039A
Party Ref. No.	NA	Batch Size	NA
Mfg. Lic. No.	G/28A/5874-A	Sample Qty.	60 TABLETS
Recd. Dt.	11-09-2025	Dt. Mfg.	JUL - 2025
Detl. of Product	FINISHED PRODUCT	Dt. Exp.	JUN - 2026

Reference	:	IP 2022	
Description	:	White oval shaped biconvex film coated tablets plain on both side.	
Identification (by HPLC)	:	Complies	
Average Weight	:	1041.85 mg	
Uniformity of weight	:	Within limits	(Limits: ± 5.0%)
Dissolution (by HPLC)	:		
For Amoxycillin Trihydrate Eq. to Amoxycillin	:	91.75 to 93.48%	(Q NLT 85%)
For Potassium Clavulanate Diluted Eq. to Clavulanic Acid	:	92.86 to 94.05%	(Q NLT 80%)
Uniformity of content (by HPLC)	:		
For Potassium Clavulanate Diluted Eq. to Clavulanic Acid.	:	94.08 to 103.60%	(85 to 115%)
Water	:	5.92% w/w	(NMT 10.0% w/w)
Assay	:	Each film coated tablet contains.	

	Result	Claim	Limit	Test Method
Amoxycillin Trihydrate Eq. to Amoxycillin	465.74 mg	500.0 mg	450.0 to 600.0 mg	IP 2022
Potassium Clavulanate Dilued Eq. to Clavulanic Acid	127.22 mg	125.0 mg	112.5 to 150.0 mg	IP 2022

Date of Testing: 11-09-2025 **Test Completed On: 16-09-2025**

Remarks: In the opinion of the undersigned the sample referred above is of Standard Quality as defined in Drugs & Cosmetics Act 1940 & rules made there under

Complies with IP

16-09-2025
Date of issue

Reviewed by Nidhi 16-09-2025

Person in Charge 16-09-2025

Institute for Industrial Research & Toxicology, HAPUR

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		Study No.:	NA
		Date of Issue:	15-09-2025
Sample Name	REMOGLIFLOZIN ETABONATE TABLETS IP 100 MG		
Manufacturer By	GLENMARK PHARMACEUTICALS LTD.		
Supplied By	THE MEDICAL SUPERINTENDENT		
Generic Name	Remogliflozin Etabonate Tablet IP	Batch NO.	18250132
Party Ref. No.	NA	Batch Size	NA
Mfg. Lic. No.	M/602/2012	Sample Qty.	60 TABLETS
Recd. Dt.	11-09-2025	Dt. Mfg.	FEB - 2025
Detl. of Product	FINISHED PRODUCT	Dt. Exp.	JAN - 2028

Reference	:	IP Addendum 2024	
Description	:	White round biconvex film coated tablet having scored on one side.	
Identification (by HPLC)	:	Complies	
Average Weight	:	326.7 mg	
Uniformity of weight	:	Within limit	(± 5.0%)
Dissolution (by HPLC)	:	88.58 to 93.31%	(Q NLT 75%)
Related Substances (by HPLC)	:		
Remogliflozin Etabonate Impurity - A	:	Not Detected	(NMT 1.0%)
Any other impurities	:	Not Detected	(NMT 0.5%)
Total Impurities	:	Not Detected	(NMT 2.0%)
Assay (by HPLC)	:	Each film coated tablet contains.	

	Result	Claim	Limit	Test Method
Remogliflozin Etabonate IP	97.49 mg	100.0 mg	90.0 to 110.0 mg	IP Add. 2024

Date of Testing: 11-09-2025 **Test Completed On: 15-09-2025**

Remarks: In the opinion of the undersigned the sample referred above is of Standard Quality as defined in Drugs & Cosmetics Act 1940 & rules made there under

Complies with IP

15-09-2025
Date of issue

Nishad 15-09-2025
Reviewed by

15-09-2025
Person in Charge

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		Study No.:	NA
		Date of Issue:	30-10-2025
Sample Name	TAMSULOSIN HYDROCHLORIDE MODIFIED RELEASE TABLETS		
Manufacturer By	OVERSEAS HEALTH CARE PVT. LTD.		
Supplied By	THE MEDICAL SUPERINTENDENT		
Generic Name	Tamsulosin HCL Modified Release Tablet	Batch NO.	UTN-85
Party Ref. No.	NA	Batch Size	NA
Mfg. Lic. No.	1544-OSP	Sample Qty.	60 TABLETS
Recd. Dt.	11-09-2025	Dt. Mfg.	JUL.- 2025
Detl. of Product	FINISHED PRODUCT	Dt. Exp.	JUN - 2027

Reference : IHS

Description : White round biconvex uncoated tablet plain on both side

Identification : Positive for Tamsulosin HCl

Average Weight : 141.65 mg

Assay (by HPLC) : Each modified release tablet contains

	Result	Claim	Limit	Test Method
Tamsulosin HCl	0.387 mg	0.4 mg	0.36 to 0.44 mg	IIRT/STP-T010

Date of Testing: 11-09-2025

Test Completed On: 30-10-2025

Remarks: Party asked for above test only

30-10-2025
Date of issue

QUALITY ASSURANCE UNIT QA HAPUR 30-10-2025

Reviewed by

Institute for Industrial Research & Toxicology IIRT HAPUR 30-10-2025

Person in Charge

Institute for Industrial Research & Toxicology
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Sample Name	FEBUXOSTAT TABLETS		
Manufacturer By	ULTRA DRUGS PVT. LTD.		
Supplied By	THE MEDICAL SUPERINTENDENT		
Generic Name	Febuxostat Tablet	Batch NO.	UT-250998J
Party Ref. No.	NA	Batch Size	NA
Mfg. Lic. No.	MNB/17/1004 & MB/17/1005	Sample Qty.	60 TABLETS
Recd. Dt.	11-09-2025	Dt. Mfg.	JUL - 2025
Detl. of Product	FINISHED PRODUCT	Dt. Exp.	JUN - 2027

Reference	: IHS		
Description	: Pink coloured round biconvex film coated tablets plain on both side.		
Identification (by HPLC)	: Positive for Febuxostat		
Average Weight	: 259.27 mg		
Uniformity of weight	: Within limit	(Limits: ± 5.0%)	
Disintegration time	: 9 to 10 Min.	(NMT 30 Min.)	
Assay (by HPLC)	: Each film coated tablet contains		

	Result	Claim	Limit	Test Method
Febuxostat	39.42 mg	40.0 mg	36.0 to 44.0 mg	IIRT/STP-F013

Date of Testing: 11-09-2025 **Test Completed On:**

Remarks: In the opinion of the undersigned the sample refered above is of Standard Quality as defined in Drugs & Cosmetics Act 1940 & rules made there under

Complies with IHS

29-10-2025
Date of issue

Reviewed by

Person in Charge

Institute for Industrial Research & Toxicology
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