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Alembic Pharma bags US FDA approval for urinary tract infection drug

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Nitrofurantoin Capsules, USP (Macrocrystals) are available in 25 mg, 50 mg and 100 mg

Alembic Pharmaceuticals has received final approval from the US Food & Drug Administration (US FDA) for its Abbreviated New Drug Application (ANDA) for Nitrofurantoin Capsules, USP (Macrocrystals), 25 mg, 50 mg and 100 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Macrodantin Capsules, 25 mg, 50 mg, and 100 mg, of Alvogen Malta Operations. Nitrofurantoin capsules, USP (Macrocrystals) is specifically indicated for the treatment of urinary tract infections when due to susceptible strains of Escherichia coli, enterococci, Staphylococcus aureus, and certain susceptible strains of Klebsiella and Enterobacter species.

Nitrofurantoin Capsules, USP (Macrocrystals), 25 mg, 50 mg and 100 mg have an estimated market size of $23 million for twelve months ending March 2021 according to IQVIA.

Alembic has a cumulative total of 146 ANDA approvals (128 final approvals and 18 tentative approvals) from the US FDA.