



CERTIFICATE OF ANALYSIS OF THE END PRODUCT

PRODUCT NAME	GYNO-RAX VAGINAL SUPPOSITORIES	MANUFACTURING DATE	03.06.2025
MANUFACTURING SITE	Cerkazkoy / Tekirdag, Turkey	EXPIRY DATE	31.05.2028
BATCH NO	250274	SAMPLING DATE	13.06.2025
CONTROL BATCH NO	4000027859	EXAMINED BY	Salih TURHAN
PRODUCT CODE	100212	CONTROL METHOD No	FP.CM.0301
COUNTRY NAME	Russia	STORAGE CONDITIONS	At temperature ≤ 25 °C
BATCH SIZE	7.032 Packages	GMP CERTIFICATE NUMBER	GMP/EAU/RU/01428-2024 Valid from 27.06.2024 to 28.03.2027

PARAMETERS	SPECIFICATIONS	RESULTS
Description	Method: Visual Inspection Yellowish vaginal suppositories with flat body and rounded tip similar to truncated ellipses and round recess at its truncated side.	Yellowish vaginal suppositories with flat body and rounded tip similar to truncated ellipses and round recess at its truncated side.
Thioconazole and tinidazole identification	Method: HPLC The retention time of the principal peak in the chromatogram of the test solution should meet the retention time of thioconazole and tinidazole on the chromatogram of the standard solution.	In the assay test main peaks retention time at the test solution chromatogram should conform to thioconazole and tinidazole peak retention time at standard solution chromatogram.
Average weight	Method: Gravimetry, Ph. Eur. 2500 mg ± 5 % (2376 mg - 2625 mg)	2517 mg
Uniformity of mass	Method: Gravimetry, Ph. Eur. (2/20) ± 6 % (8/20) ± 10 %	Conform
Dissolution time	Method: Visual Inspection, Ph. Eur. NMT 60 minutes	7 min
Uniformity of dosage units	Method: HPLC Acceptance value (AV) ≤ L1 (L1 = 15.0)	Tioconazole 2.0 Tinidazole 1.5
Assay	Method: HPLC Tioconazole (90.0 - 110.0) mg (90.0 % - 110.0 %) of the label claim Tinidazole (135.0 - 165.0) mg (90.0 % - 110.0 %) of the label claim	100.6 mg 151.3 mg
Related substances	Method: HPLC Tioconazole Impurity A NMT 1.0 % Impurity B NMT 1.0 % Impurity C NMT 1.0 % Any other impurity NMT 0.2 % Total impurities NMT 3.0 % Tinidazole Impurity A NMT 0.5 % Impurity B NMT 0.5 % Any other impurity NMT 0.2 % Total impurities NMT 1.0 %	Not Detected Not Detected 0.04 % 0.05 % 0.17 % Not Detected Not Detected 0.11 % 0.11 %
Microbial quality	Total Aerobic Microbial Count < 10 ⁷ cfu / g Total Yeast and Mold Count < 10 ⁴ cfu / g Category 2 Ph.Eur. Absence <i>Candida albicans</i> absence / g Absence <i>Staphylococcus aureus</i> absence / g Absence <i>Pseudomonas aeruginosa</i> absence / g	<100 cfu / g <10 cfu / g not found / g not found / g not found / g
Packaging	7 suppositories in a PVC/LDPE strip, 1 strip along with patient information leaflet in a carton.	7 suppositories in a PVC/LDPE strip into a cardboard box along with the leaflet.
Drug labeling	On the strip in Russian: Trade name of the drug product, dosage form, logotype of the MA holder (in Latin characters), names and content of active substances, batch number, expiry date. On the carton in Russian: Trade name of the medicinal product, generic name, dosage form, composition (names and content of active substances per suppository, list of excipients), number of suppositories per package, name, country and logotype (in Latin characters) of the MA holder, name, city and country of the manufacturer, storage conditions, dispensing conditions, pharmacological action: "antibacterial", "antiprotozoal", "antifungal", precautionary notes: "Read the enclosed leaflet before use", "Do not use after the expiry date", "Keep out of reach of children", batch number, manufacturing date "exp.", barcode, registration number, the internal manufacturing code(s) of package and/or medicinal product (manufacturing codes may change due to internal manufacturing reasons). Additionally, information can be applied to monitor the movement of the medicinal product from the manufacturer to the end user (by printing or sticker method).	The following information is indicated on the strip in Russian: Trade name of the drug product, dosage form, logotype of the MA holder (in Latin characters), names and content of active substances, batch number, expiry date. The following information is indicated on the carton in Russian: Trade name of the medicinal product, generic name, strength, dosage form, composition (names and content of active substances per suppository, list of excipients), number of suppositories per package, name, country and logotype (in Latin characters) of the MA holder, name, city and country of the manufacturer, storage conditions, dispensing conditions, pharmacological action: "antibacterial", "antiprotozoal", "antifungal", precautionary notes: "Read the enclosed leaflet before use", "Do not use after the expiry date", "Keep out of reach of children", storage conditions, batch number, manufacturing date, "exp.", barcode, registration number, the internal manufacturing code of package. The date matrix is printed on the package.

The product batch meets the requirements of MID: ЛП-000007-251022, var. 1-2
Registration certificate number: ЛП-000007.20.10.2010.

Active pharmaceutical ingredient: Tioconazole; Batch No: 2502093 Obitrus Drugs Private Limited, India; - Tinidazole: Batch No: 2500184 Aarti Drugs Limited, India;

Storage conditions: At a temperature not exceeding 25°C

Exp.Date: 3 years

QUALITY CONTROL ANALYST	CHECKED BY	APPROVED BY	RESULTS
			<input checked="" type="checkbox"/> APPROVED <input type="checkbox"/> REJECT

