

WORKING GROUP ON DRUG CLASSIFICATION (WG/DC)

COMMON INFORMATION REQUIREMENTS FOR DRUGS OVER THE COUNTER

Requirements for Drug Registration	New Entity	New Formulations	New Strength	New Association	Pharmaceutical equivalent: Generic	Pharmaceutical Equivalent: Similar	Drug Registration Renewal
Labeling/required documents							
1. Draft of the product final label	√	√	√	√	√	√	-
2. Final packaging of marketing of the product	-	-	-	-	-	-	√
3. Sample of the label final art with the first lot of verification	√	for the first lot of marketing	√	√	√	√	-
Information to include in the Primary Packaging							
4. Brand Name	√	√	√	√	-	√	-
5. Generic name (INN)	√	√	√	√	√	√	-
6. Strengths	√	√	√	√	√	√	-
7. Dosage Form	√	√	√	√	√	√	-
8. Expiration date	√	√	√	√	√	√	-
9. Batch number	√	√	√	√	√	√	-
Information to include in the Secondary Packaging							
10. Brand name	√	√	√	√		√	

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11. Generic name (INN)	√	√	√	√	√	√	-
12. Strength	√	√	√	√	√	√	-
13. Dosage Forms	√	√	√	√	√	√	-
14. Content	√	√	√	√	√	√	-
15. Registration number	√	√	√	√	√	√	-
16. Expiration date	√	√	√	√	√	√	-
17. Manufacturer	√	√	√	√	√	√	-
18. Name of the Responsible Professional	√	√	√	√	√	√	-
19. Storage conditions	√	√	√	√	√	√	-
20. Preparation Method	-	Drugs without presc	Only OTC	Only OTC	Only OTC	Only OTC	-
21. Directions for use / Instructions	-	Only OTC	Only OTC	Only OTC	Only OTC	Only OTC	-
22. Therapeutics use	√	√	√	√	√	√	-
23. Dosages	-	√ Only OTC	√ Only OTC	√ Only OTC	√ Only OTC	√ Only OTC	-
24. Prescription and use	√	√	√	√	√	√	-
25. Maximum dose for 24 hours	-	Only OTC	Only OTC	Only OTC	Only OTC	Only OTC	-
26. Information on "See the doctor if the symptoms worsen"	-	Only OTC	Only OTC	Only OTC	Only OTC	Only OTC	-
27. Warnings	√	√	√	√	√	√	-
28. Distinctive Identifications	-	Only OTC	Only OTC	Only OTC	Only OTC	Only OTC	-
29. Batch number	√	√	√	√	√	√	-

Requirements for Drug Registration	New Entity	New Formulations	New Strength	New Association	Pharmaceutical equivalent: Generic	Pharmaceutical Equivalent: Similar	Drug Registration Renewal
Information to include in Insert or Prospect							
30. Brand name	√	√	√	√	-	√	√
31. Generic name (INN)	√	√	√	√	√	√	√
32. Content (marketed presentations)	√	√	√	√	√	√	-
33. Strengths	√	√	√	√	√	√	-
34. Route of administration	√	√	√	√	√	√	-
35. Length of treatment	-	Only OTC	Only OTC	Only OTC	Only OTC	Only OTC	-
36. Use in pregnancy and breast feeding	√	√	√	√	√	√	-
37. Dosage Forms	√	√	√	√	√	√	-
38. Manufacturer	√	√	√	√	√	√	-
39. Directions for use	√	√	√	√	√	√	-
40. Therapeutic use	√	√	√	√	√	√	-
41. Dosages	√	√	√	√	√	√	-
42. Maximum dose in 24 hours	-	Only OTC	Only OTC	Only OTC	Only OTC	Only OTC	-
43. Information “see the doctor if symptoms worsen”	-	Only OTC	Only OTC	Only OTC	Only OTC	Only OTC	-
44. Warnings	√	√	√	√	√	√	-
45. Precaution	√	√	√	√	√	√	-
46. Adverse Reactions	√	√	√	√	√	√	-
47. Interactions	√	√	√	√	√	√	-
48. Overdose	√	√	√	√	√	√	-

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49. Contraindications	√	√	√	√	√	√	-
50. Conservation of the product / Storage conditions		√	√	√	√	√	-