

REGULATORY GUIDANCE FOR ASSESSMENT AND MANAGEMENT OF APPLICATIONS

FOR MARKETING
AUTHORIZATION
OF OXYTOCIN



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**World Health
Organization**



Regulatory guidance for assessment and management of applications for marketing authorization of oxytocin

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ABBREVIATIONS

API	Active Pharmaceutical Ingredient
EPI	Expanded Programme on Immunization
FPP	Finished Pharmaceutical Product
GMP	Good Manufacturing Practice
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ISO	International Organization for Standardization
LMICs	Low- And Middle-Income Countries
MNCH	Maternal, Newborn And Child Health
PQS	Performance, Quality And Safety
TTI	Time-Temperature Indicator
UNFPA	United Nations Population Fund

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